Medicinal Products for Human Use - HUNGARY

Competent authority

Contact Details

Contact Name 1

National Institute of Pharmacy and Nutrition NIPN/ OGYÉI

Contact Name 2

Clinical Trials Unit

Phone

+36 1 8869-300

Fax

+36 1 8869-460

Email General

ogyei@ogyei.hu

Email Department

clinadr@ogyei.gov.hu

Address

Zrinyi u. 3/ Mail: 1372 P.O. Box: 450

ZIP/City

1051 Budapest

Country

Hungary (HU)

Web address

http://www.ogyei.gov.hu/main_page/

Additional Information

Co-authority: ETT KFEB (Hungarian Medical Research Council Ethics Committee for Clinical Pharmacology)
Co-authority for non-interventional trials: ETT TUKEB
Co-authority for trials conntected with reproduction: ETT HRB (Committee of Human Reproduction)

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

–

CA - Submission for authorisation mandatory for

Interventional IMP trials
Non-interventional IMP trials

CA - Registration/ notification without approval required for

–

CA - Submission required to

National CA
Other

	Additional Information One single submission to NIPN/ OGYÉI. The OGYEI will forward one copy of the documentation to the CEC (Central Ethics Committee) for ethical review and opinion. In case of favourable opinion, NIPN/OGYÉI provides approval.
Submission of Application	**Responsible for study submission** Sponsor **Entitled to study submission** – **Prerequisites for submission** – **Guidance on submission of application** • Guidance on clinical trial submission procedure available on OGYÉI website in section: Authorisation > Clinical trials > Clinical Trial Submission procedure. • Non-commercial trials with IMPs: a simplified protocol should be submitted, containing minimally the justification of the trial, the number of subjects to be engaged, the proposed time of the trial and its recruitment methods (pursuant to 15 Decree No 35/2005). Detailed info available on OGYÉI website in section: Authorisation- Clinical trials -Non-commercial clinical trials) • Non-interventional trials with IMPs: Submission procedure provided on OGYÉI website in section: Authorisation of non-interventional studies
Submission Format	**Format option(s)** 2 identical copies on CD (for immunological studies: 3 copies) **Preferred format** – **Standard application form** EudraCT: Annex 1: Clinical trial Application Form Accompanying documents are specified in Annex 3 to Decree No 35/2005. **Applicable national legal framework/ Reference** Annex 3 to Decree No 35/2005
Language of Submission	**Language(s) of application** Hungarian English **Preferred language of application** – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Protocol Summary Information material, Documents and Forms intended for study participants and patient information Site related information IMPD (Investigational Medicinal Product Dossier) Labels Full title of the trial (A.3)

Submission Fees	**Fees for trial submission mandatory** Yes **Fees** Authorization fees (including fees for EC review): • New Clinical Trial Submission: 580.000 HUF (approx. €1890.-) (In case of Preliminary opinion of CEC: 261.000 HUF to CEC and 319.000 HUF to CA) • Amendments: 110.000HUF (Approx. 360€) • Non-interventional trials: 370,000 HUF (approx. €1200.-) **Waiver for academic (non-commercial) studies possible** Yes **Official guidance on required fees** Fees are provided on OGYÉI website in section: Clinical trial submission procedure Waiver for non-commercial trials: Applicable criteria are provided on OGYÉI website in section: Non-commercial clinical trials **Applicable national legal framework/ Reference** Schedule No. 1 to Act XCV of 2005
Timelines Authorisation	**General timespan (max nr days)** 75 (including EC approval process of max 42 days) - also applicable to Non-interventional trials with IMPs **Mode of approval (General)** – **ATMP/GMO trials (max nr days)** 90 (including EC approval process of max 72 days) **Mode of approval (ATMP/GMO trials)** – **External expert advice required (max nr days)** – **Xenogeneic cell therapy (max nr days)** 12 months form date of submission (including EC approval process of max 11 month) **Mode of approval (Xenogeneic cell therapy)** – **Clock-stop possible if complementary information requested** Yes **Timespan counted from** Date of submission of valid application **Applicable national legal framework/ Reference** Section 3 of 95th Act of 2005

Additional Information

Approval process in detail:
The NIPN starts its assessment and, within 8 days, sends the copy of the relevant parts of the application to the competent EC for review. The EC sends back its reasonable within 42 calendar days starting from receiving the documentation from the NIP. Within another 10 days, the NIPN sends the applicant the authorisation/ rejection, the first Annex of that is the KFEB opinion.
In case when the KFEB is consulted first, its (positive) opinion is appended to the application to the NIPN. However, the NIPN's approval time is still 60 calendar days in this case.

