Pricelist of cost reimbursements

The reimbursement decree sets the following Pricelist of the amounts to be reimbursed for the expert activities conducted upon request and reimbursements of requested activities, which SÚKL provides pursuant to the below listed legal regulations:

- Act on Pharmaceuticals – parts A, B
- Act on Free Access to Information and Act on Libraries – part C
- Act on Budgetary Rules – part D
- Act on Medical Devices – part E

The charges are stipulated in full amounts.
The marketing authorisation holder pays costs of activities of the Institute related to the existing medicinal products marketing authorisations in the form of annual maintenance fees, which have to be paid for the following year by the end of each calendar year. Should the marketing authorisation holder fail to pay this amount within the stipulated deadline, he is reminded by the Institute to make the belated payment within 15 days as of the reminder delivery. The annual maintenance fee is not paid for the year when the marketing authorisation has been granted. Should the annual maintenance fee not be paid within the deadline set for belated payment, the marketing authorisation holder is obliged to pay the annual fee increased by 50%.
The payment of the increased amount is set by an interactive form dedicated to the payment of annual maintenance fee - please tick the appropriate box "Yes" in the item "Payment after date".

In case of micro, small or medium enterprise the discount for parts A, B can be applied.
Pursuant to Section 3 of the reimbursement decree the applicant, who meets the requirements for inclusion in the category of micro, small and medium enterprise and does not carry out the activity related to the required task on the grounds of a contractual or any other similar relation on behalf of an entity, that does not meet the criteria of micro, small and medium enterprise, may ask for waiver of the payment of costs pursuant to Section 112 paragraph 3 letter b) of the Act on Pharmaceuticals together with submitting the documentation stated in Section 5 (3) of the reimbursement decree under letters a)-g).

The applicant shall reimburse the costs in compliance with the applicable legislation of the European Union amounting up to 50% of the amount stipulated in the pricelist for the required expert activity according to part A, B; to settle the actual amount within this scope the calculation formula stated in part C should be used.

With respect to the time demand of expert activities the costs for micro, small and medium enterprise are stipulated in full amount, i.e. 50% of the costs stipulated in the pricelist.
To evaluate the claim for part of the costs to be waived, the applicant shall submit the documentation stipulated in Section 5 (3) under letters of the reimbursement decree a)-g) related to the last accounting period pursuant to the reimbursement decree together with the application to carry out expert activity.
The Documents in points a) b) and c) of Section 5 (3) of the reimbursement decree are not required, when those have been already submitted by the applicant in the same year as part of a different application for expert activity.

a) data on average headcount
b) data on annual turnover of the applicant
c) applicant's balance, should the applicant be part of the consolidated body also consolidated balance; the balance, possibly consolidated balance have to be verified by an auditor should it be stipulated by any other legal regulation.
d) Applicant's declaration stating that the applicant is not in any business or other relation with any entity, that would not meet the stipulated criteria for inclusion in the category of micro, small and medium enterprise whereas business relation is considered a company where a different company or a group of companies own 25% and over of equity or voting rights, that do not meet the criteria of micro, small or medium enterprise,
e) Applicant's declaration stating that the applicant does not perform any activity related to the required activity based on a contractual or other similar relation for the entity that does not meet the stipulated criteria for inclusion in the category micro, small and medium enterprise,
f) Trade licence, trade permit certificate, a copy of an entry in the Commercial Register, possibly articles of incorporation or status issued by a competent authority of the Czech Republic or other Member State, which cannot date back more than three months at the time of submission, or any other document or licence authorising to carry out a business activity,
g) Applicant's declaration stating that all provided data and documents are up to date, complete and true.

A. Pricelist for the reimbursements of costs for the execution of expert activities upon request - Regulation No. 128/2019 Coll, http://www.sukl.eu/modules/payment2/

GENERAL			
Code	Category of conducted expert activities	Subcategory or specification	Amount of reimbursement
U-001	Annual maintenance fee as per Section 112, paragraph 2 of the Act on Pharmaceuticals	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product with the exception of cases specified under codes U-002, U-003, U-004, and U-005	19 500 CZK
U-002	Annual maintenance fee as per Section 112, paragraph 2 of the Act on Pharmaceuticals	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the Czech Republic is the Reference State	39 100 CZK
U-003	Annual maintenance fee as per Section 112, paragraph 2 of the Act on Pharmaceuticals	Conduct of expert activities in respect of the duration of marketing authorisation of a homeopathic product	3 000 CZK
U-004	Annual maintenance fee as per Section 112, paragraph 2 of the Act on Pharmaceuticals	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the marketing authorisation holder is a micro-company	5 000 CZK
U-005	Annual maintenance fee as per Section 112, paragraph 2 of the Act on Pharmaceuticals	Conduct of expert activities in respect of the duration of marketing authorisation of a medicinal product where the marketing authorisation holder is a small company and homeopathic products are not involved	9 500 CZK
O-001	Provision of a one-hour oral consultation or issuance of a written opinion concerning regulation upon request in a scope corresponding to a one-hour consultation (not related to a pending application) as per Section 13 of the Act on Pharmaceuticals.	E.g. issuance of an opinion on the use of pure alcohol per product	5 000 CZK
O-002	Provision of a one-hour oral consultation or issuance of a written expert opinion upon request in a scope corresponding to a one-hour consultation, addressing an issue relevant to the activities conducted by SÚKL in the sphere of pharmaceuticals as per Section 13 of the Act on Pharmaceuticals	E.g. a distinction to determine whether the case concerns a clinical trial, a hospital exemption, opinion on possible confusion of the name of a medicinal product requested outside the scope of a marketing authorisation procedure (max. 3 various names for a single product at one time), opinion on proposed advertising of a human medicinal product disseminated by channels other than radio and television broadcasting and preliminary assessment of the advertising materials.	5 800 CZK
O-003	Provision of a one-hour oral scientific consultation or issuance of a written expert opinion upon request in a scope corresponding to a one-hour consultation (not related to a pending application); assessment of a risk management plan (RMP) structure and content as per Section 13 of the Act on Pharmaceuticals.	E.g. an assessment of the design of the proposed clinical study, hospital exemption, preclinical testing, analytical method, statistical analysis, expert assessment of proposed texts (SPC, PIL).	20 200 CZK
O-004	Preparation and delivery of an expert lecture upon request of a business entity as per Section 13 of the Act on Pharmaceuticals.	Dissemination of education (in the sphere of pharmaceuticals) at professional workshops and lectures	2 000 CZK/hour
O-006	Application for processing of database system	Processing of specific outputs on distributed	900 CZK/hour

