Nutrition/Interventional - BELGIUM

Competent authority

Contact Details

Contact Name 1

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

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Additional Information

The FAMPH- AFMPS-FAGG acts on behalf of the minister as competent authority.

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Ethics committee(s)
Agency for data protection

Regulatory and ethics bodies involved in approval process for trials including patients

–

Regulatory and ethics bodies involved in approval process for trials including including healthy participants

–

Regulatory and ethics bodies involved in approval process for trials including vulnerable population

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CA - Registration/ notification without approval required for

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	CA - Registration requirements for clinical trials Registration not mandatory **Registration requirements for clinical trials including patients** – **Registration requirements for clinical trials including healthy participants** – **Registration requirements for clinical trials including vulnerable population** – **CA - Submission required to** Submmission not mandatory **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** – **Additional Information** Depending if the study includes a supplement and if this supplement is considered as a medicine.
Submission Format	**Standard application form available** No **Standard application form** Only in pharmaceuticals / drug trials
Language of Submission	**Language(s) of application** Official national language Dutch French German English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** – **English accepted** Yes **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 the study participant** all patient related documents (French/German/Dutch)
Timelines Authorisation	**Time to approval of CA in weeks (minimum)** 4 **Time to approval of CA in weeks (maximum)** 4 **Time to approval CA in weeks (average)** 4 **Additional Information** For Phase I trials: 15 days

Ethics committee

Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** Yes **Submission to CA and EC to be performed in the following order** – **National declaration on Ethical requirements exists** Yes **National declaration** Law 7 May 2004 concerning experiments on the human person (en) **Additional Information** FAMHP (section on Ethics Committees)
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** – **Ethical approval (favourable opinion) for trials including patients to be obtained from** – **Ethical approval (favourable opinion) for trials including healthy participants to be obtained from** – **Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from** – **Additional Information** Responsible for clinical studies in nutrition: Each EC of all participating hospitals. If study is performed for instance with GP's , 1 EC has to be chosen to submit the study.

Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC + All concerned local ECs for site-specific assessment Regional EC (authorised to issue a single opinion) **Ethical approval in trials including patients obtained from** – **Ethical approval in trials including healthy participants obtained from** – **Ethical approval in trials including vulnerable population obtained from** – **Additional Information** The EC reviewing the study must be recognised by the Federal Agency for Medicines and Health products (list of EC on their website). In case of multicentre studies, a leading EC has to be indicated and the other EC will be non –leading. There are specific criteria to be leading EC to be found on FAMHP website.
Submission of Application	**Entitled to study submission** Principal Investigator Investigator **Entitled to submission of trials including patients** – **Entitled to submission of trials including healthy participants** – **Responsible for submission of trials including vulnerable population** – **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** Yes
Language of Submission	**Language(s) of application** National language: French/German/Dutch and English **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** – **English accepted** Yes

	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** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 4 **Time in weeks from submission to positive approval (maximum)** 4 **Time in weeks from submission to positive approval (average)** 4
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** – **Responsible for notification of SA** – **Timeline Ethical review of SA (max nr days)** – **Additional Information** Notify adverse reactions of medicines at the famhp on our website or at: patientinfo@fagg-afmps.be
Safety Reporting	**Investigator shall report SAE to** Institution, Sponsor, **Investigator shall report SAE in trials with patients to** – **Investigator shall report SAE in trials with healthy participants to** – **Investigator shall report SAE in trials with volunteers to** –

Study specific Requirements

Investigator	**Entitled to be principal investigator** Physician **Entitled to be principal investigator for trials with patients** – **Entitled to be principal investigator for trials with healthy participants** – **Entitled to be principal investigator for trials with vulnerable population** Physician Any investigator experienced in related domain

Additional Information

Law of May 7, 2004 concerning experiments on the human person: definition

"investigator": a medical doctor or any other person exercising a profession referred to in the Royal Decree No. 78 of November 10, 1967 concerning the health care professions and who is qualified for conducting an experiment. The investigator is responsible for the conduct of the experiment at a certain site. If the experiment is conducted by a team of individuals at a certain site, the investigator is the leader responsible for the team and may be called the principal investigator;

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

No

Accepted format of Informed Consent (IC) form

Written consent

Accepted format of IC form for studies including patients

–

Accepted format of IC form for studies including healthy participants

–

Accepted format of IC form for studies including vulnerable population

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Study Participants - Vulnerable Population

Considered as vulnerable population

Children
Incapacitated adults

Vulnerable population - Additional information

Law of May 7, 2004 mentions minors and incapable adults as vulnerable population specifically.

