

# Medicinal Products for Human Use - POLAND

## Competent authority

### Contact Details

#### Contact Name 1

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products - URPL („The Office“)

#### Phone

+ 48 22 492 11 00

#### Fax

+ 48 22 492 11 09

#### Email Department

pl@urpl.gov.pl

#### Address

Al. Jerozolimskie 181C

#### ZIP/City

02-222 Warszawa

#### Country

Poland (PL)

#### Web address

<http://www.urpl.gov.pl>

#### Additional Information

Pharmacovigilance Department.:

Tel +48 22 49 21 301

Fax +48 22 49 21 309

• Incidents related to medicinal products: [incydenty@urpl.gov.pl](mailto:incydenty@urpl.gov.pl)

• Medicinal products AE reporting: [ndl@urpl.gov.pl](mailto:ndl@urpl.gov.pl)

Other inquires via e-mail: [dml@urpl.gov.pl](mailto:dml@urpl.gov.pl)

### Trial Authorisation / Registration / Notification

#### Regulatory and ethics bodies involved in approval process

–

#### CA - Submission for authorisation mandatory for

–

#### CA - Registration/ notification without approval required for

–

#### CA - Submission required to

–

## **Additional Information**

### (2) Non-commercial studies

Non-commercial clinical studies are defined in Art 37ia Act on Pharmaceutical Law of 6 September 2001(Dz.U. 2008 nr 45 poz. 271).

If an owner of data from a clinical study is an academic institution or another institution with rights to issue scientific titles, researcher, patients organization, researchers organizations or another organization which aim is not gaining profits from clinical studies or manufacturing or circulating medicinal products, the study is a non-commercial clinical study. Data from a non-commercial study cannot be used for an approval of a medicinal product, for changes in current approval, nor for marketing purposes. Sponsors applying for a non-commercial study, must submit a statement that there are and will be no agreements for an approval of a medicinal product, for changes in current approval, or for marketing purposes. If there are any medicinal products obtained from a manufacturer or any other item free of expense or with reduced purchases cost, or any other type of support from them, the IEC and the President of URPL. The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) and URPL - English Information) have to be informed immediately.

Submission of Application

## **Responsible for study submission**

Sponsor

### **Entitled to study submission**

Sponsor  
Investigator

### **Prerequisites for submission**

—

### **Guidance on submission of application**

The documentation of application is specified in Art 37m of the Act on Pharmaceutical Law of 6 September 2001

The application process is described in detail in a regulation issued by the Minister of Health (The Order of the Minister of Health 2 May 2012 (The Official Journal, Dz.U. 2012, item.491))

### **Applicable national legal framework/ Reference**

Art 37m of the Act on Pharmaceutical Law of 6 September 2001

Submission Format

### **Format option(s)**

—

### **Preferred format**

—

### **Standard application form available**

Yes

### **Standard application form**

A standard application form (in Polish) is provided in Annex 1 of the Order of the Minister of Health 2 May 2012 (Dz.U. 2012, item.491).

The template is also available for download on the CA website (in Polish) in section: Produkty lecznicze » Badania kliniczne » Formularze.

### **Guidance on submission format**

The application process is described in detail in a regulation issued by the Minister of Health (The Order of the Minister of Health 2 May 2012 (The Official Journal, Dz.U. 2012, item.491))

