Medical Devices - SWEDEN

Competent authority

Contact Details	**Contact Name 1** Medical Products Agency MPA - Läkemedelsverket **Contact Name 2** Department of Medical Devices **Phone** +46 (0) 18 17 46 00 **Fax** +46 (0) 18 54 85 66 **Email Department** registrator@mpa.se **Address** P.O. Box 26 **ZIP/City** 751 03 Uppsala **Country** Sweden (SE) **Web address** http://www.lakemedelsverket.se
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Competent Authority/-ies (CA) Ethics committee(s) Other **CA - Submission for authorisation mandatory for** MD CE-marked, use outside label MD CE-marked, use outside label + IMP MD without label MD without label + IMP **CA - Registration/ notification without approval required for** – **CA - Submission required to** National CA

	Additional Information (1) If GMO involved: Swedish Gene Technology Authorities (the Authorities responsible for the regulations of activities involving GMOs) In addition to MPA approval, a notification or application for permit might be necessary to be submitted to the Swedish Work Environment Authority SWEA (LVFS 2004:10). The rules are specified in SWEA Provisions (AFS 2011:2) on contained use of genetically modified micro-organisms. (2) If ionising radiation is used the following authority shall be additionally involved: Swedish Radiation Safety Authority **Submission to CA and EC to be performed in the following order** –
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application** A detailed guidance on notification procedure and required appendices are provided on the MPA website in section Medical devices > Clinical Investigations > Notification and Forms.
Submission Format	**Format option(s)** Paper hardcopy Electronically **Preferred format** e- service for notification of clinical investigation **Online portal** The online portal "Medical device – e-service for notification of clinical investigation" for upload and submission of application form and attachments can be accessed via the MPA website in section Medical Devices > Clinical Investigations > Notification and Forms. **Standard application form available** Yes **Standard application form** "Form for notification clinical investigation" + "Guidance for use of notification form": available on the MPA website in section Medical Devices > Clinical Investigations > Notification and Forms **Additional Information** A copy of the application to the concerned Ethical Review Board may be attached (and its decision and statement if available when the notification is submitted).
Language of Submission	**Language(s) of application** Swedish English

	Preferred language of application – **English accepted** Yes **Documents mandatory to be in official national language** Information material, Documents and Forms intended for study participants and patient information **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** –
Submission Fees	**Fees for trial submission mandatory** Yes **Fees** Notification fee for a clinical investigation on MD: SEK 22.000.- (~ € 2.200.-) Academic research without economic support from external commercial sponsor may be waived. **Waiver for academic (non-commercial) studies possible** Upon request **Official guidance on required fees** Fees are provided on the MPA website in section > Medical devices >Clinical Investigations > Notification Fee **Applicable national legal framework/ Reference** Medical Devices Ordinance SFS 1993:876 (sv)
Timelines Authorisation	**General timespan (max nr days)** 60 **Mode of approval (General)** Explicit **Timespan counted from** Date of submission of valid application **Additional Information** The MPA has 3 working days to validate the notification dossier after submission. In case of any discrepancies in the notification (identified during the assessment time), the sponsor is granted one opportunity to correct the discrepancies within 10 days. Submission is possible anytime, no deadlines apply.
Amendments/ Substantial Amendments (SA)	**Notification mandatory for** – **Authorisation mandatory for** Substantial amendments (changes of study plan or participating sites)

Responsible for submission of SA

Sponsor

Standard notification form available

Yes

Standard notification form

The submission can be performed online via "E-service for notification" (can be accessed on MPA website in section Medical Devices > Clinical Investigations > Notification and Forms)

Timeline for approval of SA (max nr days)

–

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Sponsor must declare reportable events to

National CA
CA(s) of EU&EFTA Member States concerned

Reportable AEs

SAE (Serious Adverse Event)
SADE (Serious Adverse Device Effect)

SUSAR being life-thereatening or leading to death must be reported

–

All other SUSARs

–

SAE /SADE must be reported

Immediately
(Reportable events must be fully recorded)

National standard reporting form available

European standard SAE reporting form MEDDEV 2.7/3 to be used

Standard Reporting Form

SAE reporting form MEDDEV 2.7/3

Reporting format - Options

–

Preferred format

–

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA

Applicable national legal framework/ Reference

Annex 10, (2.3.5) LVFS 2003:11
Annex 7 (2.3.5.) LVFS 2001:5

Additional Information

Reporting of SADE and a vigilance report is mandatory for clinical investigation on CE-marked devices used within or outside label + respective combination studies with IMPs, observational investigations on MD and registries.

Annual safety report is mandatory for clinical investigations requiring authorization by CA (CE-marked devices used outside label and non-CE-marked devices and respective combination studies with IMP).