Amendments/ Substantial Amendments (SA)

Notification mandatory for

–

Authorisation mandatory for

Any substantial amendments to the study protocol

Responsible for submission of SA

Sponsor

Timeline for approval of SA (max nr days)

22 working days (without requesting EC opinion),); 35 (if EC opinion required)

Applicable national legal framework/ Reference

Section 18 of Decree No 35/2005

Additional Information

In the application, the sponsor must state the reasons for such modification, and if this modification may have an impact on the safety of participants, then a draft of the modified patient information and informed consent must also be attached.

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
Relevant Co-Authority (acting as EC)

Reportable AEs

–

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

Immediately
Within a max of 7d upon first knowledge (+ 8d for additional information)

All other SUSARs

Within a max of 15d upon first knowledge

SAE /SADE must be reported

–

National standard reporting form available

–

Reporting format - Options

–

Preferred format

–

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA
Relevant EC(s)

Guidance on AE reporting procedure

Detailed information is available on OGYÉI website in section: AR reporting arising from clinical trials.

Applicable national legal framework/ Reference

Section 21 & 22 Decree No 35/2005

Additional Information

• Sponsors of commercial studies shall immediately report any SUSAR from clinical trials via the EudraVigilance system to EMA (OGYÉI in case of non-commercial studies).

• Safety Notification Letters should be sent to NIP/ OGYÉI immediately but at latest 24 hours, if the new events affect the conduct of the trial or the safety of the subjects considerably.

• Sponsors should report only those SUSARs to NIPN/OGYÉI where the primary source country is Hungary.
The sponsor shall notify all investigators participating in the clinical trial on any SUSAR.

• NB! Recent changes regarding AE reporting:
Development Safety Update Report (DSUR) report is mandatory to be provided to CA and competent EC on CD.
SUSAR Line Listing must be sent only to investigators according to the guideline of European Commission ("Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use" (2011/C 172/01 section 7.10.).

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)

90

Timespan counted from

–

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

15

Standard Declaration form

EU Declaration of the End of Trial Form

Applicable national legal framework/ Reference

Section 23 of Decree No 35/2005

Additional Information & Specifics

Additional Information

National Competent Authority:
National Institute of Pharmacy and Nutrition NIPN/ OGYÉI

The three central ethics committees (CEC) in Hungary are officially appointed by law as public co-authorities (in the meaning of the general rules of public authority procedures) and are all part of the ETT (Egészségügyi Tudományos Tanács) Medical Research Council:

(1) Co-authority: ETT KFEB (Hungarian Medical Research Council Ethics Committee for Clinical Pharmacology)
(2) Co-authority for non-interventional trials: ETT TUKEB
(3) Co-authority for trials conntected with reproduction: ETT HRB (Committee of Human Reproduction)

Ethics committee

Contact Details

Contact Name 1

Central Ethics Committee (CEC)/ Public co-authority for IMP studies:

Contact Name 2

Committee for Clinical Pharmacology and Ethics of the Medical Research Council – KFEB

Phone

(+36 1) 795-1195 or (+36 1) 795-4873

Fax

(+36 1) 795-0168

Country

Hungary (HU)

