Medicinrådet

Bilag til direkte indplacering af leuprorelin (Camcevi) i Medicinrådets evidens-gennemgang vedrørende lægemidler til medicinsk kastration ved prostatakræft

Vers. 1.0

Bilagsoversigt

1. Forhandlingsnotat fra Amgros vedr. leuprorelin (Camcevi)
2. Ansøgers endelige ansøgning vedr. leuprorelin (Camcevi)

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19.05.2026

MBA/KLE

Forhandlingsnotat

Dato for vurdering i Medicinrådet	24.06.2026
Leverandør	Accord Healthcare
Lægemiddel	Camcevi (leuprorelin)
Ansøgt indikation	Fremskreden, hormonafhængig prostatacancer og lokaliseret højrisiko og lokalt fremskreden hormonafhængig prostatacancer i kombination med strålebehandling.
Nyt lægemiddel / indikationsudvidelse	Direkte indplacering af nyt lægemiddel

Prisinformation

Amgros har forhandlet følgende pris på Camcevi:

Tabel 1: Forhandlingsresultat

Lægemiddel	Styrke (pakning)	AIP (DKK)	Forhandlet SAIP (DKK)	Forhandlet rabat ift. AIP
Camcevi	42 mg (1 stk.)	6.100,00	[redacted]	[redacted]

Aftaleforhold

[redacted]

Konkurrencesituationen

Camcevi indplaceres i behandlingsvejledningen for medicinsk kastration ved prostatakræft og forventes klinisk ligestillet med lægemidlerne Eligard, Zoladex, Pamorelin, Orgovyx og Firmagon.

[redacted]

Tabel 2 viser lægemiddeludgifter pr. år for de klinisk ligestillede lægemidler.

Tabel 2: Lægemiddeludgifter pr. patient

Lægemiddel	Styrke (pakning)	Dosering*	Pris pr. pakning (SAIP, DKK)	Lægemiddeludgift pr. år (SAIP, DKK)
Camcevi	42 mg (1 stk.)	42 mg hver 6. måned, s.c.	[redacted]	[redacted]
Eligard (leuprorelin)	45 mg (1 sæt)	45 mg. hver 6. måned (24. uge), s.c	[redacted]	[redacted]
Zoladex (goserelin)	10,8 mg (1 stk. implantat,)	10,8 mg (implantat) hver 3. måned (12. uge), s.c.	[redacted]	[redacted]
Pamorelin (triptorelin)	22,5 mg (1 stk.)	22,5 mg hver 6. måned (24. uge), i.m.	[redacted]	[redacted]
Orgovyx (relugolix)	120 mg (30 stk.)	360 mg 1. dag, og herefter 120 mg daglig, oral	[redacted]	[redacted]
Firmagon (degarelix)	120 mg (2 sæt) 80 mg (1 sæt)	2 x 120 mg én gang, s.c. og herefter 80 mg hver måned hver 4. uge, s.c.	[redacted]	[redacted]

*Kilde: For Camcevi: Tillæg til Medicinrådets evidensgennemgang vedrørende lægemidler til medicinsk kastration ved prostatakræft Direkte indplacering af leuprorelin (Camcevi®) til medicinsk kastration ved prostatakræft. For øvrige lægemidler: Opsummering af Medicinrådets evidensgennemgang vedrørende lægemidler til medicinsk kastration ved prostatakræft, version 1.0.

[redacted]

Status fra andre lande

Tabel 3: Status fra andre lande

Land	Status
Norge	Ikke ansøgt
Sverige	Ikke ansøgt
England	Ikke ansøgt

Opsummering

[redacted]

Medicinrådet

Instructions for companies

This is the template for submitting evidence to the Danish Medicines Council (DMC) as part of the appraisal process for a new pharmaceutical or a new indication for an existing pharmaceutical, which will be assessed by updating an existing treatment guideline. The template is not exhaustive, companies must adhere to the current version of the relevant guideline alongside using this template when preparing their submission.

Please note the following requirements:

- Headings, subheadings and appendices must not be removed. Tables must not be edited, unless it is explicitly stated in the text.
- Text in grey and [in brackets] is only for example purposes and must be deleted.
- All sections in the template must be filled in. If a section or an appendix is not applicable, state "not applicable" (N/A) and explain why.
- All applications must comply with the general data protection regulations, find more information on DMC's data policy here.
- Submissions in either Danish or English are accepted.

The assessment process will be initiated when all the requirements are met.

Documentation to be submitted

The following documentation must be sent to the DMC's email ansogning@medicinraadet.dk:

- Application in word format*
- Application in PDF format*
- The European Public Assessment Report (EPAR) should be submitted as soon as possible (draft versions will be accepted).

* Later in the appraisal process, once the application has received Day 0, the application must be assembled and sent to the DMC in one blinded version and one highlighted version (both in word and pdf).

Confidential information

- Please refer to DMC´s principles for use of unpublished data.

Version log

Version log		
Version	**Date**	**Change**
1.1	1 April 2025	New e-mail address ansogning@medicinraadet.dk is added.
1.0	29 June 2023	Application form for pharmaceutical, which will be assessed by updating an existing treatment guideline, made available on the website of the Danish Medicines Council.

Application for the assessment of Camcevi® (leuprorelin mesilate) by updating the guideline on medical castration in prostate cancer

Contact information

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Tables and Figures

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Abbreviations

Abbreviations	
ADT	Androgen deprivation therapy
AE	Adverse event
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
CENTRAL	Cochrane Central Register of Controlled Trials
CHMP	Committee for Medicinal Products for Human Use
CI	Confidence Interval
DMC	Danish Medicines Council
ECG	Electrocardiogram
EMA	European Medicines Agency
EPAR	European Public Assessment Report
ECOG	Eastern Cooperative Oncology Group

HbA1c	Glycated haemoglobin
HRQoL	Health-related quality of life
ITT	Intention to treat
LA	Long-acting
LH	Luteinizing hormone
LHRH	Luteinizing hormone-releasing hormone
LMIS	leuprorelin mesilate injectable suspension
N/A	Non applicable
NCT	National Clinical Trial
NMA	Network meta-analysis
PD	Pharmacodynamic
PK	Pharmacokinetic
PSA	Prostate specific antigen
SAE	Serious adverse event
SC	Subcutaneous
SD	Standard deviation
TEAE	Treatment-emergent adverse event
ULN	Upper limit normal

1. Regulatory information on the pharmaceutical

Overview of the pharmaceutical	
Proprietary name	Camcevi®
Generic name	Leuprorelin
Therapeutic indication as defined by EMA	Camcevi® is indicated for the treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy [1].
Marketing authorization holder in Denmark	Accord Healthcare
ATC code	L02AE02
Combination therapy and/or co-medication	N/A
Date of EC approval	May 24, 2022
Has the pharmaceutical received a conditional marketing authorization?	No
Accelerated assessment in the European Medicines Agency (EMA)	No
Orphan drug designation (include date)	No
Other therapeutic indications approved by EMA	No
Other indications that have been evaluated by the DMC (yes/no)	No
Dispensing group	A
Packaging – types, sizes/number of units and concentrations	One pack contains one pre-filled syringe with leuprorelin mesilate equivalent to 42 mg leuprorelin.