Language of Submission	<p><b>Language(s) of application</b></p> <p>Polish English</p> <p><b>Preferred language of application</b></p> <p>–</p> <p><b>English accepted</b></p> <p>Partly, not for all documents</p> <p><b>Documents mandatory to be in official national language</b></p> <p>Information material, Documents and Forms intended for study participants and patient information</p>
Submission Fees	<p><b>Fees for trial submission mandatory</b></p> <p>Yes</p> <p><b>Fees</b></p> <ul style="list-style-type: none"> <li>• Phase I-III 8 000 PLN (approx. 2000 Euro)</li> <li>• Bioequivalence trials 7 000 PLN (approx. 1800 Euro)</li> <li>• Phase IV 4 000 PLN (approx. 1000 Euro)</li> <li>• Non-commercial trials: 2 000 PLN (approx. 500 Euro)</li> <li>• Amendments: 1500 PLN (approx. 350 Euro)</li> </ul> <p><b>Waiver for academic (non-commercial) studies possible</b></p> <p>Reduced fees are charged</p> <p><b>Official guidance on required fees</b></p> <p>Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491) defines applicable fees. Current fees are also provided in English on the URPL website in section: Fees.</p> <p><b>Applicable national legal framework/ Reference</b></p> <p>Art 37m of the Pharmaceutical Law 2001 (en)/ Dz.U. 2008 nr 45 poz. 271 (pl) Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)</p>
Timelines Authorisation	<p><b>General timespan (max nr days)</b></p> <p>60</p> <p><b>Mode of approval (General)</b></p> <p>Tacit (Silent)</p> <p><b>ATMP/GMO trials (max nr days)</b></p> <p>90</p> <p><b>Mode of approval (ATMP/GMO trials)</b></p> <p>Explicit</p> <p><b>External expert advice required (max nr days)</b></p> <p>180</p> <p><b>Xenogeneic cell therapy (max nr days)</b></p> <p>No time limit</p> <p><b>Mode of approval (Xenogeneic cell therapy)</b></p> <p>–</p> <p><b>Clock-stop possible if complementary information requested</b></p> <p>Yes</p>

**Timespan counted from**

Date of submission of valid application

**Applicable national legal framework/ Reference**

Art 37 (l-p) of Pharmaceutical Law 2001 (en)/ Dz.U. 2008 nr 45 poz. 271 (pl)

**Additional Information**

In case that supplementary information is requested from sponsor/ investigator: Up to 90 days for providing the information.

NB! A positive opinion issued by the concerned EC is a prerequisite for trial authorization by the CA.

Amendments/  
Substantial  
Amendments (SA)

**Notification mandatory for**

—

**Authorisation mandatory for**

All clinical investigations requiring authorisation by CA

**Responsible for submission of SA**

Sponsor  
Investigator

**Standard notification form available**

Yes

**Standard notification form**

Available in Polish: "Wzór wniosku o wydanie pozwolenia na wprowadzenie zmian w badaniu klinicznym"

**Timeline for approval of SA (max nr days)**

35  
By silent (implicit) approval

**Guidance on submission of SA available**

Yes

**Guidance on submission of SA**

The application process is described in detail in a regulation issued by the Minister of Health (Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)). This document includes a standard application form for the submission of amendments provided in Annex 2. This template is also available for download on the URPL website (pl) in section: Produkty lecznicze » Badania kliniczne » Formularze.

**National legal framework in place**

Yes

**Applicable national legal framework/ Reference**

Art 37 (x) of Pharmaceutical Law 2001/ Dz.U. 2008 nr 45 poz. 271 (pl)  
Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)

**Additional Information**

Amendments to be authorized: Any amendments to the clinical trial protocol or to the investigational medicinal product, being substantial and likely to have an impact on the safety of the clinical trial subjects.

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  
EMA Eudravigilance CT Module (EVCTM)  
Relevant EC(s)  
All participating sites

**Reportable AEs**

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

**SUSAR being life-threatening or leading to death must be reported**

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  
CA(s) of EU&EFTA Member States concerned  
Relevant EC(s)

**Applicable national legal framework/ Reference**

7z, 37aa Pharmaceutical Law 2001 (en)/ Dz.U. 2008 nr 45 poz. 271 (pl)

**Additional Information**

The sponsor and investigation are liable for any damage caused in connection with the clinical trial conduct, pursuant to Art 37j Pharmaceutical Law 2001.

The sponsor is storing the documentation of the trial SAE and SUSARs according to Good Clinical Practice and is providing the documentation to the EU and EFTA countries if required.

The President of the Office (URPL) is also collecting the information related to reported AE of medicinal products and is analysing and processing the reports, including further reporting to EudraVigilance and WHO.

**Investigator shall report SAE to**

–

**Reporting timeline**

–

**End of trial declaration mandatory for**

All clinical investigations 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

**Reasons for early termination shall be clearly stated**

Yes

**Standard Declaration form available**

Yes

**Standard Declaration form**

Standard declaration form is provided in Annex 3 of the Minister of Health (Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)).

**Guidance on End of trial declaration**

The process for end of trial declaration is described in detail in a regulation issued by the Minister of Health (Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)).