	outputs generated based on the notifications filed by distributors and operators authorised to dispense medicinal products as per Section 99, paragraph 2(e) of the Act on Pharmaceuticals	and dispensed medicinal products extracted from the respective databases applying expert viewpoints according to the required criteria and above the scope of usually and regularly published data	

MARKETING AUTHORISATION			
Code	Category	Subcategory or specification	Amount of reimbursement

R-001	Application for a marketing authorisation of a medicinal product filed as per Section 25, paragraph 1(a) of the Act on Pharmaceuticals (national)	a) Self-standing application (as per Section 26 of the Act on Pharmaceuticals; Art. 8(3) of Directive 2001/83/EC);
		b) Application for marketing authorisation of a medicinal product based on well-established therapeutic use of active substances contained in the product as per Section 27, paragraph 7 of the Act on Pharmaceuticals, Art. 10a of Directive 2001/83/EC (hereinafter referred to as "literature application");
		c) Fixed combination (Section 27, paragraph 8 of the Act on Pharmaceuticals; Art. 10b of Directive 2001/83/EC);
		d) Homeopathic product (Section 28a of the Act on Pharmaceuticals; Art. 16(1) of Directive 2001/83/EC);
		e) Traditional herbal product (Section 30 of the Act on Pharmaceuticals; Art. 16a of Directive 2001/83/EC);
		f) Similar biological product (Section 27, paragraph 5 of the Act on Pharmaceuticals; Art. 10(4) of Directive 2001/83/EC.
			280 000 CZK

R-002	Application for a marketing authorisation of a medicinal product filed as per Section 25, paragraph 1(a) of the Act on Pharmaceuticals (national)	Applications as per Section 27 of the Act on Pharmaceuticals:
		a) generic application (Section 27, paragraph 1 of the Act on Pharmaceuticals; Art. 10(1) of Directive 2001/83/EC);
		b) hybrid application (Section 27, paragraph 4 of the Act on Pharmaceuticals; Art. 10(3) of Directive 2001/83/EC);
		c) informed consent (Section 27, paragraph 9 of the Act on Pharmaceuticals; Art. 10c of Directive 2001/83/EC);
		d) homeopathic product authorised via a simplified procedure (Section 28 of the Act on Pharmaceuticals; Art. 14 of Directive 2001/83/EC).
			230 000 CZK

R-003	Application for a marketing authorisation of a medicinal product filed as per Section 25, paragraph 1(a) of the Act on Pharmaceuticals (national)	Marketing authorisation of a completely identical product under another name (duplicate)	80 000 CZK
R-004	Application for a marketing authorisation of a medicinal product filed as per Section 25, paragraph 1(a) of the Act on Pharmaceuticals (national)	Another strength or pharmaceutical form, line extension	110 000 CZK
R-007	Application for Type II variation to a marketing authorisation as per Section 35 of the Act on		80 000 CZK

	Pharmaceuticals (national)			
R-049	Application for Type II variation to a marketing authorisation as per Section 35 of the Act on Pharmaceuticals (national) under module 3, which contains a new bioequivalence study or comparability study for biological products			100 000 CZK
R-008	Application for Type IA variation to a marketing authorisation as per Section 35 of the Act on Pharmaceuticals (national); application for a change to the package labelling or package information leaflet unrelated to the summary of the product characteristics; and application for variation of a parallelly imported medicinal product			6 000 CZK
R-040	Application for Type IB variation to a marketing authorisation as per Section 35 of the Act on Pharmaceuticals (national)			15 000 CZK
R-009	Application for renewal of a marketing authorisation of a medicinal product as per Section 34 of the Act on Pharmaceuticals (national)		For each medicinal product except for homeopathic products authorised via simplified procedure	150 000 CZK
R-010	Application for renewal of a marketing authorisation of a medicinal product as per Section 34 of the Act on Pharmaceuticals (national)		For homeopathic products authorised via simplified procedure	35 000 CZK
R-011	Application for transfer of a marketing authorisation for a medicinal product as per Section 36 of the Act on Pharmaceuticals		For medicinal products authorised via the national procedure, the Mutual Recognition Procedure (hereinafter referred to as the "MRP"), Decentralised Procedure (hereinafter referred to as the "DCP") with the Czech Republic as the Reference Member State (hereinafter referred to as the "RMS") or as the Concerned Member State (hereinafter referred to as the "CMS")	20 000 CZK
R-012	Application for approval to place a batch of a medicinal product with a foreign-language labelling on the market as per Section 38 of the Act on Pharmaceuticals			4 500 CZK
R-013	Application of a notified body for the issue of a position on a pharmaceutical forming an integral part of a medical device as per Section 13, paragraph 2(a)(5) of the Act on Pharmaceuticals			70 000 CZK
R-050	Follow-up application of a notified body for the issue of a position on a pharmaceutical forming an integral part of a medical device for which a position has been previously issued (change) as per Section 13, paragraph 2(a)(5) of the Act on Pharmaceuticals		A change that could affect the quality, safety, or benefits of the active substance in the medical device, such as a change to the active substance manufacturer, change to the active substance manufacture, change to sterilisation method, extended shelf-life	150 000 CZK
R-015	Application for revocation of marketing authorisation as per Section 13, paragraph 2(a)(1) of the Act on Pharmaceuticals		For medicinal products authorised via national procedure, MRP, DCP (with the Czech Republic acting as the RMS or CMS), with the requirement for phase-out sale	6 100 CZK
R-017	MRP – RMS (procedure as per Section 41 of the Act on Pharmaceutical	Application for MRP with the Czech Republic acting as the RMS; this application shall be submitted following completion of the national marketing authorisation	a) Self-standing application (Section 26 of the Act on Pharmaceuticals; Art. 8(3) of Directive 2001/83/EC); b) Literature application (Section 27, paragraph 7 of the Act on Pharmaceuticals, Art. 10a of	280 000 CZK

