Nutrition - 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) **Contact Name 2** Research and Development division (R&D division) **Phone** +32 2 524 80 00 **Fax** +32 2 524 80 01 **Email General** welcome@fagg-afmps.be **Email Department** ct.rd@fagg-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/ **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** Institutional Ethics Committee **CA - Registration requirements for clinical trials** Registration not mandatory **CA - Submission required to** Not applicable **Additional Information** Only in case of pharmaceuticals submission is required to national copetent authority: 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 drug trials
Language of Submission	**Language(s) of application** National language: French/German/Dutch and English **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 studies: 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
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Institutional EC **Additional Information** 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)

	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 **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 **Preferred language of application** – **English accepted** Yes **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** patient related documents have to be in the language of the patients
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
Safety Reporting	**Investigator shall report SAE to** Institution, Sponsor,

Study specific Requirements

Investigator	**Entitled to be principal investigator** Physician Any investigator experienced in related domain **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 – **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** –
Study Participants - Vulnerable Population	**Considered as vulnerable population** Children Incapacitated adults Other Not specified **Applicable ethical regulations** National **Legal framework/Reference (Minors/Children)** Law of May 7, 2004 mention minors and incapable adults **Legal framework / Reference (Incapacitated persons)** Law of May 7, 2004 mention minors and incapable adults
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** –
Funding	**Trials generally financially supported by industry** No **Additional Information** only pharmaceutical trials
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 Sponsor **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** – **Applicable national legal framework/ Reference** 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 audits** –
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 **Applicable national laws** Hospital Act Data protection Act **National regulations for volunteers exist for** Do not exist
Nutrition	**Nutrition considered as drug** Depends on product

	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
Blood & Tissue Samples	**Tissue samples permitted** No
Data Protection	**Specific Requirements** Not specified **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),.. There is no definition for “interventional studies” or “observational study”. The law defines “clinical trials and “non-interventional trials”.
Observational Study	**Definition in national law** “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