**Applicable national legal framework/ Reference**

Art 37ab, 1-2, Pharmaceutical Law 2001  
Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)

**Additional Information & Specifics****Additional Information**

President of the Office is a government administrative authority, competent for matters concerning marketing authorization of medicinal products and clinical trials - within the scope determined by the Act on Pharmaceutical Law of 6 September 2001 (the Official Journal [O.J.] Dziennik Ustaw Rzeczypospolitej Polskiej, Dz.U. 2008, No 45, Item 271, with amendments) (<http://dokumenty.rcl.gov.pl/D2008045027101.pdf>)  
The Office is a public administration body supporting the President of the Office in realization of the above matters.

The rules and the scope of responsibilities is determined by the Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (O.J. 2011, No 82, Item 451, with amendments) (<http://dokumenty.rcl.gov.pl/D2011082045101.pdf>)

**Ethics committee****Contact Details****Contact Name 1**

Local Research Ethics Committees (REC), in Polish „Komisje Bioetyczne“ - „Bioethics Committees“)

**Contact Name 2**

50 local independent RECs

**Web address**

<http://www.oil.org.pl/xml/oil/oil68/tematy/komisje/stale/bioetyki/komisje>

	<p><b>Additional Information</b></p> <p>The local ECs are established at academic institutions (e.g. medical universities), non-university medical research centres and health institutes or at the Regional Chambers of Physicians and Dentists. List of ECs is provided on the website of the Regional Chamber of Physicians and Dentists in Warsaw (Okręgowa Izba Lekarska).</p> <p>There is no central EC.</p>
Ethical Review – General	<p><b>Submission for Ethical review mandatory for</b></p> <p>Clinical IMP trials Clinical ATMP trials</p> <p><b>Submission to CA and EC to be performed in the following order</b></p> <p>–</p> <p><b>Additional Information</b></p> <p>Clinical trial must have an approval of an Ethics committee according to Art. 37l of the Pharmaceutical Law/ Dz.U. 2008 nr 45 poz. 271 (pl) and to Art. 29 of the the Physician’s Profession Act of 1996.</p> <p><b>Regulatory and ethics bodies involved in approval process</b></p> <p>–</p>
Single-Centre Studies - Ethical Review	<p><b>Ethical approval (favourable opinion) to be obtained from</b></p> <p>Local EC</p> <p><b>Additional Information</b></p> <p>The competent local Research Ethics Committee (“Bioethics Committee”) responsible for the clinical trial site evaluates the application and issues its opinion about the trial.</p>
Multi-Centre Studies - Ethical Review	<p><b>Ethical approval (favourable opinion) required from</b></p> <p>Lead EC + All concerned local ECs for site-specific assessment</p> <p><b>Submission of application required to</b></p> <p>Lead EC (authorised to issue a single opinion)</p> <p><b>Additional Information</b></p> <p>The sponsor of a trial is responsible for selecting a national coordinator among the investigators involved in the multicentre study in Poland. The sponsor or the designated coordinator must submit the application of a clinical trial to his or her local EC (“Bioethics Committee”) depending on the coordinating investigator office location. According to the Art 37s Pharmaceutical Law 2001, the coordinating EC, acting as the “lead” EC, informs all other relevant ECs for the sites involved in the multicentre trial.. All local ECs have up to 14 days to submit any concerns about participation of an investigator or a site in the clinical trial. If the coordinating EC does not receive any concerns from the local ECs within this time limit, then its opinion is accepted for all the sites in the country.</p>
Submission of Application	<p><b>Responsible for study submission</b></p> <p>Sponsor Investigator</p> <p><b>Entitled to study submission</b></p> <p>–</p> <p><b>Prerequisites for submission / approval</b></p> <p>–</p>

	<p><b>Guidance on study submission</b></p> <p>The application process is described in detail in a regulation issued by the Minister of Health (Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491). The supporting documentation of application is specified in Art 37m of the Act on Pharmaceutical Law of 6 September 2001 (en).</p> <p><b>Applicable national legal framework/ Reference</b></p> <p>37r-37x of the Pharmaceutical Law 2001 (en)/ Dz.U. 2008 nr 45 poz. 271 (pl) Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)</p>
Submission Format	<p><b>Format option(s)</b></p> <p>—</p> <p><b>Preferred format</b></p> <p>—</p> <p><b>Standard application form available</b></p> <p>Yes</p> <p><b>Standard application form</b></p> <p>The standard application form provided in Annex 1 of the Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491). The template is also available for download on the URPL website (pl) in section: Produkty lecznicze » Badania » Formularze.</p> <p><b>Guidance on submission format</b></p> <p>The application process is described in detail in a regulation issued by the Minister of Health (Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491).</p>
Language of Submission	<p><b>Language(s) of application</b></p> <p>Polish English</p> <p><b>Preferred language of application</b></p> <p>—</p> <p><b>English accepted</b></p> <p>Partly, not for all documents</p> <p><b>Documents mandatory to be in official national language</b></p> <p>Information material, Documents and Forms intended for study participants and patient information</p>
Submission Fees	<p><b>Fees for Ethical review mandatory</b></p> <p>Yes</p> <p><b>Waiver for academic (non-commercial) studies possible</b></p> <p>Yes</p>