	s)	procedure for the medicinal product concerned (R-001 to R-004)	Directive 2001/83/EC); c) Fixed combination (Section 27, paragraph 8 of the Act on Pharmaceuticals; Art. 10b of Directive 2001/83/EC); d) Traditional herbal product (Section 30 of the Act on Pharmaceuticals; Art. 16a of Directive 2001/83/EC); e) Similar biological product (Section 27, paragraph 5 of the Act on Pharmaceuticals; Art. 10(4) of Directive 2001/83/EC.	
R-017a		Application for MRP with the Czech Republic acting as the RMS providing the application for marketing authorisation of the product in respect of which the MRP with the Czech Republic acting as the RMS is being requested has been submitted to SÚKL prior to June 5 2003.	a) Self-standing application (Section 26 of the Act on Pharmaceuticals; Art. 8(3) of Directive 2001/83/EC); b) Literature application (Section 27, paragraph 7 of the Act on Pharmaceuticals, Art. 10a of Directive 2001/83/EC); c) Fixed combination (Section 27, paragraph 8 of the Act on Pharmaceuticals; Art. 10b of Directive 2001/83/EC); d) Traditional herbal product (Section 30 of the Act on Pharmaceuticals; Art. 16a of Directive 2001/83/EC); e) Similar biological product (Section 27, paragraph 5 of the Act on Pharmaceuticals; Art. 10(4) of Directive 2001/83/EC.	380 000 CZK

R-018		Application for MRP with the Czech Republic acting as the RMS; this application shall be submitted following completion of the national marketing authorisation procedure for the medicinal product concerned (R-001 to R-004)	Applications as per Section 27 of the Act on Pharmaceuticals:
			a) generic application (Section 27, paragraph 1 of the Act on Pharmaceuticals; Art. 10(1) of Directive 2001/83/EC);
			b) hybrid application (Section 27, paragraph 4 of the Act on Pharmaceuticals; Art. 10(3) of Directive 2001/83/EC);
			c) informed consent (Section 27, paragraph 9 of the Act on Pharmaceuticals; Art. 10c of Directive 2001/83/EC);
			d) homeopathic product authorised via a simplified procedure (Section 28 of the Act on Pharmaceuticals; Art. 14 of Directive 2001/83/EC).
				220 000 CZK

R-018a		MRP-RMS R-018a – If the application for marketing authorisation of a medicinal product, for which the commencement of the mutual recognition procedure for marketing authorisation has been applied for (with the Czech Republic being the reference Member State), has been submitted to SÚKL prior to June 5 2003 (as of when the amended Act No 79/1997 Coll., on Pharmaceuticals stipulates the obligation to comply with the guidance issued by the European	• Generic marketing authorisation, marketing authorisation with the consent obtained from another holder and self-standing bibliographic marketing authorisation for electrolyte solutions of ATC group B05BB01, except complicated cases • Hybrid marketing authorisation, i.e. generic marketing authorisation with data beyond the scope of essential similarity Marketing authorisation of a homeopathic product through a simplified procedure	320 000 CZK

		Commission and by the European Agency for the Evaluation of Medicinal Products), the amount shall be increased by approx. 50% due to the necessary verifications of compliance with all relevant guidelines in the submitted dossier.		
R-020		Application for MRP with the Czech Republic acting as the RMS; this application shall be submitted following completion of the national marketing authorisation procedure for the medicinal product concerned (R-001 to R-004)	Another strength or pharmaceutical form, line extension	110 000 CZK
R-021		Application for MRP with the Czech Republic acting as the RMS; this application shall be submitted following completion of the national marketing authorisation procedure for the medicinal product concerned (R-001 to R-004)	Marketing authorisation of a completely identical product under another name (duplicate)	90 000 CZK
R-022		Application for a repeated MRP with the Czech Republic acting as the RMS (hereinafter referred to as the "RUP-RMS")	For medicinal products with any legal basis	115 000 CZK
R-023		Application for Type II MA variation as per Section 35 of the Act on Pharmaceuticals		115 000 CZK
R-051		Application for Type II MA variation as per Section 35 of the Act on Pharmaceuticals under module 3, which contains a new bioequivalence study or comparability study for biological products		140 000 CZK
R-024		Application for Application for Type IB MA variation as per Section 35 of the Act on Pharmaceuticals		25 000 CZK
R-025		Application for Application for Type IA MA variation as per Section 35 of the Act on Pharmaceuticals and application for a change to the package labelling or package information leaflet unrelated to the summary of the product characteristics		12 000 CZK
R-026		Application for renewal of a marketing authorisation as per Section 34 of the Act on Pharmaceuticals		200 000 CZK
R-027	DCP/ MRP – CMS	Application for marketing authorisation via MRP or DCP with	a) Self-standing application (Section 26 of the Act on Pharmaceuticals; Art. 8(3) of Directive	125 000 CZK

	(procedure as per Section 41 of the Act on Pharmaceuticals)	the Czech Republic acting as the CMS	2001/83/EC); b) Literature application (Section 27, paragraph 7 of the Act on Pharmaceuticals, Art. 10a of Directive 2001/83/EC); c) Fixed combination (Section 27, paragraph 8 of the Act on Pharmaceuticals; Art. 10b of Directive 2001/83/EC); d) Traditional herbal product (Section 30 of the Act on Pharmaceuticals; Art. 16a of Directive 2001/83/EC); e) Similar biological product (Section 27, paragraph 5 of the Act on Pharmaceuticals; Art. 10(4) of Directive 2001/83/EC.	