E-Mail

kfebtitkarsag@emmi.gov.hu

Web address

http://www.ett.hu/kfeb.htm

Additional Information

For Safety Reporting/ SUSARs: safetyreport@emmi.gov.hu

Ethical Review – General

Submission for Ethical review mandatory for

All research projects involving humans

Submission to CA and EC to be performed in the following order

–

Procedural interaction between CA and EC during approval process

Yes

	Procedural interaction - Additional information (1) Common Procedure: One single submission to NIPN/ OGYÉI (National Institute of Pharmacy and Nutrition). One copy of the documentation will be sent to the relevant Central Ethics Committee (CEC) - acting as co-authority- for ethical review and opinion. In case of favourable opinion, CA provides approval. (2) Direct submission to EC: same formal requirements as for submission to CA apply **Additional Information** The three central ethics committees (CEC) in Hungary are officially appointed by law as public co-authorities (in the meaning of the general rules of public authority procedures) and are all part of the ETT (Egészségügyi Tudományos Tanács) Medical Research Council: 1. Committee for Clinical Pharmacology and Ethics of the Medical Research Council – KFEB 2. Committee for other biomedical research involving human subjects and non-interventional trials with IMP: Scientific Research Ethics Committee of the Medical Research Council - ETT TUKEB 3. Committee for trials connected with human reproduction, human genetics and ATMP: Human Reproduction Committee of the Medical Research Council (ETT HRB) **Regulatory and ethics bodies involved in approval process** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Central EC **Additional Information** • KFEB is the only competent Ethics Committee authorised to approve single- and multi-site clinical trial protocols with IMPs. • HRB evaluates single- and multi-site clinical trials dealing with interventions for human reproduction, with human genetics and advanced medicinal products (cell and gene therapy). • Non-interventional single-centre trials are evaluated by TUKEB. • Institutional Research Ethics Committees (IKEB): The role of the local (hospital) ethics committees is to safeguard patients' interest during the trials and give only advice on the feasibility of a medicinal products trial.
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion) **Submission of application required to** Central EC (authorised to issue a single opinion) **Additional Information** • KFEB is the only competent Ethics Committee authorised to approve single- and multi-site clinical trial protocols with IMPs. • HRB evaluates single- and multi-site clinical trials dealing with interventions for human reproduction, with human genetics and advanced medicinal products (cell and gene therapy). • Non-interventional single-centre trials are evaluated by TUKEB. • Institutional Research Ethics Committees (IKEB): The role of the local (hospital) ethics committees is to safeguard patients' interest during the trials and give only advice on the feasibility of a medicinal products trial.
Submission of Application	**Responsible for study submission** Sponsor

	Entitled to study submission – **Prerequisites for submission / approval** – **Guidance on study submission** Same requirements as for submission to CA. **Additional Information** (1) Common Procedure: Submission via National Institute of Pharmacy and Nutrition/ OGYÉI; no extra submission to CEC required. (2) Direct submission to EC: same formal requirements as for submission to CA apply.
Submission Format	**Format option(s)** Same as for CA submission **Preferred format** – **Additional Information** Common submission procedure: via National Institute of Pharmacy and Nutrition/ OGYÉI; in case of direct submission to EC: same formal requirements as for submission to CA apply!
Language of Submission	**Language(s) of application** Hungarian **Preferred language of application** – **English accepted** Partly, not for all documents **Documents mandatory to be in official national language** Protocol Summary Information material, Documents and Forms intended for study participants and patient information Site related information IMPD (Investigational Medicinal Product Dossier) Labels Full title of the trial (A.3)
Submission Fees	**Fees for Ethical review mandatory** Yes **Waiver for academic (non-commercial) studies possible** Yes **Fees for Ethical review** Authorization fees (including fees for EC review): • New Clinical Trial Submission: 580.000 HUF (approx. €1890.-) (In case of Preliminary opinion of CEC: 261.000 HUF to CEC and 319.000 HUF to CA) • Amendments: 110.000HUF (Approx. 360€) • Non-interventional trials: 370,000 HUF (approx. €1200.-)