Investigator shall report SAE to

–

Reporting timeline

–

End of Trial

End of trial declaration mandatory for

All clinical trials requiring authorisation by CA

Responsible for End of trial declaration

Sponsor

Regular Termination - Declaration timespan (max nr days)

Not specified

Timespan counted from

–

Early/premature Termination - Declaration timespan (max nr days)

Not specified

Additional Information

Any trial interruptions for reasons of safety must be reported with an explanation as well as the restart of interrupted investigation with a justification.
Premature termination must be notified to the CA with a justification.

Additional Information & Specifics

Additional Information

The only CA for IMPs and MDs is the Medical Products Agency (MPA). Whether clinical trials with tissue or cell therapy will require a submission to the CA depends on the degree of manipulation and on the commercial potential of the “product”. A technique being offered by a specialist clinic provided at a certain hospital may be regulated by the National Board of Health and Welfare only (transplantation). If the technique or procedure is likely to be marketed, it will be regulated by the MPA and requires approval like a medicinal product. There is an option to create a system within the hospital for a specific patient, or for a group of patients, e.g. a new machine for renal dialysis. It is assumed that this is not research, but within the hospital

Ethics committee

Contact Details

Contact Name 1

Central Ethical Review Board/ Centrala Etikprövningsnämnden (EPN)

Contact Name 2

c/o Vetenskapsrådet

Address

Box 1035

ZIP/City

101 38 Stockholm

	Country Sweden (SE) **E-Mail** kansli@cepn.se **Web address** http://www.epn.se **Additional Information** Responsibility: Supervision, Appeals
Ethical Review – General	**Submission for Ethical review mandatory for** All clinical investigations of MD **Submission to CA and EC to be performed in the following order** In parallel Sequentially (in any order) **Additional Information** In Sweden, all research involving humans or their integrity must be reviewed by the Ethical Review board(s). Non-interventional studies (e.g. Epidemiological studies following AE on the market) will only be assessed by EC, not CA. Interventional studies will be judged by both CA and EC. **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Regional EC competent for the study site resp. health facility **Additional Information** The competent Regional Ethical Review Board of the catchment area of the trial site is responsible for evaluation of the single-centre study. Appeals against regional EC’s decisions can be submitted to the Central EC (pursuant to Section 36 2003:460).
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion) **Submission of application required to** Lead EC + All concerned local ECs for site-specific assessment

	Additional Information There are 6 Regional Ethical Review Boards in Sweden who are authorized to issue a (single) vote in mono- and multi-centre trials (according to Chapter 5 (7) LVFS 2003:6). The favourable single opinion shall be requested from the geographically relevant Regional Ethical Review Board depending where the responsible research body/ Principal Investigator is located. If a responsible research body is located in a country other than Sweden, or if its location is undetermined, the application is to be submitted to the board in whose catchment area most of the research is to be conducted. The geographically defined catchment areas for the Regional ECs are listed in Annex 1 of 2003:615. The EC's review of the application includes an assessment for each trial site of the PI's qualification and the suitability of the trial site (Chapter 4 (6) LVFS 2003:6). Appeals against regional EC's decisions can be submitted to the Central EC (pursuant to Section 36 2003:460).
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission / approval** – **Additional Information** There are no formal requirements, beside the application form. The application dossier should further include a proof of payment, the protocol and the patient information. A certificate indicating that there are adequate resources for the study available at the trial site is mandatory, signed by the manager of the clinic.
Submission Format	**Format option(s)** – **Preferred format** – **Standard application form available** Yes **Standard application form** "Ansökningsblanketten" (.doc) The standard application form for submission to all regional boards is available on the Central EC website in section Application. CAVE: Only the Swedish form is accepted! **Additional Information** There are no formal requirements, beside the application form. The application dossier should further include a proof of payment, the protocol and the patient information. A certificate indicating that there are adequate resources for the study available at the trial site is mandatory, signed by the manager of the clinic.
Language of Submission	**Language(s) of application** Swedish

	Preferred language of application – **English accepted** Annex for professional experts (research plan, protocol) **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Submission Fees	**Fees for Ethical review mandatory** Yes **Fees for Ethical review** Fees range from 5,000 SEK (approximately 500€) for an amendment to 16,000 SEK (approximately 1,600€) for pharmaceutical trials, or multi-centre studies. The detailed fees are provided in the Application form (Ansökningsblanketten) resp. in Annex 2 of 2003:615. **Official guidance on required fees** The detailed fees are provided in the Application form (Ansökningsblanketten) available on the EPN website resp. in Annex 2 of 2003:615. **Applicable national legal framework/ Reference** Annex 2 of 2003:615
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 60 **General timespan for multi-centre studies (max nr days)** 60 **External expert advice required: Timespan (max nr days)** – **Timespan counted from** – **Additional Information** Timeline for ethical review includes one round of complimentary questions to the investigator.
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** Sponsor **Standard notification form available** No