R-028		Application for marketing authorisation via MRP or DCP with the Czech Republic acting as the CMS	Applications as per Section 27 of the Act on Pharmaceuticals:
			a) generic application (Section 27, paragraph 1 of the Act on Pharmaceuticals; Art. 10(1) of Directive 2001/83/EC);
			b) hybrid application (Section 27, paragraph 4 of the Act on Pharmaceuticals; Art. 10(3) of Directive 2001/83/EC);
			c) informed consent (Section 27, paragraph 9 of the Act on Pharmaceuticals; Art. 10c of Directive 2001/83/EC);
			d) homeopathic product authorised via a simplified procedure (Section 28 of the Act on Pharmaceuticals; Art. 14 of Directive 2001/83/EC).
				105 000 CZK

R-030		Application for marketing authorisation via MRP or DCP with the Czech Republic acting as the CMS	Another strength or pharmaceutical form, line extension	45 000 CZK
R-031		Application for marketing authorisation via MRP or DCP with the Czech Republic acting as the CMS	Marketing authorisation of a completely identical product under another name (duplicate)	35 000 CZK
R-052		Application for Type II MA variation as per Section 35 of the Act on Pharmaceuticals under module 3, which contains a new bioequivalence study or comparability study for biological products		80 000 CZK
R-032		Application for Type II MA variation as per Section 35 of the Act on Pharmaceuticals		55 000 CZK
R-033		Application for Application for Type IB MA variation as per Section 35 of the Act on Pharmaceuticals		10 000 CZK
R-034		Application for Application for Type IA MA variation as per Section 35 of the Act on Pharmaceuticals and application for a change to the package labelling or package information		4000 CZK

		leaflet unrelated to the summary of the product characteristics		
R-035		Application for renewal of a marketing authorisation as per Section 34 of the Act on Pharmaceuticals		80 000 CZK
R-036	Application for authorisation of parallel import of a medicinal product as per Section 45 of the Act on Pharmaceuticals		Authorisation valid for one country of origin from which the product is to be imported	60 000 CZK
R-037	Application for authorisation of parallel import of a medicinal product as per Section 45 of the Act on Pharmaceuticals		Authorisation for any other strength of the same medicinal product from the same country of origin	25 000 CZK
R-038	Application for authorisation of parallel import of a medicinal product as per Section 45 of the Act on Pharmaceuticals		Authorisation valid for one country of origin from which the product is to be imported, involving more complicated assessment of therapeutic comparability data (e.g. a bio-equivalence study or independent stability study)	80 000 CZK
R-039	Application for renewal of authorisation of parallel import of a medicinal product as per Section 45, paragraph 8 of the Act on Pharmaceuticals			30 000 CZK
R-041	DCP/RMS (procedure as per Section 41 of the Act on Pharmaceuticals)	Application for marketing authorisation via DCP with the Czech Republic acting as the RMS	a) Self-standing application (Section 26 of the Act on Pharmaceuticals; Art. 8(3) of Directive 2001/83/EC); b) Literature application (Section 27, paragraph 7 of the Act on Pharmaceuticals, Art. 10a of Directive 2001/83/EC); c) Fixed combination (Section 27, paragraph 8 of the Act on Pharmaceuticals; Art. 10b of Directive 2001/83/EC); d) Traditional herbal product (Section 30 of the Act on Pharmaceuticals; Art. 16a of Directive 2001/83/EC); e) Similar biological product (Section 27, paragraph 5 of the Act on Pharmaceuticals; Art. 10(4) of Directive 2001/83/EC.	430 000 CZK

R-042		Application for marketing authorisation via DCP with the Czech Republic acting as the RMS	Applications as per Section 27 of the Act on Pharmaceuticals:
			a) generic application (Section 27, paragraph 1 of the Act on Pharmaceuticals; Art. 10(1) of Directive 2001/83/EC);
			b) hybrid application (Section 27, paragraph 4 of the Act on Pharmaceuticals; Art. 10(3) of Directive 2001/83/EC);
			c) informed consent (Section 27, paragraph 9 of the Act on Pharmaceuticals; Art. 10c of Directive 2001/83/EC);
			d) homeopathic product authorised via a simplified procedure (Section 28 of the Act on Pharmaceuticals; Art. 14 of Directive 2001/83/EC).
				340 000 CZK

R-044			Another strength or pharmaceutical form, line extension	190 000 CZK
R-045	DCP/RMS (procedure as per Section 41	Application for marketing authorisation via DCP with the Czech Republic acting as the RMS	Marketing authorisation of a completely identical product under another name (duplicate)	140 000 CZK

	of the Act on Pharmaceuticals)			
R-048	Application to take over the role of RMS (change from CMS to RMS) – per procedure			100 000 CZK
R-053	Application for exemption as per Section 34a, paragraph 3 of the Act on Pharmaceuticals		For a medicinal product authorised via national procedure, MRP, DCP (with the Czech Republic acting as the RMS or CMS)	5 400 CZK

Formula for the calculation of the total amount of reimbursement of costs of marketing authorisation variations submitted as per so called grouped variations and worksharing procedure within one application:
Individual amounts of costs to be reimbursed for each marketing authorisation variation applied for in a single application shall be paid in the full amount for the first marketing authorisation number, while each additional marketing authorisation number included in the given application is subject to a 50% discount on the determined amount of costs to be reimbursed.
The amount of costs to be reimbursed (in CZK) = (IA*mIA) + (IB*mIB) + (II*mII) + (n-1)*0.5*((IA*mIA) + (IB*mIB) + (II*mII))
where:
IA, IB, II = amount of reimbursement of costs associated with the respective type IA, IB or II marketing authorisation variation
mIA, mIB, mII = number of marketing authorisation variations of the given type filed in one application, and
(n-1) = number of additional marketing authorisation numbers within a single application.