## **Fees for Ethical review**

Fees for issuing opinions on medical research projects vary from EC to EC, depending on the founding bodies.

The fee for medical experiments sponsored by industry (clinical trials of medicinal products or medical devices) is on average € 2000.-.

An example of fees from a REC is:

Clinical trial – one site 6000 PLN (approx. 1500 Euro)

Clinical trial – up to 10 sites 8000 PLN (approx. 2000 Euro)

Additional site above the 10th site – 1000 PLN each (approx. 250 Euro)

Amendments – 1500 PLN (approx. 350 Euro)

## **Additional Information**

Non-commercial academic trials from the investigators from the same centre are usually exempted from fees.

## Timelines Ethical Review

### **General timespan for single-centre studies (max nr days)**

60

### **General timespan for multi-centre studies (max nr days)**

60

### **ATMP/GMO trials (max nr days)**

90

### **External expert advice required: Timespan (max nr days)**

+ 90

### **Xenogeneic cell therapy: Timespan (max nr days)**

No time limit

### **Clock-stop possible if complementary information requested**

Yes

### **Timespan counted from**

Date of submission of valid application

### **National legal framework in place**

Yes

### **Applicable national legal framework/ Reference**

Art 37t, 37n, 37p, 37x Pharmaceutical Law 2001 (en)/ Dz.U. 2008 nr 45 poz. 271 (pl)

### **Additional Information**

In case that supplementary information is requested from sponsor or investigator: 90 days max for providing the information.

The EC shall communicate its opinion to the sponsor or the (coordinating) investigator and to the CA.

The sponsor and the (coordinating) investigator have the right to appeal against an unfavourable opinion to the Bioethics Committee of Appeal. The sponsor or coordinator has 14 days from receiving the opinion of the local EC to apply for Appeal Bioethics Committee. The Appeal Bioethics Committee respond with its decision within 2 months from receiving the complete documentation.

Art. 37u of the Pharmaceutical Law and Art. 29 of the Physicians' Act

## Amendments/ Substantial Amendments (SA)

### **Ethical review mandatory for**

Any substantial amendments

**Responsible for notification of SA**

Sponsor  
Investigator

**Standard notification form available**

Yes

**Standard notification form**

Available in Polish: "wzór wniosku o wydanie pozwolenia na wprowadzenie zmian w badaniu klinicznym"

**Timeline Ethical review of SA (max nr days)**

35

**Guidance on submission of SA available**

Yes

**Guidance on submission of SA**

The application process is described in detail in a regulation issued by the Minister of Health (Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)).  
This document includes a standard application form for the submission of amendments provided in Annex 2. This template is also available for download on the URPL website (pl) in section: Produkty lecznicze » Badania kliniczne » Formularze.

**Applicable national legal framework/ Reference**

Art 37x Pharmaceutical Law 2001 (en)  
Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)

**Additional Information**

Amendments to be authorized: Any amendments to the clinical trial protocol or to the investigational medicinal product, being substantial and likely to have an impact on the safety of the clinical trial subjects.

## Safety Reporting

**Adverse Events (AE) - Definitions (pursuant to national law)**

AE of IMP is defined in the Art.3 of the Pharmaceutical Law 2001.  
SAE of IMP is defined in the Art. 3c) and 3d) of the Pharmaceutical Law 2001.

