Medical Devices - BELGIUM

Competent authority

Contact Details

Contact Name 1

Federal Agency for Medicines and Health Products (FAMHP) / Agence Fédérale des Médicaments et des Produits de santé (AFMPS) / Federal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG)

Contact Name 2

Health Products Division

Phone

+ 32 2 528 40 00 (reception)

Fax

+32 (0)2 524 81 20

Email Department

meddev@afmps.be

Address

Eurostation II - Victor Horta Place 40/40

ZIP/City

1060 Brussels

Country

Belgium (BE)

Web address

http://www.fagg-afmps.be/en/famhp/

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)/ For certain types of MDs
Ethics committee(s)
Agency for data protection
Other (e.g. in case of radiation)

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

CE-marked MD used within label are exempted from any notification obligation to CA

Yes

Additional Information

For MD combined with IMP considered as ancillary, in addition to the MD notification to the CA a scientific advice will be required by a medicine Agency (FAGG, EMEA or other).

	Submission to CA and EC to be performed in the following order In parallel Sequentially (in any order) Note: For an investigation with a medical device, the FAMHP will not deliver its approval before having received the written LEC approval
Submission of Application	**Responsible for study submission** Sponsor Manufacturer Legal representative domiciled in the EU/EEA **Entitled to study submission** – **Prerequisites for submission** –
Submission Format	**Format option(s)** Paper hardcopy Data carrier (CD-rom/DVD) **Preferred format** Data carrier (CD-rom/DVD) **Standard application form** A standard form for Notification is available on the FAMPH website. Notification form plus 3 copies of the application file must be submitted. **Guidance on submission format** A standard form for Notification of a Clinical Investigation with Medical Devices plus a list of required documents for the complete application dossier is available on the FAMPH website in section: Human medicines > Health Products > Medical devices and their accessories >Clinical evaluation > Dossier content
Language of Submission	**Language(s) of application** Dutch French English **Preferred language of application** English **English accepted** – **Documents mandatory to be in official national language** The documents for patient consent must be written in the language of the patients (French, Dutch or German). **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

Medical Devices: € 2267,02.-
Active implantable medical devices: € 2373,65.-
Clinical trial on Medicinal Products: € 3672,23.-

When there is a submission for both medical device & drug, the fees are to be paid twice (for commercial trials)
e.g € 2267,02.-/ € 2373,65.- + 3672.23.-
(Status: Nov 2015)

Waiver for academic (non-commercial) studies possible

Yes

Official guidance on required fees

The current submission rates for clinical trials with MDs are provided on the FAMHP website in section: Human medicines > Health Products > Medical devices and their accessories >Clinical evaluation > Dossier content

Additional Information

NB: No fees are charged for non-commercial, academic studies (pursuant to Chapter XIX Art 31 (5) Law 7/2004.

Timelines Authorisation

General timespan (max nr days)

28
60 (for class III MD and of devices that are implantable or invasive for the long-term as in class IIa and IIb + Registries)

Mode of approval (General)

Tacit (Silent)
Explicit approval possible before expiration of time period

Clock-stop possible if complementary information requested

Yes

Timespan counted from

–

Additional Information

Evaluations conducted with devices, that do not belong to the classes mentioned above, do not require a 60 day waiting period.
Combined products (CE-marked MD used within label + IMP): 15 (Phase I) resp. 28 days

Amendments/ Substantial Amendments (SA)

Notification mandatory for

–

Authorisation mandatory for

–

Responsible for submission of SA

–

Timeline for approval of SA (max nr days)

–

Additional Information

No info currently available

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

National standard reporting form available

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

Standard Reporting Form

European form from MEDDEV 2.7/3 (Guidelines on Medical Devices- SAE Reporting)

Reporting format - Options

Email
To meddev@fagg.be

Preferred format

–

Provision of Annual safety report mandatory

Recommended

Annual safety report shall be provided by sponsor to

National CA
(not mandatory)

Guidance on AE reporting procedure

Reporting obligations are provided on FAMHP website in section: Human medicines Health Products Medical devices and their accessories Clinical evaluation Adverse events

Investigator shall report SAE to

–

Reporting timeline

–

End of Trial

End of trial declaration mandatory for

–

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 info currently available.

Ethics committee

Contact Details

Contact Name 1

Recognized local Ethics Committees (currently 24)

Contact Name 2

List and contact details provided on FAMHP- AFMPS-FAGG website

Country

Belgium (BE)

Web address

http://www.fagg-afmps.be/en/human_use/medicines/medicines/research_development/ethic_committee/

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)
Note: For an investigation with a medical device, the FAMHP will not deliver its approval before having received the written LEC approval

Additional Information

Circular 619 (08/04/2015) (french version): Provides a list of Ethics Committees having full accreditation status according to the law dated 7th May 2004 related to experiments on human people.