INSPECTIONS			
Code	Category	Subcategory or specification	Amount of reimbursement
1-001	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals A variation to manufacturing authorisation consists of a change to the required type and scope of manufacture, incl. quality control tests which are to be performed, or addresses of all manufacturing and quality control sites.	a) Import from third countries; b) Batch release only; c) Manufacture of other medicinal products; d) Manufacture of investigational medicinal products for authorised manufacture of medicinal products or vice versa (both sterile and non-sterile).	51 300 CZK
I-002	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals In case of a variation to the manufacturing authorisation, it concerns a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites.	Non-sterile medicinal products – one pharmaceutical form and/or one manufacturing unit/line at a single manufacturing site, including primary packaging, secondary packaging, and release	79 200 CZK
I-003	Application for manufacturing authorisation for medicinal products/investigational medicinal products as per Section 63 of the Act on Pharmaceuticals or for a variation to manufacturing authorisation with an inspection In case of a variation to the manufacturing authorisation, it concerns a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites.	Non-sterile medicinal products – increase for any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture, including primary packaging, secondary packaging and release; cannot be used separately	21 600 CZK
I-004	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals	Sterile medicinal products – one pharmaceutical form and/or one manufacturing unit/line at a single manufacturing site, including secondary packaging and release	104 400 CZK

	In case of a variation to the manufacturing authorisation, it concerns a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites.		
I-005	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals In case of a variation to the manufacturing authorisation, it concerns a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites.	Sterile medicinal products – increase for any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture, including secondary packaging and release; cannot be used separately	29 025 CZK
I-006	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals In case of a variation to the manufacturing authorisation, it concerns a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites.	An increase of the basic fee for the above-mentioned cases where biotechnological or technologically complex manufacture of biological products is concerned; cannot be used separately	62 550 CZK
I-007	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals In case of a variation to the manufacturing authorisation, it concerns a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites.	Separately conducted primary packaging of non-sterile products – one pharmaceutical form and/or one manufacturing unit/line at a single manufacturing site	53 550 CZK
I-008	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals In case of a variation to the manufacturing authorisation, it concerns a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites.	A separately conducted primary packaging of non-sterile products – increase for any other pharmaceutical form and/or manufacturing unit/line different in terms of manufacture; cannot be used separately; item I-001 shall not apply.	22 500 CZK
I-009	Application for manufacturing authorisation for medicinal products/investigational medicinal products or variations to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals In case of a variation to the manufacturing authorisation, it concerns a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites.	Separately conducted secondary packaging at a single manufacturing site Item I-001 shall not apply	49 500 CZK
I-010	Application for a variation to manufacturing authorisation for medicinal products without an inspection as per Section 63 of the Act on	a) Change to identification data; b) Change or addition of a new qualified person;	14 625 CZK

	Pharmaceuticals In case of a variation to the manufacturing authorisation, it concerns a change to the following data: • Name(s), surname, place of operation and identification number, if assigned, of the natural person who is applying for this authorisation; where this authorisation is applied for by a legal person: its company/business name, registered office, mailing address, and identification number, if assigned; • name(s), surname, qualifications and expertise of qualified persons; • name(s), surname, place of operation and identification number, if assigned, of the natural person who is contracted out to undertake parts of the manufacture or quality control; for legal persons: company/business name, registered office, mailing address, and identification number, if assigned. In the case of a change to the company registration number (IČ) it is necessary to apply for a new authorisation.	c) Change or addition of a new contractor for manufacture or quality control; d) Where the type and scope of manufacture has been reduced or a manufacturing plant closed, the reimbursement is the same as in the case of variation without inspection; joint payment for all variations	
I-011	Application for distribution authorisation for medicinal products or variation to the distribution authorisation with inspection submitted as per Section 76, paragraph 1 of the Act on Pharmaceuticals	a) With the inspection of a single warehouse; b) Variation to the requested type and scope of distribution or address of all sites from which distribution is carried out	41 900 CZK
I-012	Application for distribution authorisation for medicinal products or variation to the distribution authorisation with inspection submitted as per Section 76, paragraph 1 or 3 of the Act on Pharmaceuticals	For any other warehouse within the scope of a single authorisation	21 600 CZK
I-013	Application for extension of distribution authorisation for the distribution of active substances and excipients, gases used in the delivery of healthcare services or for the distribution of blood, its components and intermediate products submitted as per Section 77, paragraph 4 of the Act on Pharmaceuticals	With the inspection of a single warehouse	41 900 CZK
I-014	Application for extension of distribution authorisation for the distribution of active substances and excipients, gases used in the delivery of healthcare services or for the distribution of blood, its components and intermediate products submitted as per Section 77, paragraph 4 of the Act on Pharmaceuticals	For any other warehouse within the scope of a single authorisation	21 600 CZK
I-015	Application for variation to distribution authorisation for medicinal products without inspection submitted as per Section 76, paragraph 3 of the Act on Pharmaceuticals	a) Reduction of the type and scope of distribution or winding-up of any site from which distribution is carried out; b) Downsized distribution premises without change to their layout; c) Change of name, surname or place of operation of the natural person who is the holder of the authorisation; d) Change of company/business name, registered office or mailing address of a legal person; e) Change of name(s) and surname of the qualified person.	12 800 CZK