**Reportable AEs**

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

**Investigator shall report SAE to**

Sponsor

**Reporting timeline**

Immediately (without delay)

**Responsible for AE reporting to relevant EC(s)**

Sponsor

**SUSAR being life-threatening or leading to death must be reported**

—

**All other SUSAR must be reported**

—

**SAE/SADE must be reported**

—

	<p><b>National Standard Reporting form available</b></p> <p>–</p> <p><b>Reporting format - Options</b></p> <p>–</p> <p><b>Preferred reporting format</b></p> <p>–</p>
End of Trial	<p><b>End of trial Declaration mandatory</b></p> <p>Yes</p> <p><b>Responsible for End of trial Declaration</b></p> <p>Sponsor</p> <p><b>Regular Termination - Declaration timespan (max nr days)</b></p> <p>90</p> <p><b>Timespan counted from</b></p> <p>–</p> <p><b>Early/premature Termination - Declaration timespan (max nr days)</b></p> <p>15</p> <p><b>Reasons for early termination shall be clearly stated</b></p> <p>Yes</p> <p><b>Standard Declaration form available</b></p> <p>Yes</p> <p><b>Standard Declaration form</b></p> <p>Standard declaration form is provided in Annex 3 of the Minister of Health (Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491).</p> <p><b>Guidance on End of trial declaration available</b></p> <p>Yes</p> <p><b>Guidance on End of trial declaration</b></p> <p>The process for end of trial declaration is described in detail in a regulation issued by the Minister of Health (Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491).</p> <p><b>Applicable national legal framework/ Reference</b></p> <p>Art 37ab, 1-2, Pharmaceutical Law 2001/ Dz.U. 2008 nr 45 poz. 271 (pl) Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491)</p>
<b>Study specific Requirements</b>	
Sponsor	<p><b>Sponsor - Definition available in national law</b></p> <p>Yes</p>

**Sponsor - Definition (pursuant to national law)**

Sponsor (pursuant to Art 2 (37a) of the Pharmaceutical Law 2001):  
"A sponsor shall mean a natural person, a legal person or an organisational unit without legal personality, responsible for initiating, conducting and financing a clinical trial, with the registered office in the territory of one of the European Union Member States or European Free Trade Association (EFTA) Member States – parties to the Agreement on the European Economic Area, if the sponsor does not have its registered office in the territory of one of the European Economic Area Member States, it may act solely through its legal representative having its registered office in this territory"

**Sponsorship mandatory**

Yes

**Co-Sponsor - Definition available in national law**

No

**Co-sponsorship allowed**

No

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

Yes

Investigator

**Entitled to be principal investigator**

–

**Additional Information**

Definition of Investigator (pursuant to Art 2 (2a) Pharmaceutical Law 2001 (en):  
"a physician, or a dentist if the clinical trial is related to dentistry, or a veterinarian in the case of a veterinary clinical trial, holding the professional licence in the territory of the Republic of Poland and adequately high professional qualifications, scientific knowledge and experience in work with patients, necessary for the conducted clinical trial or veterinary clinical trial, responsible for conducting these trials at the given site; if the clinical trial or the veterinary clinical trial is conducted by a team of persons, the investigator designated by the sponsor, with consent of the manager of the healthcare establishment where the clinical trial is conducted, shall be the team manager responsible for conducting this trial at the given site;"

Study Participants -  
Informed Consent (IC)

**Standard IC form (ICF) available**

Not specified

**IC is regulated by law**

Yes

**Informed Consent - Definition/ Requirements**

Prior to the commencement of a clinical trial, informed consent must be obtained from study subjects. Specific provisions specified in 37b(2) and 37f Pharmaceutical Law 2001 (en) and Art 25(1) Physician's Profession Act 1996 (Dz.U. 1997 nr 28 poz. 152).

**Applicable national legal framework/ Reference**

37b(2) and 37f Pharmaceutical Law 2001 (en)  
Art 25(1) Physician's Profession Act 1996 (Dz.U. 1997 nr 28 poz. 152)

**Additional Information**

Special provisions apply to vulnerable populations such as minors, incapacitated adults and subjects in emergency situations according to Art 37h & 37i Pharmaceutical Law 2001.

### **Minors / Children - Studies allowed**

Yes  
Special provisions apply

#### **Specific provision**

Clinical trials on minors include trials on: preterm newborns, full-term newborns (0-27 days), infants and small children (28 days-23 months), children (24 months-11 years) and teenagers (12-18 years). (Dz.U. 2004 nr 104 poz. 1108).