2. Summary table

Summary	
Therapeutic indication relevant for the assessment	Camcevi® is indicated for the treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy [1].
Dosage regiment and administration:	Each pre-filled syringe with prolonged-release suspension for injection contains leuprorelin mesilate equivalent to 42 mg leuprorelin. Each dose of 42 mg leuprorelin is administered as a single subcutaneous (SC) injection every six months [1]. Leuprorelin in the form of a mesilate salt eliminates the need for a mixing procedure before administration, as is otherwise the case for Eligard® 45 mg [1,2].
Choice of comparator [if any]	45 mg Eligard® (leuprorelin) subcutaneous every 6 months (24 weeks) is the relevant comparator. The free base equivalent is the same between the Camcevi® 42 mg and the currently approved 45 mg leuprorelin acetate product Eligard® 45 mg [2]. Camcevi® is a ready-to-use depot formulation, while Eligard® requires mixing before administration [1,3].
Most important efficacy endpoints (Difference/gain compared to comparator)	The relevant efficacy outcomes available for Camcevi® that were included in the pivotal trial, FP01C-13-001, are the percentage of subjects that reached serum testosterone castration level (<50 ng/dL) on Day 28 and day 336, as well as adverse events (AEs) [1,4,5]. Health-related quality of life (HRQoL) was also collected with a questionnaire consisting of a scale of X questions from delighted (0) to XXXXXXXX [4,6]. Overall survival and health-related quality of life assessed with Functional Assessment of Cancer Therapy–Prostate are also listed as relevant outcomes in the guideline on medical castration for prostate cancer patients [5]. These outcomes are not available from the FP01C-13-001 trial. **Results from FP01C-13-001:** 98.5% (95% CI: 94.8-99.8) of patients in the study reached castrate levels of testosterone by day 28 as defined by serum testosterone ≤50 ng/dL. The percentage of subjects with testosterone suppression (≤ 50 ng/dL) from Day 28 to Day 336 was 97.0% (95% CI: 92.2–98.9). In the HRQoL questionnaire, 68.6% (94/137) felt satisfied (answered 0, 1, or 2) with their lives at current condition at baseline [4]. The respective figures on Day 168 and Day 336 were 69.7% (90/129) and 65.9% (87/132). No comparative analysis has been undertaken, as Camcevi® is a hybrid medicine with the same active substance as the

Summary	
	reference product Eligard® [2]. The efficacy of Eligard is described in the Danish Medicines Council (DMC) guideline on medical castration in prostate cancer [5].
Most important serious adverse events for the intervention and comparator	In FP01C-13-001 serious adverse events (SAEs) occurred in 20 patients (14.6%), and the most common SAE was subdural hematoma (1.5%, two patients). Only three SAEs were drug-related: blurred vision, left hip fracture, and myocardial infarction. No comparative analysis has been undertaken, as Camcevi® is a hybrid medicine with the same active substance as the reference product Eligard® [2]. The safety profile of Eligard is described in the DMC guideline on medical castration in prostate cancer [5].

3. The patient population, intervention and relevant outcomes

3.1 The medical condition, patient population, current treatment options and choice of comparator(s)

Camcevi® was developed to create a leuprorelin formulation that eliminates a potential source of error of drug administration that has been shown to affect the clinical efficacy of Eligard® and similar castration treatments that require pre-mixing before administration [2,3].

Camcevi® is relevant for the DMC treatment guideline on medical castration of prostate cancer patients [5]. Relevant information on patient population, current treatment options and relevant outcomes is listed in the DMC guideline and associated documents [5,7,8].

The European Medicines Agency (EMA) has determined that Camcevi® can be regarded as equivalent to the reference medicine Eligard® in terms of safety and efficacy, as Camcevi® is a hybrid medicine containing the same active substance as Eligard® (leuprorelin) [1,2]. This is based on the pharmacodynamic (PD) responses of testosterone suppression, supported by in vitro release characteristics, non-clinical findings, and clinical pharmacokinetic (PK) findings [1,2].

3.2 The intervention

Overview of intervention	
Therapeutic indication relevant for the assessment	Camcevi® is indicated for the treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy [1].
Method of administration	Camcevi is administered subcutaneously [1].
Dosing	Each dose of 42 mg leuprorelin is administered as a single SC injection every six months [1].
Should the pharmaceutical be administered with other medicines?	No [1].
Treatment duration / criteria for end of treatment	Treatment duration is dependent on disease stage [5]. Patients with metastatic disease are recommended to receive life-long androgen deprivation therapy (ADT), whereas radiotherapy intended to be curative is often given in combination with time-limited ADT, either for 6 months or for 36 months [5].
Necessary monitoring, both during administration and during the treatment period	Response to leuprorelin should be monitored by clinical parameters and by measuring prostate specific antigen (PSA) serum levels [1]. According to the DMC treatment guideline on medical castration in prostate cancer, all patients should be screened for diabetes at the start of treatment and regularly thereafter, with monitoring of glycated haemoglobin (HbA1c) and blood lipid levels. A cardiology consultation prior to initiation of medical castration should be considered in men with severe cardiovascular disease, including patients with conduction disorders and prolonged QT interval. Patients should be offered calcium and vitamin D supplementation, and serum vitamin D and calcium levels should be routinely monitored during treatment with castration. In addition, monitoring of liver and renal function is recommended in patients with known or suspected liver disease or severe renal impairment during treatment. Finally, regular clinical and biochemical monitoring of treatment response is recommended [5]. No additional monitoring that has not already been described in the DMC guideline on medical castration in prostate cancer is relevant [5].
Need for diagnostics or other tests (e.g. companion diagnostics). How are these included in the model?	None that are not already described in the DMC treatment guideline on medical castration in prostate cancer [5].