I-016	Application for authorisation to engage in an activity as a control laboratory or variation to an authorisation to engage in an activity as a control laboratory with inspection as per Section 69 of the Act on Pharmaceuticals. Variations to an authorisation to engage in an activity as a control laboratory concern changes to quality control tests, which are to be conducted, or address of all quality control sites; in the event of abandoning certain authorised quality control tests or winding-up of a quality control site, reimbursement shall be made analogously to the variation without inspection.	Partial testing single reimbursement for the inspection of manufactured and/or imported medicinal products and/or investigational medicinal products	50 850 CZK
I-017	Application for authorisation to engage in an activity as a control laboratory or variation to an authorisation to engage in an activity as a control laboratory with inspection as per Section 69 of the Act on Pharmaceuticals. Variations to an authorisation to engage in an activity as a control laboratory concern changes to quality control tests, which are to be conducted, or address of all quality control sites; in the event of abandoning certain authorised quality control tests or winding-up of a quality control site, reimbursement shall be made analogously to the variation without inspection.	Full-scope testing (physico-chemical testing, microbiological testing, or biological testing, if applicable)	64 800 CZK
I-018	Application for variation to an authorisation to engage in an activity as a control laboratory without inspection as per Section 69 of the Act on Pharmaceuticals Variations to an authorisation to engage in an activity as a control laboratory concern changes to the following data: Name(s), surname, place of operation and identification number, if assigned, of the natural person who is applying for this authorisation; where this authorisation is applied for by a legal person, its company/business name, registered office, mailing address, and identification number, if assigned. Where the identification number is changed, it is necessary to apply for a new authorisation. In the event of contracted-out controls of pharmaceuticals in third countries where the results of the inspection of another authority may not be recognised, reimbursement shall be made analogously to that for the Application for the issuance of Certificate of Compliance with GMP Requirements, with the conduct of an inspection at a foreign manufacturer's premises.	a) Inspection of investigational medicinal products in addition to an authorised inspection of medicinal products or, on the contrary, in the same scope; b) Inspection of import in addition to manufacture and, on the contrary, specification in the same scope; c) Change to the applicant's identification data, new/changed or additional contractor for quality control, joint payment for all variations	14 625 CZK
I-019	Application for the authorisation to manufacture transfusion products and starting materials for further production in blood centres or variation to an authorisation to manufacture transfusion products and starting materials for further production with inspection as per Section 67 of the Act on Pharmaceuticals. A variation to an authorisation to manufacture transfusion products and raw materials for further production consists of a change to the requested type and scope of manufacture, including quality control tests, which are to be carried out, or address of all manufacturing and quality control sites; where a reduction of the type and scope of manufacture or	Manufacture of transfusion products and starting materials for further production	64 800 CZK

	winding-up of a manufacturing site is concerned, reimbursement shall be made as for a variation without inspection.		
I-020	Application for the authorisation to manufacture transfusion products and starting materials for further production in blood centres or variation to the authorisation to manufacture transfusion products and starting materials for further production with inspection as per Section 67 of the Act on Pharmaceuticals	Blood or blood component collection only without further processing and/or whole blood production for autotransfusions	43 650 CZK
I-021	Application for the authorisation to manufacture transfusion products and starting materials for further production in blood centres or variation to the authorisation to manufacture transfusion products and starting materials for further production with inspection as per Section 67 of the Act on Pharmaceuticals	For any additional manufacturing site within the scope of a single authorisation	11 925 CZK
I-022	Application for variation to the authorisation to manufacture transfusion products and starting materials for further production in blood centres without inspection as per Section 67 of the Act on Pharmaceuticals. A variation to an authorisation to manufacture transfusion products and raw materials for further production consists of a change to the following data: • Name(s), surname, place of operation and identification number, if assigned, of the natural person who is applying for this authorisation; if the authorisation is sought by a legal person: business/company name, registered office, mailing address, and company registration number, if assigned; • the name(s), surname(s), qualification and expertise of qualified persons; • the name(s), surname, place of business and company registration number (if assigned) of a natural person undertaking part of the manufacture or quality control on the basis of a contract; for a legal person: business/company name, registered office, mailing address, and company registration number, if assigned. Where the identification number is changed, it is necessary to apply for a new authorisation. In the case of a contracted-out manufacture and quality control of pharmaceuticals in third countries where the results of inspection by another authority cannot be recognised, the reimbursement shall be made as for an application for certification of GMP compliance with inspection at a foreign manufacturer's.		14 625 CZK
I-023	Application for the issuance of Certificate of Compliance with the Conditions of Good Manufacturing Practice in the manufacture of medicinal products, import from third countries, operation of a control laboratory, and good distribution practice for the holders of the respective authorisations submitted as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals		2 700 CZK
I-024	Application for the issuance of Certificate of Compliance with the Conditions of Good Manufacturing Practice for a specific medicinal product	Certificate for a Pharmaceutical Product in the WHO scheme.	3 600 CZK