A specific regulation issued by the Minister of Health covers in detail the provisions for the conduct of clinical trials on minors: Order of the Minister of Health 30 April 2004

#### **Legal framework/Reference (Minors/Children)**

Art 37h Pharmaceutical Law 2001(en)  
Order of the Minister of Health 30 April 2004/ Dz.U. 2004 nr 104 poz. 1108 (pl)

### **Incapacitated persons - Studies allowed**

Yes  
Special provisions apply

#### **Legal framework / Reference (Incapacitated persons)**

Art 37i Pharmaceutical Law 2001(en)/ Dz.U. 2008 nr 45 poz. 271 (pl)

### **Emergency situations - Studies allowed**

Yes  
Special provisions apply

#### **Specific provisions**

Clinical trials involving subjects unable to provide their written informed consent but able to consent verbally with two witnesses present are possible under special provisions according to Art 37f.2 of the Pharmaceutical Law 2001.

Clinical trials involving subjects unable to provide their informed consent are possible under special provisions according to Art 37i of the Pharmaceutical Law 2001.

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

Yes  
Special provisions apply

#### **Conditions allowing trial participation in emergency setting without prior consent**

Immediate life saving interventions in sudden emergency situations without chances to obtain consent can be performed according to Art. 25. 8 of the Physicians Act.

#### **Legal framework / Reference (Emergency Situation)**

Art 37f.2 & Art 37i of the Pharmaceutical Law 2001  
Art. 25. 8 of the Physicians Act

### **Pregnant or breastfeeding women - Studies allowed**

Yes  
Special provisions apply

#### **Specific provisions**

Clinical trials on pregnant and lactating women are possible under special provisions according to Art 26(1&2) Physician's Profession Act 1996 (Dz.U. 1997 nr 28 poz. 152).

Not explicitly mentioned in Pharmaceutical Law 2001.

**Legal framework / Reference (Pregnant or breastfeeding women)**

Art 26(1&2) Physician's Profession Act 1996 (Dz.U. 1997 nr 28 poz. 152)

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**

No incentives or financial inducements shall be given to study subjects, except compensation for any expenses incurred, such as reimbursement of travel expenses (pursuant to Art 37e Pharmaceutical Law 2001). Payment may be made to healthy volunteers of age taking part in bioavailability studies, or Phase I studies conducted in Poland.

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**

Bureau of the Commissioner for Patients' Rights

**Phone**

+48 22 532 82 50

**E-Mail**

sekretariat@bpp.gov.pl

**Web address**

<http://www.bpp.gov.pl/en/about-us/commissioner/>

**Address**

Ul. Młynarska 46

**ZIP/City**

01-171 Warsaw

**Country**

Poland (PL)

### **Additional Information**

The source data are stored in a secure location at the trial site. Access is restricted according to national law. Patients' consent has to include statement about access to the data for monitoring, audit and inspection. Electronic forms of documentation have to comply with national legal requirements, including restricted access and security.

Legal framework:

- Act on Patients' Rights and the Commissioner for Patients' Rights 6 November 2008 (Dz.U. 2009 nr 52 poz. 417)
- Act of 29 August 1997 on the Protection of Personal Data (en) (unified text: Journal of laws of 2002 No. 101 item 926 with amendments)

### **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**

Investigator(s)  
Sponsor  
Study participants

#### **Responsible for covering insurance**

Sponsor

#### **Insurance fee: A minimum coverage sum is defined**

Yes

#### **Minimum coverage sum**

The guaranteed insurance sums depend on the number of persons (pers) in the trial: up to 10 pers : 500 000 € / 11-25 pers: 1 000 000 € / 26-50 pers: 2 000 000 € / 51-100 pers: 4 000 000 € / above 100 pers: 5 000 000€

#### **Applicable national legal framework/ Reference**

- Order of the Minister of Finance 30 Apr 2004 (Dz.U. 2004 nr 101 poz. 1034) regulating mandatory civil liability insurance of investigators and sponsors
- Order of the Minister of Finance 6 Oct 2010 (Dz.U. 2010 nr 194 poz. 1290) concerning the mandatory civil liability insurance of investigators and sponsors in clinical trials of medicinal products
- Order of the Minister of Health 10 Feb 2012 (Dz.U. 2012 poz. 207) for detailed Conditions for Determining Level of Compensation in Case of Medical Adverse Event

### **Additional Information**

Insurance of civil liability (in Polish, „odpowiedzialność cywilna, OC“) of sponsor and investigator of a clinical trial is mandatory. The document confirming the civil liability must be provided for the whole time of the study.