Overview of intervention	
Package size(s)	One pack contains one pre-filled syringe with leuprorelin mesilate equivalent to 42 mg leuprorelin [1].

3.2.1 The intervention in relation to Danish clinical practice

EMA has determined that Camcevi® can be regarded as equivalent to the reference medicine Eligard® in terms of safety and efficacy, as Camcevi® is a hybrid medicine containing the same active substance as Eligard® (leuprorelin) [2]. As such, Camcevi® can be used interchangeably where Eligard® would be used [2]. The use of Eligard is described in DMC guideline on medical castration in prostate cancer [7].

The DMC has noted that the mixing procedure required for Eligard® may give rise to occupational health concerns for nurses performing the preparation, as it involves repeated transfers between two syringes (powder and solvent), making the process time-consuming and physically demanding for the fingers [7]. As Camcevi® contains leuprorelin in the form of a mesilate salt the need for a mixing procedure before administration is eliminated [1,2].

4. Overview of literature

No head-to-head studies including both Camcevi® and Eligard® have been identified. In accordance with prior dialogue with the DMC secretariate, no systematic literature review has been conducted, as the pivotal trial, FP01C-13-001, and its extension, FP01C-13-001-EX, have been deemed as appropriate documentation of the efficacy and safety of Camcevi®.

Evidence on the safety and efficacy of Eligard® is described in the DMC guideline on medical castration in prostate cancer [5]. Consequently, no studies including Eligard® are presented in this section.

Table 1 Relevant literature included in the assessment of efficacy and safety

Trial name, NCT identifier and reference (Full citation incl. reference number)	Study design	Study duration	Dates of study (Start and expected completion date, data cut-off and expected data cut-offs)	Patient population (specify if a subpopulation in the relevant study)	Intervention	Comparator	Relevant for PICO nr. in treatment guideline	Outcomes and follow-up period
FP01C-13-001, NCT02234115 Reference: Shore N, Mincik I, DeGuenther M, Student V, Jievaltas M, Patockova J, et al. A phase 3, open-label, multicenter study of a 6-month pre-mixed depot formulation of leuprolide mesylate in advanced prostate cancer patients. World J Urol. 2020;38(1). [4] Reference: EMA. Camcevi: EPAR - Public Assessment Report. 2022. [2] Data on file not previously published from FP01C-13-001. [6]	Phase 3, uncontrolled, multicentre, open-label, single-arm, 12-month, two-part PK, safety and PD/efficacy study.	FP01C-13-001 has 12 months of follow-up.	Start: August 2014 Primary Completion: 30/08/16 Data cut-off 05/01/17	Patients with prostate carcinoma who were candidates for ADT.	Two doses of leuprorelin mesilate injectable suspension (LMIS) 50 mg SC, 6 months apart.	No comparator was included.	1, 2 and 3.	Percentage of subjects that reached serum testosterone castration level (<50 ng/dL) on Day 28 and day 336, as well as AEs [1,4,5]. Profound castration (serum testosterone <20ng/dL) was also measured on Day 28 and Day 336. HRQoL was also collected with a questionnaire consisting of a scale of X questions from delighted (0) to XXXXXXXXX [4,6]. Safety.

Trial name, NCT identifier and reference (Full citation incl. reference number)	Study design	Study duration	Dates of study (Start and expected completion date, data cut-off and expected data cut-offs)	Patient population (specify if a subpopulation in the relevant study)	Intervention	Comparator	Relevant for PICO nr. in treatment guideline	Outcomes and follow-up period
FP01C-13-001-EX, NCT02712320 Reference: EMA. Camcevi: EPAR - Public Assessment Report. 2022. [2]	Multi-center, open-label, single-arm safety extension study.	FP01C-13-001-EX included 30 patients from FP01C-13-001 and provided 12 months' additional safety follow up.	Start: February 2016 Completion: May 2017 Data cut-off 2017-12-19	30 patients from FP01C-13-001 with prostate carcinoma who had received two doses of LMIS 50.	LMIS 50 mg in up to two single SC injections, 6 months apart.	No comparator was included.	1, 2 and 3.	Safety, 24 months total follow up.

5. Clinical questions 1, 2, and 3 in the DMC guideline

Camcevi® was developed to create a leuprorelin formulation that eliminates a potential source of error of drug administration that has been shown to affect the clinical efficacy of Eligard® and similar castration treatments that require pre-mixing before administration [3]. In the following sections, Accord has included the Committee for Medicinal Products for Human Use (CHMP) considerations from the European public assessment report (EPAR) regarding the decision to consider Camcevi® as equivalent to Eligard®. The Marketing Authorisation Application for leuprorelin mesilate injectable suspension (LMIS) 50 mg (Camcevi® 42 mg) was submitted under Article 10(3) of Directive 2001/83/EC [1]. For the marketing authorisation approval of this hybrid application, bridging between LMIS 50 mg and the EU-sourced reference product Eligard® 45 mg was required [2]. This bridging was established using comparative quality data, non-clinical evidence and clinical (PK/PD) data demonstrating comparable and sustained testosterone suppression [2]. The CHMP concluded that Camcevi® provides comparable efficacy and safety to Eligard® 45 mg, and that the benefit–risk balance is positive. On this basis, Camcevi® was considered therapeutically equivalent to Eligard® and granted marketing authorisation [2].

No comparative analysis has been undertaken, as Camcevi® is a hybrid medicine with the same active substance as the reference product Eligard® [2]. The European Medicines Agency (EMA) has assessed Camcevi® as therapeutically equivalent to Eligard®, based on comparative quality data, non-clinical evidence, and clinical PK/PD data. Accordingly, this section presents the key clinical evidence underpinning the EMA's decision.

As a consequence, the same clinical evidence for Camcevi® is applicable to all three clinical questions listed in the DMC guideline on medical castration in prostate cancer. All relevant data on Eligard® 45 mg has been comprehensively assessed and is presented in the guideline; therefore, these data are not repeated here, in accordance with prior dialogue with the DMC secretariate.

5.1 Efficacy of Camcevi®

5.1.1 Relevant studies

FP01C-13-001 and its extension FP01C-13-001-EX are the only studies relevant for the assessment of efficacy and safety of Camcevi® in medical castration of prostate cancer. These include the clinical evidence which the CMHP found sufficient to support the bridging of Camcevi® to Eligard® [2].

5.1.2 Comparability of studies

The study population of the FP01C-13-001 study included patients with histologically confirmed prostate cancer where androgen deprivation therapy (ADT) was needed [4]. The CHMP determined that the baseline characteristics was comparable with those from the studies of Eligard®, mainly the pivotal Eligard® 45mg study [1,9].