	as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals		
I-025	Application for the issuance of Certificate of Compliance with the Conditions of Good Manufacturing Practice in the manufacture of active substances as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals	With inspection of a single manufacturing unit/line	63 000 CZK
I-026	Application for the issuance of Certificate of Compliance with the Conditions of Good Manufacturing Practice in the manufacture of active substances as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals	For any additional manufacturing unit/line	21 600 CZK
I-027	Application for the issuance of Certificate of Compliance with the Conditions of Good Laboratory Practice as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals	Partial testing, studies using physical, chemical, and biological testing systems with the exception of laboratory animals	50 850 CZK
I-028	Application for the issuance of Certificate of Compliance with the Conditions of Good Laboratory Practice as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals	Studies using laboratory animals	63 000 CZK
I-029	Application for revocation of authorisation to engage in an activity		0
I-030	Application for the issuance of Certificate of Compliance with GMP Requirements, with the conduct of inspection at a foreign manufacturer's ("Certificate") as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals. If the applications for Certificates of Compliance with GMP Requirements requiring an inspection at a foreign manufacturer's premises are submitted as part of the marketing authorisation procedure for a medicinal product of the concerned manufacturer, they shall be handled regardless of the pending marketing authorisation procedure. Applications for marketing authorisation without adequate evidence of compliance with GMP requirements may not be successfully concluded, and it is therefore pointless to submit Type I-030 application at the same time or subsequently, in order to have the verification of the GMP compliance completed in parallel with the pending marketing authorisation.	Where it is possible to conduct several inspections within the scope of a single journey, several applicants may share the reimbursement of travel expenses and costs of stay	Reimbursement as per the requested type of inspection incremented by 50 % + reimbursement of travel expenses and costs of stay
I-031	Application for the issuance of Certificate of compliance with the conditions of: • good manufacturing practice in the manufacture of active substances • good laboratory practice without on-site inspection as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals		2 700 CZK
I-037	Application for entry into the register of medicinal product brokers submitted as per Section 77a, paragraph 4 of the Act on Pharmaceuticals		5 400 CZK
I-038	Application for change of data in the register of medicinal product brokers submitted as per Section 77a, paragraph 4 of the Act on Pharmaceuticals		2 500 CZK
I-039	Application for the issuance of Certificate of Compliance with the Conditions of Good Clinical Practice with the conduct of inspection based on an	Where it is possible to conduct several inspections within the scope of a single journey, several	77 400 CZK + reimbursement of travel expenses and costs

	application for marketing authorisation of a medicinal product by a company/sponsor of a clinical trial within a DCP as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals	applicants may share the reimbursement of travel expenses and costs of stay; for inspections in the Czech Republic attended by inspectors from other Member States, calculation of the costs of translation services.	of stay
I-040	Application for the issuance of Certificate of Compliance with the Conditions of Good Clinical Practice with the conduct of inspection based on an application for marketing authorisation of a medicinal product by a company/sponsor of a clinical trial within a DCP as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals	For each additional site to be inspected within one application + reimbursement of travel expenses and costs of stay.	55 800 CZK
I-041	Application for manufacturing authorisation for medicinal products or for a variation to manufacturing authorisation with an inspection as per Section 63 of the Act on Pharmaceuticals Application for authorisation of a separate manufacturing warehouse of the medicinal product manufacturer	With the inspection of a single warehouse; separate manufacturing warehouse	40 950 CZK
I-042	Application for manufacturing authorisation for medicinal products or for a variation to manufacturing authorisation with an inspection Application for authorisation of a separate manufacturing warehouse of the medicinal product manufacturer Application as per Section 63 of the Act on Pharmaceuticals	For any additional warehouse within the scope of a single authorisation	21 600 CZK
I-043	Application for the issuance of Certificate of Compliance with the Conditions of Good Clinical Practice as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals	Check of the clinical site, sponsor, and laboratories in order to establish compliance with the conditions of good clinical practice	50 850 CZK

PHARMACIES, VENDORS, LABORATORY ANALYSES, BATCH RELEASE			
Code	Category	Subcategory or specification	Amount of reimbursement
L-001	Application for the issuance of Certificate of Compliance with the Conditions of Good Practice of Vendors of Selected Medicinal Products submitted as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals		11 900 CZK
L-002	Application for the issuance of a binding opinion on the technical and material facilities of a healthcare facility where pharmaceutical care is to be provided submitted as per Section 15, paragraph 2 of the Act on Healthcare Services and Section 13, paragraph 2(a)(8) of the Act on Pharmaceuticals	For pharmacies or medical device dispensaries of starting up in new premises	35 800 CZK
L-003		a) For pharmacies or medical device dispensaries starting up in premises of a formerly authorised pharmacy; b) Starting up a detached dispensing unit for medicinal products and medical devices; c) Change to the scope of operation of a pharmacy or starting up a specialised unit requiring a change to the	13 700 CZK

		pharmacy layout.	
L-004		a) Change to the scope of operation of a pharmacy or medical device dispensary; b) Change to the technical and material facilities of a pharmacy or medical device dispensary; c) Formal change to the data provided in a binding opinion.	3 400 CZK
L-005	Laboratory analysis upon request as per Section 13, paragraph 2(f) or Section 101, paragraph 3 of the Act on Pharmaceuticals		Reimbursement as per the applied methods (part B hereof refers)
L-006	Application for the issuance of Certificate of Compliance with the Conditions of Good Pharmaceutical Practice submitted as per Section 13, paragraph 2(a)(3) of the Act on Pharmaceuticals		35 800 CZK
L-007	Retesting of a batch of a medicinal product prior to its release onto the market as per Section 102 of the Act on Pharmaceuticals	With the submission of a certificate issued by an EU Member State	1 250 CZK
L-008		Without the submission of a certificate issued by an EU Member State	1 250 CZK + reimbursement as per the applied methods (part B hereof refers)
L-009	Issuance of a pharmacopoeia reference substance with a certificate upon request as per Section 13, paragraph 2(f) of the Act on Pharmaceuticals	Per bottle	800 CZK