### Quality Assurance/ Quality Control (QA/QC)

#### **Monitoring**

Compulsory

#### **Audit by sponsor**

Compulsory

#### **Standard Operating Procedures (SOPs)**

Compulsory

### **Additional Information**

The quality control related to the Good Clinical Practice can be performed by the Clinical Trials Inspectorate according to the Art. 37ae of the Pharmaceutical Law.

The President of URPL informs EMA about the results of the control of a clinical trial. The report from the control can be available to EMA, EU or EFTA countries and the local EC, if officially requested.

### **Additional Information & Specifics**

#### **Additional Information**

Accreditation for Research Centres:  
Polish Centre for Accreditation (PCA)  
Website: <http://www.pca.gov.pl/english/>

## **National legislation**

### **General Information: Applicable Legislation & Conventions**

#### **Official website providing relevant national legislation available**

Yes

#### **Official website providing relevant national legislation**

All relevant and binding legal provisions are available (in Polish) on the URPL website.

#### **Official governmental legal database available**

Yes

#### **Official governmental legal database**

ISAP (Internetowy System Aktów Prawnych): Online Database system of legal acts containing bibliographic and legal texts published in official publications (the Journal of Laws and the Polish Monitor) issued by the Prime Minister.

### **Clinical Trials on IMPs in Humans**

#### **Applicable national regulations**

General Act(s) on Medical/Clinical Research in Humans  
Transposition of (CT) Directive 2001/20/EC  
Transposition of (GCP) Directive 2005/28/EC  
Other

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

- Act of 6 September 2001 Pharmaceutical Law, published in Journal of Laws from 2008, No. 45, item 271 (Dz.U. 2008 nr 45 poz. 271), hereinafter referred to as "Pharmaceutical Law 2001 (en)".

#### **Transposition of (GCP) Directive 2005/28/EC**

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#### **Act transposing (GCP) Directive 2005/28/EC**

- Order of the Minister of Health of 2 May 2012 (Dz.U. 2012 poz. 489) concerning special requirements of Good Clinical Practice
- Order of the Minister of Health of 11 Mar 2005 (Dz.U. 2005 nr 57 poz. 500) concerning special requirements of Good Clinical Practice

#### **General legislation on Medical/ Clinical Research in Humans**

- Act of 5 December 1996 on the professions of a physician and a dentist, hereinafter referred to as "Physician's Profession Act 1996" (Dz.U. 1997 nr 28 poz. 152, Dz.U. 2005 nr 226, poz. 1943 with amendments), covers medical experiments on humans and basic regulations concerning Bioethics Committees.



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

Pharmaceutical Law 2001 (en) & Physician's Profession Act 1996 are specified by several ordinances and regulations issued by the Minister of Health (or Finance). Some of the most relevant regulations published in the Journal of Laws (Dziennik Ustaw, Dz.U):

(1) Clinical trial application to the CA/ EC:

- Order of the Minister of Health 2 May 2012 (Dz.U. 2012 poz.491) regulates the documentation and fees for submitting an application to the CA and the Bioethics Committee (includes templates for trial application, submission of amendments and trial termination).
- Order of the Minister of Health 15 Nov 2010 (Dz.U. 2010 nr 222 poz. 1453) on clinical trial application, the submission fees for authorization and the final report on the conduct of a clinical trial
- Order of the Minister of Health 11 Feb 2011 (Dz.U. 2011 nr 40 poz. 210) concerning detailed requirements for the basic documentation of clinical trials (drafting, monitoring, preparing and storing)

(2) Adverse Event Reporting

- Order of the Minister of Health 30 Apr 2004 (Dz.U. 2004 nr 104 poz. 1107) on reporting of unexpected serious adverse reaction to a medicinal product

(3) Central Record of Clinical Trials

- Order of the Minister of Health 29 November 2002 Dz.U. 2002 nr 209 poz. 1783 in matter of the Central Register of Clinical Trials

(4) Inspection

- Order of the Minister of Health 7 Apr 2005 (Dz.U. 2005 nr 69 poz. 623) regulates the nature and extent of inspection of clinical trials

(5) Patients' Rights

- The Act on Patients' Rights of 6 Nov 2008 (Dz.U. 2012 poz. 159)

(6) Clinical trials on Minors

- Order of the Minister of Health 30 April 2004 (Dz.U. 2004 nr 104 poz. 1108) on the conduct of clinical trials in minors

### **Additional Information**

There has been an ongoing process of adjusting the legal framework to the European Union directives (European Directive 2001/20/EC and European Directive 2005/28/EC).