5.1.3 Comparability of patients across studies and with Danish patients eligible for treatment

Baseline characteristics from FP01C-13-001 are listed in Table 2 below. The patient population in FP01C-13-001 is considered comparable to the Danish patient population eligible for ADT. This assumption is supported by the DMC guideline on medical castration in prostate cancer, in which studies of leuprorelin were deemed to include patients representative of the relevant Danish clinical population [5]. Furthermore, in its assessment of Camcevi®, the CHMP concluded that the baseline characteristics of patients enrolled in FP01C-13-001 were comparable to those observed in studies of Eligard®. As Eligard® forms part of the clinical evidence base underpinning the DMC guideline, this supports the conclusion that there is no clinically meaningful difference between the FP01C-13-001 population and Danish patients eligible for ADT [2].

Table 2 Baseline characteristics of patients in FP01C-13-001 [2,4].

	FP01C-13-001		
	Part I (n=33)	**Part II (N=104)**	**Total (n=137)**
Age, median (range)	74.0 (54–86)	70.0 (51–88)	71.0 (51–88)
Male gender, n (%)	33 (100)	104 (100)	137 (100)
Years since diagnoses, mean (SD)	8.0 (7.19)	3.9 (6.08)	4.9 (6.58)
Race, n (%)			
White	25 (75.8)	98 (94.2)	123 (89.8)
Black	4 (12.1)	4 (3.8)	8 (5.8)
Asian	4 (12.1)	1 (1.0)	5 (3.6)
Unknown	0 (0)	1 (1.0)	1 (0.7)
Staging			
I	1 (3.0%)	3 (2.9%)	4 (2.9%)
II	8 (24.2%)	23 (22.1%)	31 (22.6%)

	FP01C-13-001		
	Part I (n=33)	Part II (N=104)	Total (n=137)
III	5 (15.2%)	32 (30.8%)	37 (27.0%)
IV	9 (27.3%)	23 (22.1%)	32 (23.4%)
Unknown	10 (30.3%)	23 (22.1%)	33 (24.1%)
Eastern Cooperative Oncology Group (ECOG) performance status			
0	30 (90.9%)	84 (80.8%)	114 (83.2%)
1	3 (9.1%)	19 (18.3%)	22 (16.1%)
2	0 (0.0%)	1 (1.0%)	1 (0.7%)

5.2 Comparative analyses of efficacy and safety

5.2.1 Efficacy and safety outcomes from FP01C-13-001

Of the 137 enrolled subjects in FP01C-13-001, 15 (10.9%) subjects did not complete the study. The most common reason for withdrawal was AEs (5 patients). Other reasons were lack of efficacy (1), lost to follow-up (1), disease progression (1), withdrew consent (3), treated with prohibited medications due to medical need (3) or taking Humalog® 18 units three times a day (1) [2,4].

Castration:

There were 137 patients enrolled in the study (intention-to-treat population). 135/137 patients (98.5%; 95% CI: 94.8-99.8) reached castrate levels of testosterone by day 28 as defined by serum testosterone ≤50ng/dL [4]. The percentage of subjects with testosterone suppression (≤50 ng/dL) from Day 28 to Day 336 was 97.0% (95% CI: 92.2–98.9). Of 135 subjects who achieved the castrated level serum testosterone (≤ 50 ng/dL), 95 subjects (95/135, 70.4%) reached profound castration, (defined as serum testosterone level <20 ng/dL) on Day 28. On Day 336, all subjects who completed the study (122/122) achieved castrated serum testosterone level (≤50 ng/dL), among which 117 subjects (117/122, 95.9%) achieved serum testosterone level <20 ng/dL [4].

Only two subjects (2/137, 1.5%) exhibited post-suppression elevations of serum testosterone to>50 ng/dL after reaching castrate level of testosterone on Day 28 [4].

Health-related quality of life:

All 137 patients were asked on day 1, day 168 (the day of administration of the second dose of LMIS 50), and day 336 (end of study) to complete the quality of life questionnaire that consisted of questions on a scale of 0 to 6, with 0 being delighted, 1 being pleased, 2

being mostly satisfied, [redacted] [6]. HRQoL results are based on the safety population, which included any patient receiving a dose of LMIS 50 mg. 68.6% (94/137) felt satisfied (answered 0, 1, or 2) with their lives at current condition at baseline [4]. The respective figures on Day 168 and Day 336 were 69.7% (90/129) and 65.9% (87/132), indicating that the administration of LMIS 50 mg did not appear to cause additional discomfort in subjects during the study [4]. The complete results are listed in Table 3 below [6].

Table 3 Quality of Life from FP01C-13-001 [6].

Score	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Other outcomes:

Overall survival and HRQoL assessed with Functional Assessment of Cancer Therapy-Prostate are also listed as relevant outcomes in the guideline on medical castration for prostate cancer patients [5]. These outcomes are not available from the FP01C-13-001 trial.

Safety:

The safety population in FP01C-13-001 was defined as any subject receiving at least one dose of LMIS 50 mg (in total 137 patients). AEs were defined in accordance with the National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0.3 [2]. Averse events frequency from FP01C-13-001 are listed in Table 4 below.

Table 4. List of adverse events frequency from FP01C-13-001 [2].

	LMIS 50mg (n=137)
Number of treatment-emergent adverse events, n	553
Number and proportion of patients with ≥1 adverse events, n (%)	114 (83.2)
Number of serious adverse events, n	34
Number and proportion of patients with ≥ 1 serious adverse events, n (%)	20 (14.6)
Number of drug-related adverse events, n	144
Number and proportion of patients with ≥ 1 drug-related adverse events, n (%)	85 (62.0)
Number and proportion of patients who discontinue treatment regardless of reason, n (%)	15 (10.9)
Number and proportion of patients who discontinue treatment due to adverse events, n (%)	5 (3.6)

5.2.2 Please provide a qualitative description of safety data. Differences in definitions of outcomes between studies

In FP01C-13-001 SAEs occurred in 20 patients (14.6%), and the most common SAE was subdural hematoma (1.5%, two patients). Only three SAEs were drug-related: blurred vision, left hip fracture, and myocardial infarction. Of three deaths in the main trial none was related to the use of LMIS 50 mg. The most common treatment emergent adverse events (TEAEs) were hot flush (48.9%), hypertension (14.6%), pain in extremity (9.5%), injection site pain (7.3%), arthralgia (6.6%), fatigue (6.6%), nocturia (5.8%), back pain (5.1%), and nasopharyngitis (5.1%) [2,4]. The most common (≥5%) drug-related AEs observed were hot flush (48.2%), followed by injection site pain (7.3%) and fatigue (5.8%). All these AE are well known reactions to prostate cancer and castration treatment [5].