	Standard notification form There is no specific procedure for submission of amendments to the EC. A letter including the content and reason for the amendment is sufficient. **Timeline Ethical review of SA (max nr days)** –
Safety Reporting	**Reportable AEs** No AE reporting obligation **Investigator shall report SAE to** – **Reporting timeline** – **Responsible for AE reporting to relevant EC(s)** – **SUSAR being life-thereatening or leading to death must be reported** – **All other SUSAR must be reported** – **SAE/SADE must be reported** – **National Standard Reporting form available** – **Reporting format - Options** – **Preferred reporting format** – **Provision of Annual safety report mandatory** No **Additional Information** There is no obligation to report AE to the EC. The decision is up to the sponsor/investigator.
End of Trial	**End of trial Declaration mandatory** No **Responsible for End of trial Declaration** – **Regular Termination - Declaration timespan (max nr days)** – **Timespan counted from** – **Early/premature Termination - Declaration timespan (max nr days)** –

Additional Information

No explicit declaration obligations to ECs are legally fixed in the Swedish Acts (GCP is regulated in the Drug Act, but mostly referred to and not incorporated; GCP not a part of the Act regulating the ECs, however it is also here referred to).

So in practice, very few reports are submitted to ECs, e.g., in the case of:
- the sponsor is a company, the declaration and final report are sent to ECs because the company SOPs ask for it
- a new application, if this is a continuing work, based on a previously approved study

There is no offense in no shipping reports to ECs, taking for granted that they have been shipped to the CA.

Study specific Requirements

Sponsor

Sponsorship mandatory

Yes

Sponsorship mandatory - Additional information

It is mandatory to have a sponsor for clinical investigations on MD (MD CE-marked use outside label, MD without label + respective combination studies with IMP).

The sponsor can be the sponsoring company or, for academic studies, the employer of the investigator will formally be the sponsor (not the investigator personally).

Co-Sponsor - Definition available in national law

No

Co-sponsorship allowed

No

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Not specified

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

The research may only be carried out if the trial subject has consented to the research after she/ he has previously been given information on the overall plan and purpose of the research, the used methods, the consequences and risks, the identity of the sponsor and the participant’s right to revoke the consent at any time. The consent is to be voluntary, explicit and specific to particular research and is to be documented even if it not given in writing. (The literal definition of Informed Consent is provided in Chapter 1 (3j) LVFS 2003:6, corresponding to the EU Directive 2001/20/EC.)

Applicable national legal framework/ Reference

Section 16,17,19 SFS 2003:460
Chapter 1 (3j) LVFS 2003:6

Additional Information

Special provisions apply to vulnerable persons such as minors (less than 18 years of age) or persons incapable of giving consent (in case of illness, mental disorder, weakened state of health) (pursuant to Chapter 3 (2,3) LVFS 2003:6 and Section 18 resp. 20-22 2003:460).

Study Participants - Vulnerable Population	**Minors / Children - Studies allowed** Yes Special provisions apply **Legal framework/Reference (Minors/Children)** Chapter 3 (2) LVFS 2003:6 Section 18 SFS 2003:460 **Incapacitated persons - Studies allowed** Yes Special provisions apply **Legal framework / Reference (Incapacitated persons)** Chapter 3 (2-3) LVFS 2003:6 Section 20-22 SFS 2003:460 **Emergency situations - Studies allowed** Yes Special provisions apply **Emergency situation without prior consent of patient or proxy - Studies allowed** Yes Special provisions apply **Legal framework / Reference (Emergency Situation)** Chapter 3 (2-3) LVFS 2003:6 Section 20-22 SFS 2003:460 **Pregnant or breastfeeding women - Studies allowed** No national legal framework available **Specific provisions** No explicit provisions for the conduct of clinical trials on pregnant or lactating women are mentioned in Swedish legislation. **National legal framework for protection of vulnerable populations in place** Yes **Applicable legal framework / Reference (Vulnerable Population)** Chapter 3 (2,3) LVFS 2003:6 Section 18 resp. 20-22 2003:460
Data Protection	**Approval/ authorisation required** Not specified **Specific notification timelines before operations start** – **Language of notification** – **Notification format** – **Data Protection Authority/ Agency - Contact Details** Data Inspection Board/ Datainspektionen

Phone

+46 8-657 61 00

Fax

+46 8-652 86 52

E-Mail

datainspektionen@datainspektionen.se

Web address

http://www.datainspektionen.se/in-english/

Address

Box 8114

ZIP/City

104 20 Stockholm

Country

Sweden (SE)

Additional Information

According to the applicable law (Data Protection Acts and Ordinances), the processing and treatment of integrity-sensitive personal data (e.g. genetic predisposition that appear in a genetic study) shall be notified to the Swedish Data Inspection Board for control (in advance).