	Official guidance on required fees Fees are provide on OGYÉI website in section: Clinical trial submission procedure Waiver for non-commercial trials: Applicable criteria are provided on OGYÉI website in section: Non-commercial clinical trials **Applicable national legal framework/ Reference** Schedule No. 1 to Act XCV of 2005
Timelines Ethical Review	**General timespan for single-centre studies (max nr days)** 60 (including EC approval process of max 42 days) - also applicable to Non-interventional trials with IMPs **General timespan for multi-centre studies (max nr days)** 60 (including EC approval process of max 42 days) - also applicable to Non-interventional trials with IMPs **ATMP/GMO trials (max nr days)** 90 (including EC approval process of max 72 days) **External expert advice required: Timespan (max nr days)** – **Xenogeneic cell therapy: Timespan (max nr days)** 12 months form date of submission (including EC approval process of max 11 month) **Timespan counted from** – **Applicable national legal framework/ Reference** Section 3 of 95th Act of 2005 **Additional Information** Approval process in detail: The NIPN starts its assessment and, within 8 days, sends the copy of the relevant parts of the application to the competent EC for review. The EC sends back its reasonable within 42 calendar days starting from receiving the documentation from the NIP. Within another 10 days, the NIPN sends the applicant the authorisation/ rejection, the first Annex of that is the KFEB opinion. In case when the KFEB is consulted first, its (positive) opinion is appended to the application to the NIPN. However, the NIPN's approval time is still 60 calendar days in this case.
Amendments/ Substantial Amendments (SA)	**Ethical review mandatory for** Any substantial amendments to the study protocol **Responsible for notification of SA** Sponsor **Timeline Ethical review of SA (max nr days)** 22 working days (without requesting EC opinion),); 35 (if EC opinion required) **Applicable national legal framework/ Reference** Section 18 of Decree No 35/2005

Additional Information

In the application, the sponsor must state the reasons for such modification, and if this modification may have an impact on the safety of participants, then a draft of the modified patient information and informed consent must also be attached.

Safety Reporting

Reportable AEs

SAE (Serious Adverse Event)
SUSAR (Suspected Unexpected Serious Adverse Reaction)

Investigator shall report SAE to

Sponsor + Institutional Research Ethics Committees (IKEB)

Reporting timeline

Immediately (without delay)

Responsible for AE reporting to relevant EC(s)

Sponsor

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

Immediately
Within a max of 7d upon first knowledge (+ 8d for additional information)

All other SUSAR must be reported

Within a max of 15d upon first knowledge

SAE/SADE must be reported

–

National Standard Reporting form available

–

Reporting format - Options

–

Preferred reporting format

–

Provision of Annual safety report mandatory

Yes

Guidance on AE reporting procedure

Detailed information is available on OGYÉI website in section: AR reporting arising from clinical trials.

Applicable national legal framework/ Reference

Section 21 & 22 Decree No 35/2005

Additional Information

• Sponsors of commercial studies shall immediately report any SUSAR from clinical trials via the EudraVigilance system to EMA (OGYÉI in case of non-commercial studies).

• Safety Notification Letters should be sent to NIP/ OGYÉI immediately but at latest 24 hours, if the new events affect the conduct of the trial or the safety of the subjects considerably.

• Sponsors should report only those SUSARs to NIPN/OGYÉI where the primary source country is Hungary.
The sponsor shall notify all investigators participating in the clinical trial on any SUSAR.

• NB! Recent changes regarding AE reporting:
Development Safety Update Report (DSUR) report is mandatory to be provided to CA and competent EC on CD.
SUSAR Line Listing must be sent only to investigators according to the guideline of European Commission ("Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use" (2011/C 172/01 section 7.10.).

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

Standard Declaration form

EU Declaration of the End of Trial Form

Applicable national legal framework/ Reference

Section 23 of Decree No 35/2005

Study specific Requirements

Sponsor

Sponsor - Definition available in national law

Yes

Sponsor - Definition (pursuant to national law)

„any natural person or legal entity, unincorporated business entity initiating, leading or funding the clinical trial. The investigator and the sponsor may be the same entity" (pursuant to Section 2(d) of Decree No 35/2005).

Sponsorship mandatory

Yes

Sponsorship mandatory - Additional information

It is mandatory to have a sponsor or a legal representative established in a state being a party to the EEA-agreement (pursuant to 12(1) Decree No 35/2005).

Co-Sponsor - Definition available in national law

No

Legal representative based in the EU/EEA is mandatory where Sponsor is located outside EU/EEA:

Yes

Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Not specified

IC is regulated by law

Yes

Informed Consent - Definition/ Requirements

Informed Consent is covered in the Act 154 of 1997 on Health Care as well as in Decree No 35/2005 in detail.