Five out of 137 subjects (3.6%) in FP01C-13-001 who experienced an AE discontinued from the study prematurely. These AEs included: acute kidney injury, atrial fibrillation, cerebrovascular accident, death, hormone refractory prostate cancer, and prostate cancer metastatic. None of these AEs were determined to be related to the administration of 50 mg LMIS [2].

In the extension, FP01C-13-001-EX, 30 patients from FP01C-13-001 received two additional doses of LMIS 50 6 months apart. Thus, total follow up for patients in FP01C-

13-001-EX was 2 years in total. There were seven new SAEs reported in four patients during the extension. None was related to LMIS 50 mg. No deaths occurred during the extension study. Only one drug related AE, a moderate neutropenia, was reported during FP01C-13-001-EX. The most common TEAEs that became more frequent during the safety extension period compared with the main study were acute kidney injury, blood triglycerides increased, dehydration, dizziness, fall, and fatigue. These occurred in 2 out of 30 patients each (6.67%). The AEs that remained the most prominent during the extension period were hypertension and dizziness [2].

Medication errors with Eligard®:

Medication errors linked to the complex handling during mixing have been reported with Eligard® as mentioned in 3.2.1 [3]. This prompted warnings in 2014 from EMA and The Danish Medicines Agency regarding practical handling difficulties and the increased risk of medication errors [10]. The EPAR highlights a potential benefit of Camcevi® in this regard: “Due to fewer preparatory steps (lack of reconstitution/mixing steps) before injection, it can be presumed that handling errors will occur less likely with Camcevi® Pre-filled syringe compared to Eligard®. [2]”

5.2.3 Method of synthesis (N/A)

This section is not relevant as no comparative analysis has been prepared in accordance with prior dialogue with the DMC secretariate.

5.2.4 Results from the comparative analysis (N/A)

This section is not relevant as no comparative analysis has been prepared in accordance with prior dialogue with the DMC secretariate.

Table 5 N/A

Outcome measure	[Intervention] (N=x)	[Comparator] (N=x)	Result
[Outcome measure 1], time point	[xx]	[xx]	[xx]
[Outcome measure 2], time point	[xx]	[xx]	[xx]
[Outcome measure 3], time point			
OS	Median: X months (95 % CI: X;Y)	Median: X months (95 % CI: X;Y)	X months HR: X;X (95 % CI: X;X)
Proportion of patients achieving ASAS40 (week 12)	**n/N, %** (95 % CI: X;Y)	**n/N, %** (95 % CI: X;Y)	**Absolute risk: X %** **Relative risk: X %**

Outcome measure	[Intervention] (N=x)	[Comparator] (N=x)	Result
Proportion of patients with AE ≥ grade 3	**n/N, %** (95 % CI: X;Y)	**n/N, %** (95 % CI: X;Y)	**Absolute risk: X %** **Relative risk: X %**

6. References

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Appendix A. Main characteristics of studies included

Tabel 6 Main characteristics of FP01C-13-001

Trial name: FP01C-13-001	**NCT number: NCT02234115**
Objective	To determine the safety, efficacy and pharmacokinetic (PK) profile of a pre-mixed depot formulation of leuprolide mesylate SC injectable suspension (LMIS) 50 mg for up to 1 year of treatment for subjects with advanced prostate cancer.
Publications – title, author, journal, year	Shore N, Mincik I, DeGuenther M, Student V, Jievaltas M, Patockova J, et al. A phase 3, open-label, multicenter study of a 6-month pre-mixed depot formulation of leuprolide mesylate in advanced prostate cancer patients. World J Urol. 2020;38(1). [4]
Study type and design	Phase 3, uncontrolled, multicentre, open-label, single-arm, 12-month, two-part PK, safety and PD/efficacy study.
Sample size (n)	137
Main inclusion criteria	1. Males aged ≥ 18 years old. 2. Males with histologically confirmed carcinoma of the prostate. 3. Subjects who are judged by the attending physician and/or Principal Investigator to be a candidate for androgen ablation therapy. 4. Baseline morning serum testosterone level > 150 ng/dL performed at Screening Visit. 5. Eastern Cooperative Oncology Group (ECOG) Performance score ≤ 2. 6. Life expectancy of at least 18 months. 7. Laboratory values ○ Absolute neutrophil count ≥ 1,500 cells/µL. ○ Platelets ≥ 100,000 cells/µL. ○ Haemoglobin ≥ 10 gm/dL. ○ Total bilirubin ≤ 1.5 × upper limit of normal (ULN). ○ Aspartate aminotransferase (AST) ≤ 2.5 × ULN. ○ Alanine aminotransferase (ALT) ≤ 2.5 × ULN. ○ Serum creatinine ≤ 1.5 mg/dL.

	○ Lipid profile within acceptable range according to investigator's judgment. ○ HbA1c within acceptable range according to investigator's judgment. ○ Clinical chemistries (K, Na, Mg, Ca and P) within acceptable range according to investigator's judgment. ○ Serum glucose within acceptable range according to investigator's judgement. ○ Urinalysis within normal range according to the investigator's judgment. 8. Agree to use male contraceptive methods during study trial. 9. Based on the Investigator's judgment, the ability to understand the nature of the study and any hazards of participation, and to communicate satisfactorily with the Investigator and to participate in, and to comply with, the requirements of the entire protocol. 10. All aspects of the protocol explained and written informed consent obtained.
Main exclusion criteria	• Receipt of chemotherapy, immunotherapy, cryotherapy, radiotherapy, or anti- androgen therapy concomitantly, or within 8 weeks prior to Screening Visit, for treatment of carcinoma of the prostate. Radiation for pain control will be allowed during the study. • Receipt of any vaccination (including influenza) within 4 weeks of Baseline. • History of blood donation within 2 months of Baseline. • History of anaphylaxis to any luteinizing hormone-releasing hormone (LHRH) analogues. • Receipt of any LHRH suppressive therapy within 6 months of Baseline. • Major surgery, including any prostatic surgery, within 4 weeks of Baseline. • History and concomitant clinical and radiographic evidence of central nervous system/spinal cord metastases. Subjects at risk for spinal cord compression will be excluded. • Clinical evidence of active urinary tract obstruction and subjects at risk for urinary obstruction. • History of bilateral orchiectomy, adrenalectomy, or hypophysectomy.