Further information is provided on the website.

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

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Insurance

Liability insurance or alternative arrangements for damages mandatory for

Study participants

Responsible for covering insurance

Sponsor

Insurance fee: A minimum coverage sum is defined

No

Applicable national legal framework/ Reference

Patient Injury Act SFS 1996:799

Additional Information

The Act requires those responsible for the subjects' safety and well-being, i.e. the clinical investigator and his principal, to hold a patient injury insurance policy. For a study within CE, the company must cover the insurance.

A copy of the policy or a document of similar signification shall be amended to the notification documents. The sponsor is advised to acquire an insurance policy covering for possible reclaims raised by the patient injury insurance provider as well as claims raised in accordance with the Swedish Product Liability Act.
No insurance needed with a registry study.

Archiving & Data Management	**Study documents must be kept at least (in years)** 5 10 15 Depending on type of MD and data **Additional Information** Pursuant to LVFS 2003:11 (Annex 8 (4.) 93/42/EEC): “The information contained in the declarations concerned by this Annex shall be kept for a period of time of at least five years. In the case of implantable devices the period shall be at least 15 years”, Pursuant to LVFS 2001:5 (Annex 6 (4) 90/385/EEC): “The information included in the declarations covered by this Annex shall be kept for a period of at least 15 years from the date of manufacture of the last product”. Public data must be stored for 10 years.

National legislation

General Information: Applicable Legislation & Conventions	**Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** Details on legal requirements can be found on the MPA website in section Legislation OR Medical Devices > Statutes and guidance documents.
Investigations on Medical Devices	**Applicable national regulations** National Act on Medical Devices **Act on Medical Devices (or comparable national legal framework)** (1) Medical Devices Act SFS 1993:584 (in Swedish): it is harmonised with the EC Directives and incorporates the provisions of 90/385/EEC, 93/42/EEC, 98/79/EC (2) Medical Devices Ordinance SFS 1993:876 (in Swedish): The Ordinance extends the provisions set forth in the Act (3) Code of Statutes LVFS: - LVFS 2001:5 for AIMD (90/385/EEC) - LVFS 2003:11 for MD (93/42/EEC) - LVFS 2001:7 for in-vitro diagnostic MD **Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)** (1) SOSFS 2008:1: the responsibility within the health care sector to report accidents and near-accidents with MD (2) Act on Public Access to Information and Secrecy Act: SFS 2009:400 covers information in the notification Medicinal Products Act SFS 1992:859 (3) If a medicinal product, or a substance that is considered to be a medicinal product, is included in the investigation, the requirements of this act apply to the section concerning the medicinal product/substance **Additional Information** Code of Statutes LVFS: Detailed Regulations issued by MPA (available on the MPA website in Swedish only). The implementation of the EC Directives into the national regulations is almost a word by word transformation of the directives texts.
Radiation & Radiotherapy	**Use of radiation or radioactive compounds - Specific requirements** Yes

	Applicable legal framework Swedish Radiation Protection Act SFS 1988:220 must be regarded; unofficial English translation is provided on the Swedish Radiation Safety Authority website.
Data Protection	**Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** National Data Protection Act Implementing Decrees and Ordinances Other legislation covering DP related issues **National DP act** (1) Personal Data Act: SFS 1998:204 (2) Personal Data Ordinance: SFS 1998:1191 (3) Patient Data Act (Patientdatalag, SFS 2008:355). The Act provides coherent regulation of the processing of personal data in the healthcare sector (how medical records must be kept for all patient care and how the information may be used by the health care providers' staff). The purpose of the legislation is to ensure increased patient security and protection of patients' privacy.
EC operations/ Fees	**Separate legal framework available** Yes **Applicable legal framework** Relevant provisions and regulations for the Ethical review of clinical trials are specified in: - Ethical Review 2007 Act: SFS 2003:460 (concerning Ethical Review of Research involving Humans) Changes made to the Ethical Review Act came into force in 2008 as a result of SFS 2008:192. - Statute SFS:1069 (Instructions for Regional Ethical Review Boards); - Statute SFS 2007:1068 (for the Central Ethical Review Board). **Additional Information** The unofficial English versions of the above mentioned Act and Statutes are provided on the Central EC's website in section Regulations.

Definition

MD/MD Investigation	**MD - Definition available in national law** Yes **MD - Definition** Definitions for MDs provided in: LVFS 2003:11 (93/42/EEC) and LVFS 2001:5 (90/386/EEC)