Radiation & Radiotherapy

### **Use of radiation or radioactive compounds - Specific requirements**

Yes

#### **Applicable legal framework**

- Regulation of the Minister of Health of 25 August 2005 on the conditions for the safe use of ionizing radiation exposure for all types of medical research
- Act of 29 November 2000 on Nuclear Law
- Pharmaceutical Law 2001

Gene Therapy

### **Specific requirements**

Yes

#### **Applicable legal framework**

Advanced therapies, like gene therapy, cell therapy and therapies involving genetic modifications have additional restrictions implemented as stated in The Act on Pharmaceutical Law of 6 September 2001, Dz.U. 2008, No 45, item 271.

A clinical study involving these therapies can only be started after the President of URPL issued his/her approval for the study. The President can prolong his/her time for issuing an approval to 90 days if an expert opinion is needed for clinical studies on gene therapy, cell therapy and therapies involving genetic modifications (Art. 37p.). Manufacturing of these agents has to be regulated specifically by the directive of the Ministry of Health.

	<p><b>Additional Information</b></p> <p>Harvesting, storage and transplantation of cells, tissue and organs are regulated with additional restrictions and must have agreements from the Ministry of Health and the Centre for Organization and Coordination for Transplantation POLTRANSPLANT and the National Transplantation Council.</p>
Blood & Tissue Samples	<p><b>Specific requirements</b></p> <p>Yes</p> <p><b>Applicable legal framework</b></p> <p>Order of the Minister of Health 1 Jul 2005 (Dz.U. 2005 nr 169 poz. 1411) about sampling, storage and transplanting of cells, tissues and organs.</p> <p><b>Additional Information</b></p> <p>Harvesting, storage and transplantation of cells, tissue and organs are regulated with additional restrictions and must have agreements from the Ministry of Health, the Centre for Organization and Coordination for Transplantation (Poltransplant) and the National Transplantation Council.</p>
Data Protection	<p><b>Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)</b></p> <p>National Data Protection Act Other legislation covering DP related issues</p> <p><b>National DP act</b></p> <p>Act of 29 August 1997 on the Protection of Personal Data (en) (unified text: Journal of laws of 2002 No. 101 item 926 with amendments)</p> <p><b>Other applicable regulations (covering DP related issues)</b></p> <p>The Act on Patients' Rights and the Commissioner for Patients' Rights 6 November 2008 (Dz.U. 2009 nr 52 poz. 417)</p>
EC operations/ Fees	<p><b>Separate legal framework available</b></p> <p>Yes</p> <p><b>Applicable legal framework</b></p> <p>Order of the Minister of Health 11 May 1999 (Dz.U. 1999 nr 47 poz. 480) regulates in detail the establishment, financing and the operational mode of bioethics committees.</p>

## Definition

IMP/IMP Study	<p><b>IMP - Definition available in national law</b></p> <p>Yes</p> <p><b>IMP - Definition</b></p> <p>IMP (pursuant to Art 2 (2c) Pharmaceutical Law 2001: "a substance or a combination of substances, which have been given an active substance or placebo pharmaceutical form, studied or used as a reference product in a clinical trial, including also a product already authorised for marketing but used or prepared differently than the form authorised for marketing, or used in a non-authorised indication, or used to obtain additional information concerning the forms which have already been authorised for marketing"</p> <p><b>IMP Study - Definition available in national law</b></p> <p>Yes</p>
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### **IMP Study - Definition**

Clinical trial (pursuant to Art 2 (2) Pharmaceutical Law 2001 (en):  
"each trial conducted in humans to discover or confirm the clinical, pharmacological, including pharmacodynamic, effects of action of one or more investigational medicinal products, or to identify the adverse reactions to one or more investigational medicinal products, or to monitor absorption, distribution, metabolism and excretion of one or more investigational medicinal products, taking into consideration their safety and efficacy;"

### **Additional Information**

Clinical trials must be performed according to the Act of Pharmaceutical Law.  
Clinical trials including humans must be performed according to the Physician's Profession Act 1996.  
Clinical trials must be performed according to the Good Clinical Practice.