Trial name: FP01C-13-001	NCT number: NCT02234115
	• History or presence of hypogonadism, or receipt of exogenous testosterone supplementation within 6 months of Baseline. • Clinically significant abnormal electrocardiograms (ECGs) and/or history of clinically significant cardiovascular disease as judged by the investigator. • History of drug and/or alcohol abuse within 6 months of Baseline. • Contraindication to leuprolide or an LHRH agonist as indicated on package labeling. • Use of 5-alpha reductase inhibitor within the last 6 months of Baseline. • History or presence of insulin-dependent diabetes mellitus (Type I). Presence of well controlled diabetes mellitus Type II will be allowed. • Use of systemic corticosteroids at a dose >10 mg/d or anti-androgens. • Use of any investigational agent within 4 weeks of Baseline. • Use of any over-the-counter medication within 4 weeks of Baseline except for those listed in the permitted Concomitant Treatment section. • Uncontrolled intercurrent illness that would jeopardize the subject's safety, interfere with the objectives of the protocol, or limit the subject's compliance with study requirements, as determined by the Investigator in consultation with the Sponsor.
Intervention	SC injection of 50mg Leuprolide Mesilate, equivalent to 42 mg leuprorelin.
Comparator(s)	No comparator was included in the study.
Follow-up time	122 of 137 patients completed the study and was assessed at day 336.
Primary, secondary and exploratory endpoints	Primary outcome: • To determine the percentage of subjects with a serum testosterone concentration suppressed to castrate levels (≤ 50 ng/dL) by Day 28 ± 1 (day) following the first injection of LMIS 50 mg. • To determine the percentage of subjects with serum testosterone suppression (≤ 50 ng/dL) from Day 28 through Day 336 (remaining duration of the study). • Full PK profiles from serum leuprorelin concentrations in Part I subjects. Additional serum leuprorelin concentration data during Part II. Secondary outcomes:

Trial name: FP01C-13-001	NCT number: NCT02234115
	• The proportion of subjects exhibiting post-suppression excursions of serum testosterone to > 50 ng/dL, either through "breakthrough" (i.e., episodes unrelated to LMIS 50 mg dosing), or through the "acute-on-chronic" (i.e., related to the second dose of LMIS 50 mg) also called surge phenomenon. • The proportion of patients with serum testosterone concentration suppressed to reach profound castration (< 20 ng/dL) by Day 28 ± 1 (day). • The proportion of patients with serum testosterone concentration suppressed to reach profound castration (≤ 20 ng/dL) from Day 28 through Day 336 (remaining duration of the study). • Effect of LMIS 50 mg on serum PSA levels. • Effect of LMIS 50 mg on serum LH levels. • Safety and tolerability were assessed by American Urological Association Symptom Score sheet, complete blood count with platelets, clinical chemistries, urinalysis, serum glucose, lipid profile (low-density lipoprotein, high-density lipoprotein, triglycerides), haemoglobin A1c, and 12-lead resting ECGs. **Endpoints included in this application:** • Percentage of subjects with a serum testosterone concentration suppressed to castrate levels (≤ 50 ng/dL) by Day 28 ± 1 (day) following the first injection of LMIS 50 mg. • Percentage of subjects with serum testosterone suppression (≤ 50 ng/dL) from Day 28 through Day 336 (remaining duration of the study). • HRQoL.
Method of analysis	All efficacy analyses were ITT analyses. The ITT population was defined as any subject who received at least one dose of LMIS 50 mg. The PP population was defined as subjects who received 2 doses of LMIS 50 mg and met the inclusion/exclusion requirements of the protocol without major protocol deviations. The safety population was defined as any subject who received a dose of LMIS 50 mg. All 137 subjects were included in the ITT and safety populations.
Subgroup analyses	No subgroup analysis has been prepared.
Other relevant information	None.

Tabel 7 Main characteristics of FP01C-13-001-EX

Trial name: FP01C-13-001-EX	**NCT number: NCT02712320**
Objective	The primary objective was to determine the safety and tolerability of LMIS 50 mg for up to 1 year under Protocol FP01C-130-01-EX (2 years of total exposure) in subjects with advanced prostate carcinoma.
Publications – title, author, journal, year	EMA. Camcevi: EPAR - Public Assessment Report. 2022. [2,11]
Study type and design	Phase 3, uncontrolled, multicentre, open-label, single-arm, 12-month, two-part PK, safety and PD/efficacy study.
Sample size (n)	30
Main inclusion criteria	Main inclusion criteria*: 1. Complete 12 months of treatment with LMIS 50 mg under Protocol FP01C13001. If a subject wishes to enter the Extension study after more than 28 days following his end of study visit for Protocol FP01C13001, his serum testosterone level should be repeated at the screening visit to confirm that his castrate level testosterone has been maintained. 2. Laboratory values a. Absolute neutrophil count ≥ 1,500 cells/µL. b. Platelets≥100,000 cells/µL. c. Hemoglobin ≥ 10 gm/dL. d. Total bilirubin ≤ 1.5 × ULN. e. AST ≤ 2.5 × ULN. f. ALT ≤ 2.5 × ULN. g. Serum creatinine ≤ 1.5 mg/dL. h. Lipid profile within acceptable range according to investigator's opinion. i. Serum glucose within acceptable range according to investigator's opinion. j. HbA1c within acceptable range according to investigator's opinion. k. Clinical chemistries (K, Na, Mg, Ca and P) within acceptable range according to investigator's judgment. l. Urinalysis within normal range according to the investigator's judgment. 3. Agree to use male contraceptive methods during study trial.