Regulations concerning the inclusion or exclusion available

Not specified

Applicable ethical regulations

–

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Optional

Reimbursement for patients

–

Reimbursement for healthy participants

–

Reimbursement for vulnerable population

–

Compensation is limited to/provided for

–

Compensation for patients is limited to/provided for

–

	Compensation for healthy participants is limited to/provided for – **Compensation for vulnerable population is limited to/provided for** –
Funding	**Trials generally financially supported by industry** Yes **Additional Information** Pharmaceutical/ Drug trials are generally sponsored by industry
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Investigator(s) **Obligation to contract a liability insurance for trials including patients for** – **Obligation to contract a liability insurance for trials including healthy participants for** – **Obligation to contract a liability insurance for trials including vulnerable population for** – **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** – **Additional Information** No fault insurance required by EC for all experiments covered by the law and also for non interventional trials. Sponsor should be established in EU (EU representative required).
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Standard Operating Procedures (SOP) Case Report Form (CRF) **Regularly performed methods in trials including patients** – **Regularly performed methods in trials including healthy participants** – **Regularly performed methods in trials including vulnerable population** –

Regularly performed audits

–

Regularly performed audits in trials including patients

–

Regularly performed audits in trials including healthy participants

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Regularly performed audits in trials including vulnerable population

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Archiving & Data Management

Study documents must be kept at least (in years)

–

Legal framework for data management exists

No

National legislation

General Information: Applicable Legislation & Conventions

Applied regulatory conventions

Declaration of Helsinki
ICH-GCP Guidelines
National regulatory requirements

Applied regulatory conventions in studies including patients

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Applied regulatory conventions in studies including healthy participants

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Applied regulatory conventions in studies including vulnerable population

–

Applicable national laws

–

Applicable national laws for patients

Hospital Act
Data protection Act
Drug act

Applicable national laws for healthy participants

–

Applicable national laws for vulnerable population

–

National regulations for volunteers exist for

Do not exist

Network providing information on regulations and ethical requirements in studies

Federal agency for medicines and health products - famhp

Network Email

welcome@fagg-afmps.be

	Additional Information General Telephone contact: +32 2 528 40 00 Additional Email contacts. Information concerning medicines and health products. info.medicines@fagg-afmps.be Research and Development. ct.rd@fagg-afmps.be Products of which the status is unclear borderline.hum@fagg-afmps.be borderline.vet@fagg-afmps.be
Nutrition	**Nutrition considered as drug** – **Additional Information** The law of 25th March 1964 about medicines gives the following definition of a medicine: « any substance or composition claiming to possess properties that cure or prevent human sickness, or any substance or composition that can be used by humans or can be given to restitute, correct or change some physiological functions by providing an action that is pharmacological, immunological or metabolic, or for establishing a medical diagnostic. » For some products it is not always clear what their status is. They are in the "gray area" between medicinal products, food supplements, cosmetics, biocides, nutrients or products of regular consumption. The Mixed Commission, set up by the Royal Decree of 28/10/2008 (French version) clarifies the status of these products. The Mixed Commission is composed of representatives from: • FAMHP • FPS Health, Food Chain Safety and Environment: DG Animals, Plants and Food and DG Environment • FPS Economy, SMEs, and Energy • FASFC Its mission is to express an opinion on cases of products for which there is doubt about the status. The Minister or his representative makes a decision based on that opinion. This review may be requested by a manufacturer who wants to be clear about the status of his product for the relevant public services or for third parties. There is a commission for medicinal products for human use and one for medicinal products for veterinary use. borderline.hum@fagg-afmps.be; borderline.vet@fagg-afmps.be
Blood & Tissue Samples	**Specific requirements** No **Tissue samples permitted** Yes **Tissue samples permitted - Additional information** if EC has given favorable opinion
Data Protection	**Specific Requirements** Yes **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** – **National DP act** Belgian Data Protection Act, 8 December 1992

	Additional Information Privacy Commission Rue de la Presse 35, B-1000 Brussels, Tel : +32 (0)2 274 48 79, Fax : +32 (0)2 274 48 35 commission@privacycommission.be
Invasive Catheters	**Invasive catheters permitted** Yes **Additional Information** if EC has given favorable opinion

Definition

Clinical Research	**Definition in national law** The existing law in Belgium for clinical trials, Law 7 May 2004 (Law concerning experiments on the human person) is transposed from the EU Directive 2001/20. Scope of law: Experiments (including clinical trials) apply to drugs, medical devices & non-drug experiments, all experiments on human beings, commercial as well as non-commercial, interventional as well as non-interventional. “Interventional” has a broad sense: prospective questionnaires, additional blood sampling, supplementary visits,.. are considered as interventional (anything outside normal clinical practice). Not in scope of law: Data collection only, retrospective data analysis (epidemiologic, cost),.. “clinical trial": any investigation in human persons intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.
Interventional Study	**Definition in national law** “clinical trial": any investigation in human persons intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.
Observational Study	**Definition in national law** There is no definition for “interventional studies” or “observational study”. The law defines “clinical trials and “non-interventional trials”. “non-interventional trial": a study where the medicinal products are prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.
Nutrition Study	**Definition available in national law** Yes