Legal representatives give the consent on behalf of the vulnerable patient who may be involved into the trial only if there is a direct benefit for them. This is the same for trials both with investigational medicinal products and other biomedical ones.

Applicable national legal framework/ Reference

Act 154 of 1997 on Health Care
Art 6 Decree No 35/2005

Study Participants - Vulnerable Population

Minors / Children - Studies allowed

Yes
Special provisions apply

Specific provision

The prerequisites are that the research can’t be conducted on adults and the legal representatives (parents) or the child him/herself gave his/her consent.

Legal framework/Reference (Minors/Children)

Art 7 of Decree No 35/2005
Section 169(5) of Act 154 of 1997 on Health Care

Incapacitated persons - Studies allowed

Yes
Special provisions apply

Legal framework / Reference (Incapacitated persons)

Section 9-11 of Decree No 35/2005
Section 159(4) of Act 154 of 1997 on Health Care

Emergency situations - Studies allowed

Yes
Special provisions apply

Emergency situation without prior consent of patient or proxy - Studies allowed

Yes
With limitations

Conditions allowing trial participation in emergency setting without prior consent

In special urgent cases, when the study is expected to be of direct benefit for the health of the research subject, it may be done without consent.

	Legal framework / Reference (Emergency Situation) Section 9-11 of Decree No 35/2005 Section 160 of Act 154 of 1997 on Health Care **Pregnant or breastfeeding women - Studies allowed** Yes Special provisions apply **Legal framework / Reference (Pregnant or breastfeeding women)** Section 161(1) of Act 154 of 1997 on Health Care **National legal framework for protection of vulnerable populations in place** Yes **Applicable legal framework / Reference (Vulnerable Population)** Section 7, 9-11 of Decree No 35/2005 Section 159-161 Act 154 of 1997 on Health Care
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** Expenses arising from study participation (e.g. Travel) **Additional Information** Subjects may receive a reimbursement of income lost, their costs actually incurred and substantiated in connection with their participation in the clinical trial, in particular with their travel. No other benefit or fee may be offered to the subject, save for first-phase trials (pursuant to 5(11) of Decree No 35/2005)
Data Protection	**Notification to DP Authority/ Ombudsmann is mandatory** No **Approval/ authorisation required** No **Specific notification timelines before operations start** – **Language of notification** – **Notification format** – **Data Protection Authority/ Agency - Contact Details** Hungarian National Authority for Data Protection and Freedom of Information/ Nemzeti Adatvédelmi és Információszabadság Hatóság **Phone** +36 -1-391-1400 **Fax** +36-1-391-1410 **E-Mail** privacy@naih.hu

	Web address http://www.naih.hu/ **Address** Szilágyi Erzsébet fasor 22/C. **ZIP/City** 1125 Budapest **Country** Hungary (HU) **Additional Information** National Data Protection Act: Act CXII of 2011 (hu) on Informational Self-Determination and Freedom of Information “Privacy Act 2011 (en)”. This act regulates all data control and data processing activities undertaken in Hungary. Clinical trials shall be governed by the provisions of the Data Protection Act and Act XLVII of 1997 on protection and processing of health data, and in different legislation on data management. (pursuant to 5(8) of Decree No 35/2005) **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 **Applicable national legal framework/ Reference** Section 3 and 21 of Act 95 of 2005 (Medicine Act) **Additional Information** The sponsor must possess an indemnity insurance to cover any health or other injury in connection with the trial. The insurance company must be within the European Economic Area or within States being parties to the EEA-Agreement.
Quality Assurance/ Quality Control (QA/QC)	**Monitoring** Not specified **Audit by sponsor** Not specified **Standard Operating Procedures (SOPs)** Not specified
Archiving & Data Management	**Study documents must be kept at least (in years)** 5 **Applicable national legal framework/ Reference** Section 24 Decree No 35/2005

Additional Information

Sponsor and investigator must archive basic clinical trial documents for a minimum of 5 years.