Trial name: FP01C-13-001-EX	NCT number: NCT02712320
	4. In the Investigator's opinion, the ability to understand the nature of the study and any hazards of participation, and to communicate satisfactorily with the Investigator and to participate in, and to comply with, the requirements of the entire protocol. 5. All aspects of the protocol explained and written informed consent obtained. *If the patient completed 12 months of treatment with LMIS 50 mg more than 28 days prior to entering the Extension study, the ECOG, PE, ECG, laboratory and PSA tests should be repeated. If the patient has completed 12 months of treatment with LMIS 50 mg under Protocol FP01C13001 within the last 28 days, they will be allowed to enter the Extension study without repeat.
Main exclusion criteria	Main exclusion criteria: 1. Receipt of chemotherapy, immunotherapy, cryotherapy, radiotherapy, or antiandrogen therapy other than LMIS 50 mg under Protocol FP01C-13-001 for treatment of carcinoma of the prostate during the subject's participation in Protocol FP01C-13-001. Radiation for pain control will be allowed during the study. 2. Receipt of any LHRH suppressive therapy within 6 months of Screening Visit OTHER THAN LMIS 50 mg under Protocol FP01C-13-001. 3. Subject has used prohibited treatments during participation in Protocol FP01C-13-001. 4. Any pathological event, clinical AE, or any change in the subject's status at the end of FP01C-13-001 giving indication to the investigator that further participation in the study may not be the best interest of the subject. 5. Investigator considers that it is no longer feasible for the subject to be included in the extension study of LMIS 50 mg. 6. Subjects with persistent, non-castrate testosterone levels judged by the investigator. 7. Uncontrolled intercurrent illness that would jeopardize the subject's safety, interfere with the objectives of the protocol, or limit the subject's compliance with study requirements, as determined by the Investigator in consultation with the Sponsor.
Intervention	50 mg leuprolide mesylate administered SC, when given as two separate injections 6 months apart (Month 12 and Month 18 from the initiation of Protocol FP01C-13-001).
Comparator(s)	No comparator was included in the study.

Trial name: FP01C-13-001-EX		NCT number: NCT02712320
Follow-up time	1 year	
Primary, secondary and exploratory endpoints	Primary endpoints: 1. Determine the safety and tolerability by: a. Clinically significant abnormal laboratory assessment (including liver function (AST, ALT, ALP), renal function (BUN, serum Cr), complete blood count with platelets, clinical chemistries (K, Na, Mg, Ca and P), urinalysis, serum glucose, lipid profile (LDL, HDL, triglycerides) and HbA1c. b. AE reporting. c. Clinically significant change from baseline in 12lead resting ECGs per the Investigator's judgment. **Endpoints included in this application:** • AEs	
Method of analysis	The Safety population consists of any subject receiving a dose of LMIS 50 mg under Protocol FP01C-13-001-EX.	
Subgroup analyses	No subgroup analysis has been prepared.	
Other relevant information	None.	

Appendix B. Efficacy results per study

Results from FP01C-13-001

Table 8 Results from FP01C-13-001

Results of [trial name (NCT number)]											
				Estimated absolute difference in effect			Estimated relative difference in effect			Description of methods used for estimation	References
Outcome	**Study arm**	**N**	**Result (CI)**	**Difference**	**95% CI**	***P* value**	**Difference**	**95% CI**	***P* value**		
Castration (serum testosterone ≤50ng/dL) on day 28	LMIS 50 mg	137	98.5% (95% CI: 94.8-99.8)	N/A	N/A	N/A	N/A	N/A	N/A	Percentage of subjects that reached serum testosterone castration level (<50 ng/dL)	[4]
	N/A	N/A	N/A								
Castration (serum testosterone ≤50ng/dL) from Day 28 to Day 336	LMIS 50 mg	137	97.0% (95% CI: 92.2–98.9)	N/A	N/A	N/A	N/A	N/A	N/A	Percentage of subjects that reached serum testosterone castration level (<50 ng/dL)	[4]
	N/A	N/A	N/A								
	LMIS 50 mg	137	95/135, 70.4%	N/A	N/A	N/A	N/A	N/A	N/A		[4]

Results of [trial name (NCT number)]											
				Estimated absolute difference in effect			Estimated relative difference in effect			Description of methods used for estimation	References
Outcome	**Study arm**	**N**	**Result (CI)**	**Difference**	**95% CI**	***P* value**	**Difference**	**95% CI**	***P* value**		
Profound castration (serum testosterone ≤20ng/dL) on day 28	N/A	N/A	N/A							Percentage of subjects which had reached castration that also that reached serum testosterone castration level (<20 ng/dL).	
Profound castration (serum testosterone ≤20ng/dL) from Day 28 to Day 336	LMIS 50 mg	137	117/122, 95.9%	N/A	N/A	N/A	N/A	N/A	N/A	Percentage of subjects who completed the study and reached castration that also reached serum testosterone castration level (<20 ng/dL).	[4]
	N/A	N/A	N/A								

Appendix C. Comparative analysis of efficacy (N/A)

This appendix is not relevant as no comparative analysis has been prepared in accordance with prior dialogue with the DMC secretariat.

Table 9 Comparative analysis of studies comparing [intervention] to [comparator] for patients with [indication]

Outcome		Absolute difference in effect			Relative difference in effect			Method used for quantitative synthesis	Result used in the health economic analysis?
	Studies included in the analysis	Difference	CI	P value	Difference	CI	P value		
Example: median overall survival		NA	NA	NA	HR: 0.70	0.55–0.90	0.005	The HRs for the studies included were synthesized using random effects meta-analysis (DerSimonian–Laird).	Yes/No
Example: 1-year survival		10.7	2.39–19.01	0.01	HR: 0.70	0.55–0.90	0.005	The HRs for the studies included were synthesized using random effects meta-analysis (DerSimonian–Laird). The absolute difference was estimated by applying the resulting HR to an assumed 1-year survival rate of 64.33% in the comparator group.	

Outcome		Absolute difference in effect			Relative difference in effect			Method used for quantitative synthesis	Result used in the health economic analysis?
	Studies included in the analysis	Difference	CI	P value	Difference	CI	P value		
Example: HRQoL		**−4.5**	−8.97 to −0.03	0.04	NA	NA	NA	HRQoL results for the studies included were synthesized using the standardized mean difference (SMD). The estimated meta-analytical SMD of −0.3 (95% CI −2.99 to −0.01) was transformed to the scale of ZZZ* assuming a population standard deviation of 15 on the ZZZ* scale. *Fill in the name of an appropriate measure of HRQoL.	
Insert outcome 4									

Appendix D. Literature searches for the clinical assessment (N/A)

This appendix is not relevant as no literature search has been prepared in accordance with prior dialogue with the DMC secretariat.

D.1 Efficacy and safety of the intervention and comparator(s)

Table 10 Bibliographic databases included in the literature search

Database	Platform/source	Relevant period for the search	Date of search completion
Embase	e.g. Embase.com	E.g. 1970 until today	dd.mm.yyyy
Medline			dd.mm.yyyy
CENTRAL	Wiley platform		dd.mm.yyyy

Abbreviations:

Table 11 Other sources included in the literature search

Source name	Location/source	Search strategy	Date of search
e.g. NICE	www.nice.org.uk		dd.mm.yyyy
e.g. EMA website			dd.mm.yyyy

Abbreviations:

Table 12 Conference material included in the literature search

Conference	Source of abstracts	Search strategy	Words/terms searched	Date of search
Conference name	e.g. conference website	Manual search	List individual terms used to search in the conference material:	dd.mm.yyyy
	Journal supplement [insert reference]	Skimming through abstract collection		dd.mm.yyyy

Abbreviations:

D.1.2 Search strategies

[Describe the development of the search strategy and search string. Specify the inclusion and exclusion criteria for the search and justify (e.g. patient population, intervention, comparator, outcomes, study design, language, time limits, etc.).]