Regulatory and ethics bodies involved in approval process

–

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

Local EC linked to the trial site

Additional Information

The opinion has to be issued by an EC with full accreditation status (Apr 2014- Apr 2018: n=24 - Status 2015)

If the EC linked to the site has not been awarded full accreditation, but only partial accreditation status, the sponsor of the research project designates a committee with the required status to be authorized to issue a single opinion.
The EC with partial accreditation, linked to the site where the study will be conducted, should issue an opinion on the competencies of the researcher, the appropriateness of the facility and the adequacy and completeness of the patient information materials.

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

The formal opinion should be issued by one of the ECs with full accreditation status (see Circular).

The situation in the hierarchy (Academic Hospital ECs authorised to issue a single opinion > Non- Academic Hospital ECs authorised to issue a single opinion > Hospital ECs not authorised to issue a single opinion) will guide the sponsor in his choice of the leading EC (LEC) to issue the single opinion for the multi-centre research project.

The LEC reviews the experiment and issues a single opinion on the trial protocol considering all the aspects of the trial. The other “non-leading” ECs (n-LEC) send remarks to the LEC on the following aspects of the trial: suitability of investigator, suitability of facilities, Informed consent form.

Submission of Application

Responsible for study submission

Principal Investigator
Sponsor (EC selection)

Entitled to study submission

–

Prerequisites for submission / approval

–

Guidance on study submission

The submission mode (paper/online) depends on the EC.

Additional Information

Multi-centre trials: Submission to the LEC and n-LEC has to take place in parallel.

Submission Format

Format option(s)

Paper hardcopy
Electronically
Depends on EC concerned

Preferred format

–

Standard application form available

No

Language of Submission

Language(s) of application

Dutch
French
English

Preferred language of application

–

English accepted

–

Documents mandatory to be in official national language

The documents for patient consent must be written in the language of the patients (French, Dutch or German)

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 **Waiver for academic (non-commercial) studies possible** Yes **Fees for Ethical review** Research ECs charge fees for trials with a commercial sponsor as fixed by the Royal Decree of 15 July 2004, but they are subject to an indexation each year (e.g. in 2015: fixed fees given as follows + 25 % approximately): 1. Interventional studies: • Initial evaluation: single opinion committee: €1000.-; other committees: €300.- (local advice only). • Amendments: €250.- to the EC that gave the single advice. 2. Non-interventional studies: • Initial evaluation: single opinion committee. €400; other committees: €100 (local advice only). • Amendments: €100 to the EC that gave the single advice. No fees for non-commercial, academic trials are charged. **Applicable national legal framework/ Reference** Royal Decree of 15 July 2004 **Additional Information** Moreover, the committees receive each year a certain amount of money from the CA : 75 % of the fees paid by commercial sponsors to the CA should be redistributed to the EC. This redistribution is done on the basis of the number of trial protocols evaluated by each committee- further details on the particular procedure is provided in the latest circular “Pending payments for ethics committees”, available on the FAMHP website in section Ethics committee.
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 28 15 (for monocentric Phase I trials) **General timespan for multi-centre studies (max nr days)** 28 **External expert advice required: Timespan (max nr days)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** – **Additional Information** Note: Some EC’s do not meet during the summer period (July, August).
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments **Responsible for notification of SA** Investigator **Timeline Ethical review of SA (max nr days)** –

Applicable national legal framework/ Reference

Chapter X Art 19 Law 7/2004

Additional Information

No specific procedure for submitting a substantial amendment to the EC.

Safety Reporting

Reportable AEs

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

Investigator shall report SAE to

–

Reporting timeline

–

Responsible for AE reporting to relevant EC(s)

Principal Investigator

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

–

All other SUSAR must be reported

–

SAE/SADE must be reported

As soon as possible

National Standard Reporting form available

No

Reporting format - Options

–

Preferred reporting format

–

Provision of Annual safety report mandatory

Yes

End of Trial

End of trial Declaration mandatory

Yes

Responsible for End of trial Declaration

Sponsor

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

–

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

15

Reasons for early termination shall be clearly stated

Yes

Applicable national legal framework/ Reference

Chapter XI Art 21 Law 7/2004

Study specific Requirements

Sponsor

Sponsorship mandatory

Yes

Sponsorship mandatory - Additional information

It is mandatory to have a sponsor in all investigations on Medical Devices (Inverventional, observations and registries)

Co-sponsorship allowed

No

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Yes

Standard IC form (ICF)

For the purpose of simplification, harmonization and better information to the patient, Belgian ECs developed 4 different validated templates for informed consent (see Circular n° 604)

1. A basic model for interventional clinical trials on adults capable of autonomy,
2. A specific introduction for the inclusion of a participant with consent of a legal representative,
3. A specific introduction for the inclusion of a participant in an emergency situation,
4. A basic model for non-interventional studies on adults.