National legislation

General Information: Applicable Legislation & Conventions

Official website providing relevant national legislation available

Yes

Official website providing relevant national legislation

Hungarian legislation concerning medical issues can be found on the NIPH/ OGYÉI website in section „jogszabályok/ irányelvek“ resp. „Laws and regulations“ (some documents available in English)

Official governmental legal database available

Yes

Official governmental legal database

“Nemzeti Jogszabálytár”: the official public source of national legislation (according to the Hungarian Act CXXX. of 2010). Acts and Decrees are available only in Hungarian.

Clinical Trials on IMPs in Humans

Applicable national regulations

General Act(s) on Medical/Clinical Research in Humans
National Act on Medicinal Products
Other

Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)

(1) Act XCV of 2005 on the Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (as amended) – the 'Medicine Act'

(2) Decree 35/2005 (VIII.26) on the Clinical Trials of Investigational Substances for Human Use and the Good Clinical Practice - the ‘Clinical Trial Decree'

ATMP/ GMO trials: Applicable regulations (if separate legal text)

Decree No 4/2009 (of 17 March 2009) of the Ministry of Health – on Medical Devices (available in Hungarian only). It also applies to Advanced Therapy Medicinal Products, taking into account Regulation (EC) No 1394/2007 of the European Parliament and the Council of 13 November 2007 on ATMP and amending Directive 2001/83/EC and Regulation (EC) 726/2004/EC .

Transposition of (GCP) Directive 2005/28/EC

Incorporated in transposition act(s) of Directive 2001/20/EC

General legislation on Medical/ Clinical Research in Humans

Act CLIV of 1997 on Health Care (as amended)- the "Health Care Act"
Articles 157 – 164 cover biomedical research involving human subjects

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

(1) Biomedical Research/ Non-interventional clinical trials:
- Decree 23/2002 (of 9th May 2002) of the Minister of Health on biomedical research on human individuals (as amended):
Applicable to non-interventional clinical trials and biomedical research and clinical investigations on Medical Devices and In-vitro Diagnostics
- Decree 1/2007 (I. 24.) EüM on the amendment of Decree No. 23/2002 (V. 9) EüM of the Minister of Health on medical research in humans

(2) Authorisation Procedures:
Executive Decree No 235/2009 (of 20 October 2009) on rules governing authorisation procedures of biomedical research, clinical trials with investigational medicinal products for human use as well as clinical investigations on medical devices intended for human use.

Additional Information

NB: The legislation on clinical trials on investigational medicinal products (CTIMPs) has been almost completely separated from those of other biomedical research.

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
Other legislation covering DP related issues

National DP act

Act CXII of 2011 (hu) on Informational Self-Determination and Freedom of Information “Privacy Act 2011”.
This act regulates all data control and data processing activities undertaken in Hungary.

Implementing decrees / ordinances

Clinical trials shall be governed by the provisions of the Data Protection Act and Act XLVII of 1997 on protection and processing of health data, and in different legislation on data management (pursuant to 5(8) of Decree No 35/2005)

CA operations/ Fees

Separate legal framework available

Yes

Applicable legal framework

- Decree 50/1996 (of 27 December 1996) NM of the Minister of Welfare on the fees payable for of administrative and authoritative procedures of the Welfare area.

- Decree 1/2009 (of 30 January 2009) on the fees payable for administrative and civil service procedures of the National Public Health Service.

Definition

IMP/IMP Study

IMP - Definition available in national law

Yes

IMP - Definition

IMP (Definition pursuant to Section 1 of 95th Act of 2005):
'investigational medicinal product' shall mean a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products that already have a marketing authorization but are used or assembled (formulated or packaged) in clinical trials in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form of the medicinal product in question;'

IMP Study - Definition available in national law

Yes

IMP Study - Definition

Clinical trial (Definition pursuant to Section 1 of 95th Act of 2005):
'shall mean any investigation in human subjects conducted at a single site or according to a single protocol but at more than one site:
a) intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or,
b) to identify any adverse reactions to one or more investigational medicinal product(s) and/or,
c) 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, and the risk-benefit balance,
not including non-interventional trials;'

Additional Information

Definition of a 'non-interventional trial' is provided in Section 1 of 95th Act of 2005.