[The search must be documented with exact search strings line by line as run, incl. results, for each database.]

Table 13 of search strategy table for [name of database]

No.	Query	Results
#1		88244
#2		85778
#3		115048
#4		7011
#5		10053
#6		12332
#7		206348
#8		211070
#9	#7 OR #8	272517
#10	#3 AND #6 AND #9	37

D.1.3 Systematic selection of studies

[Describe the selection process, incl. number of reviewers and how conflicts were resolved. Provide a table with criteria for inclusion or exclusion.]

Table 14 Inclusion and exclusion criteria used for assessment of studies

Clinical effectiveness	Inclusion criteria	Exclusion criteria
Population		
Intervention		
Comparators		
Outcomes		

Study design/publication type	
Language restrictions	

[Insert the PRISMA flow diagram(s) here (see example here) or use the editable diagram at the end of this document.]

Table 15 Overview of study design for studies included in the technology assessment

Study/ID	Aim	Study design	Patient population	Interven-tion and compara-tor (sample size (n))	Primary outcome and follow-up period	Secondary outcome and follow-up period
Study 1						
Study 2						

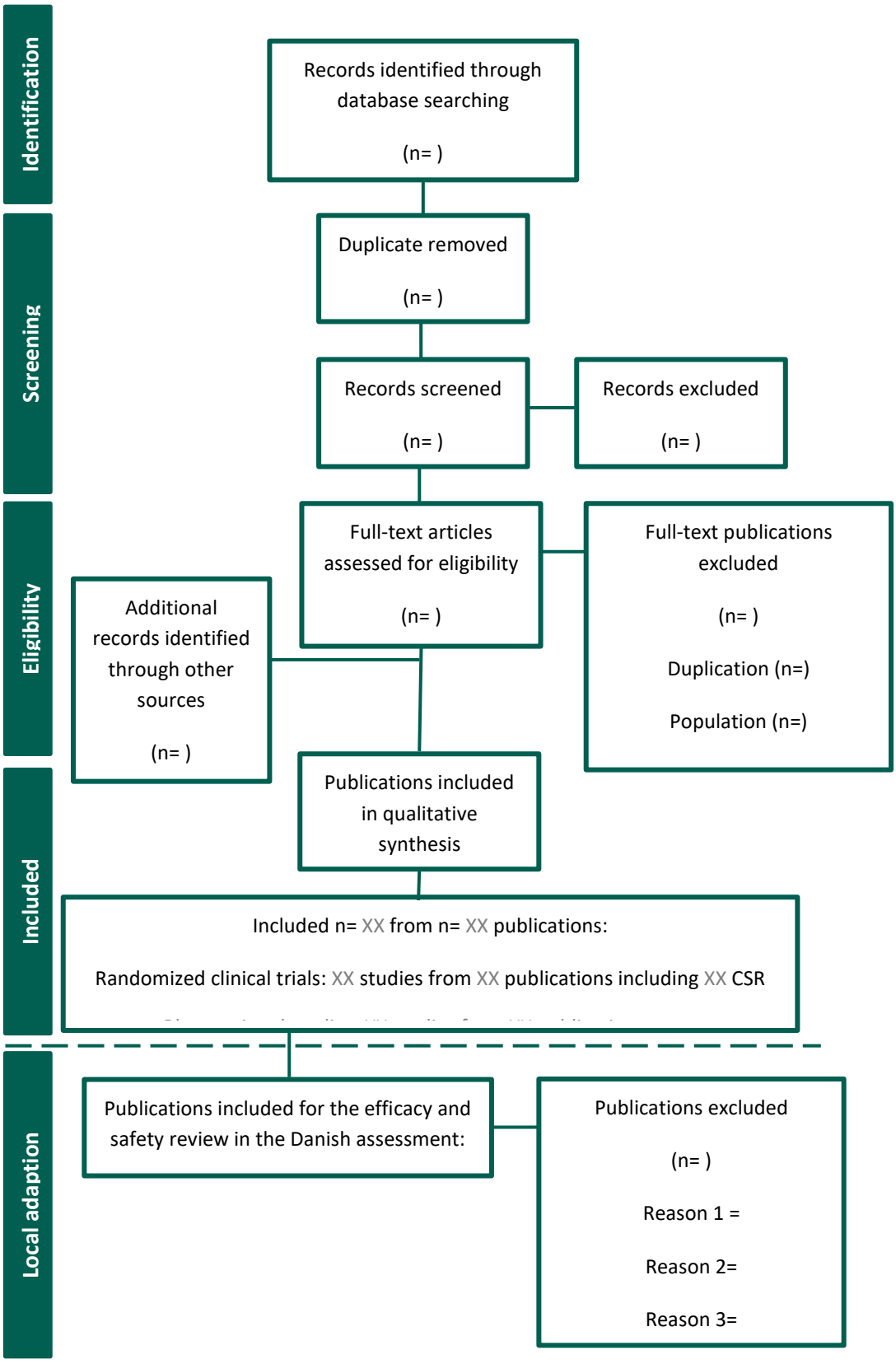
D.1.4 Quality assessment

[Describe strengths and weaknesses of the literature search performed.]

D.1.5 Unpublished data

[The quality of any unpublished data must be specifically addressed and a publication plan for unpublished data must be submitted].

Example of PRISMA diagram. The diagram is editable and may be used for recording the records flow for the literature searches and for the adaptation of existing SLRs.


Identification
Screening
Eligibility
Included
Local adaption
Records identified through database searching
(n=)
Duplicate removed
(n=)
Records screened
(n=)
Records excluded
(n=)
Full-text articles assessed for eligibility
(n=)
Full-text publications excluded
(n=)
Duplication (n=)
Population (n=)
Additional records identified through other sources
(n=)
Publications included in qualitative synthesis
Included n= XX from n= XX publications:
Randomized clinical trials: XX studies from XX publications including XX CSR
Publications included for the efficacy and safety review in the Danish assessment:
Publications excluded
(n=)
Reason 1 =
Reason 2=
Reason 3=

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