With some adjustments they can be used for clinical studies on Medical devices as well.

All four templates can be downloaded at the FAMHP website under section: Human medicines > Research & Development > Ethic Committee >Templates for informed consent.

Standard ICF - Additional Information

The templates for informed consent have been published in August 2013, they will be re-evaluated after an evaluation period in the presence of all Ethics Committees with a complete recognition.

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

Participants must give their free and informed consent before the commencement of a trial (according to the provisions specified in Chapter III Art 6 of Law 7 May 2004)

Applicable national legal framework/ Reference

Chapter III Art 6 of Law 7 May 2004

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Legal framework/Reference (Minors/Children)

Chapter IV Art 7 of Law 7/2004

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

Chapter V Art 8 Law 7 May 2004

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 VI Art 9 Law 7 May 2004

Pregnant or breastfeeding women - Studies allowed

No national legal framework available

Specific provisions

There are no explicit provisions for pregnant or lactating women mentioned in Law 7/2004.

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

Yes

Specific notification timelines before operations start

–

Language of notification

Official National Language(s)

Notification format

Paper hardcopy
Electronically

Notification fee required

Yes

Fee

For all investigation on Medical Devices: 25€ (electronically), 125€ (paper version)

Guidance on notification requirements

Further details on the declaration procedure are provided on the Commission's website in section "Privacy topics" (in French or Dutch only).

Data Protection Authority/ Agency - Contact Details

The Commission for the Protection of Privacy (CPP)

Contact Name 2

"The Privacy Commission"

Phone

+32 (0)2 274 48 79

Fax

+32 (0)2 274 48 35

E-Mail

commission@privacycommission.be

Web address

https://www.privacycommission.be/en

Address

Rue de la Presse 35

ZIP/City

1000 Brussels

Country

Belgium (BE)

Additional Information

Clinical Trials must comply with data protection rules as specified in the Belgian Data Protection Act and its implementing Royal Decrees provided on the CPP website.

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

–

Insurance

Liability insurance or alternative arrangements for damages mandatory for

–

Responsible for covering insurance

Sponsor

Additional Information

A no-fault insurance is required for all investigations on Medical Devices (interventional, observational, registries).

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation available

Yes

Official website providing relevant national legislation

On overview on the applicable legal texts including corresponding links is provided on the FAMHP (Federal Agency for Medicines and Health Products) website in section: Human medicines > Health Products > Medical devices and their accessories >Generalities > Legislation.

Investigations on Medical Devices

Applicable national regulations

National Act on Medicinal Products and Medical Devices
Transposition of EU Directives on MD
Other

Act on Medical Devices (or comparable national legal framework)

Clinical trials on MD for human use are covered by:
The Law of 7 May 2004 relating to experiments on human people (Loi relative aux expérimentations sur la
personne humaine).
This law applies to all experiments on humans including Medicinal Products and Medical Devices. The general provisions have to be followed for all clinical research. Please note thate there are some articles that are only relevant for clinical trials on Medicinal Products.

Transposition of Directive 90/385/EEC

Royal Decree of 15 July 1997 implementing EU Directive 90/385/EEC (active implantable medical devices) modified by the Royal Decree of 10 December 2002 & the Royal Decree of 21 January 2009

Transposition of Directive 93/42/EEC

Royal Decree of 18 March 1999 implementing EU Directive 93/42/EEC (medical devices) modified by the
Royal Decree of 17 March 2009

Transposition of Directive 98/79/EC

Royal Decree of 14 November 2001 implementing EU Directive 98/79/EC (in vitro diagnostic medical devices)
modified by the Royal Decree of 05 November 2012;

Other applicable regulations / implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)

Royal Decree of 1 March 2000 establishing the remunerations to finance the missions of the administration regarding medical devices amended by the Royal Decree dated 13th May 2005.

Definition

MD/MD Investigation

MD - Definition available in national law

Yes

MD - Definition

Definitions for various types of MDs (MD, active MD, active implantable MD, etc.) are provided on the FAMPH website in section: Human medicines > Health Products > Medical devices and their accessories > Generalities > Definitions

MDs are listed according to four product categories (class I, IIa, IIb and III) according to the degree of risk when used. The classification rules are described in appendix IX of the Royal Decree of 18 March 1999 (fr) relating to medical devices.
(see also European guidelines for classification: document MEDDEV 2.4/1 part 1 and part 2).