CLINICAL TRIALS ON PHARMACEUTICALS – national submissions (outside the EU portal); THERAPEUTIC PROGRAMMES; DISTINCTIONS BETWEEN PHARMACEUTICALS AND OTHER PRODUCTS			
Code	Category	Subcategory or specification	Amount of reimbursement
K-001	Authorisation of a clinical trial on a medicinal product as per Section 55, paragraph 1(b), paragraph 2, 3, and 8 of the Act on Pharmaceuticals	Application for authorisation of a clinical trial on a medicinal product. The same amount of reimbursement shall apply also if a previously authorised/notified trial has not commenced within 12 months and major changes have been made to the originally submitted documentation.	98 100 CZK
K-002	Notification of a clinical trial on a medicinal product as per Section 55, paragraph 1(b), paragraphs 4, 5, and 8 of the Act on Pharmaceuticals	Notification of a clinical trial on an authorised medicinal product (30 days) The same amount of reimbursement shall apply also if a previously authorised/notified trial has not commenced within 12 months and major changes have been made to the originally submitted documentation.	20 700 CZK
K-003	Notification of a clinical trial on a medicinal product as per Section 55, paragraph 1(b), paragraph 4, 5, and 8 of the Act on Pharmaceuticals	Other notifications of a clinical trial on a medicinal product (60 days). The same amount of reimbursement shall apply also if a previously authorised/notified trial has not commenced within 12 months and major changes have been made to the originally submitted documentation.	45 000 CZK
K-004	Assessment of notified amendments to the protocol		20 500 CZK

	as per Section 56, paragraph 1(c) of the Act on Pharmaceuticals		
	Amendment to the protocol requiring assessment due to a major change to the protocol, which is likely to affect the safety of trial subjects or to alter the scientific hypothesis of the concerned clinical trial or if the change is significant for another reason. The same amount of reimbursement shall apply also if a previously authorised/notified trial has not commenced within 12 months and minor changes have been made to the originally submitted documentation.		
K-005	Application for the issuance of an opinion on the conditions of use of a medicinal product, method of its distribution, dispensing and monitoring, and its quality, safety and efficacy evaluations within a specific therapeutic programme as per Section 13, paragraph 2(a)(6) of the Act on Pharmaceuticals		17 100 CZK Advance payment shall not be required for urgent opinions
K-006	Application for the issuance of a decision whether a product is a pharmaceutical, incl. a distinction between a medicinal product and an active substance, a medicinal product subject to marketing authorisation or any other product, or a homeopathic product, where applicable as per Section 24a of the Act on Pharmaceuticals		11 700 CZK
K-007	Approval of a hospital exemption as per Section 13, paragraph 2(I) and Section 49b of the Act on Pharmaceuticals		90 000 CZK
K-008	Variation to a hospital exemption – changes to the manufacturing process or to the quality of the starting material as per Section 49b of the Act on Pharmaceuticals		20 000 CZK
K-009	Variation to a hospital exemption – addition of a new facility that would administer the medicinal product subject to the hospital exemption, or increase of the maximum number of patients as per Section 49b of the Act on Pharmaceuticals		2 500 CZK
K-010	Issuance of a Certificate of Good Clinical Practice to a natural person (e.g. to the investigator, monitor) as per Section 13, paragraph 2(a)(4) of the Act on Pharmaceuticals		21 600 CZK
K-011	Issuance of a follow-up Certificate of Good Clinical Practice to a natural person as per Section 13, paragraph 2(a)(4) of the Act on Pharmaceuticals		10 800 CZK

Table 6

CLINICAL TRIALS – submitted via the EU portal in compliance with the requirements set forth by Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (hereinafter referred to as the "Clinical Trial Regulation") – documentation for assessment report part I			
Code	Category	Subcategory or specification	Amount of reimbursement
K-012	Authorisation of a clinical trial on a medicinal product produced by a biotechnological process (including advanced therapy products) not authorised in the EU and/or authorised or not authorised in a third country as referred to under	a) With the Czech Republic acting as the reporting Member State; b) Repeated submission of the application with the Czech Republic acting as the reporting Member State; Art. 13 of the Clinical Trial	153 900 CZK

	Art. 5, 6, 8, 9, 86, and 87 of the Clinical Trial Regulation	Regulation.	
K-013	Authorisation of a clinical trial on a medicinal product produced by a biotechnological process (including advanced therapy products) not authorised in the EU and/or authorised or not authorised in a third country as referred to under Art. 5, 6, 8, 9, 86, and 87 of the Clinical Trial Regulation	a) With the Czech Republic acting as the Concerned Member State; b) National clinical trial; c) Repeated submission of the application with the Czech Republic acting as the Concerned Member State; Art. 13 of the Clinical Trial Regulation; d) Repeated submission of the application concerning a national clinical trial; Art. 13 of the Clinical Trial Regulation; e) Subsequent addition of a Member State concerned, with the Czech Republic acting as the reporting Member State; Art. 14 of the Clinical Trial Regulation; f) Subsequent addition of the Czech Republic as another Member State concerned; Art. 14 of the Clinical Trial Regulation.	118 800 CZK
K-014	Authorisation of a clinical trial on a medicinal product produced by other than a biotechnological process not authorised in the Czech Republic and/or another EU Member State and/or authorised or not authorised in a third country as referred to under Art. 5, 6, 8, 9, 86, and 87 of the Clinical Trial Regulation	a) With the Czech Republic acting as the reporting Member State; b) Repeated submission of the application with the Czech Republic acting as the reporting Member State; Art. 13 of the Clinical Trial Regulation.	125 100 CZK
K-015	Authorisation of a clinical trial on a medicinal product produced by other than a biotechnological process not authorised in the Czech Republic and/or another EU Member State and/or authorised or not authorised in a third country as referred to under Art. 5, 6, 8, 9, 86, and 87 of the Clinical Trial Regulation	a) With the Czech Republic acting as the Concerned Member State; b) National clinical trial; c) Repeated submission of the application with the Czech Republic acting as the Concerned Member State; Art. 13 of the Clinical Trial Regulation; d) Repeated submission of the application concerning a national clinical trial; Art. 13 of the Clinical Trial Regulation. Subsequent addition of a Member State concerned, with the Czech Republic acting as the reporting Member State; Art. 14 of the Clinical Trial Regulation. Subsequent addition of the Czech Republic as another Member State concerned; Art. 14 of the Clinical Trial Regulation	97 200 CZK
K-016	Authorisation of a clinical trial on a medicinal product produced by a biotechnological process (including advanced therapy products) authorised in the EU, but in off-label use, and/or on a medicinal product produced by other than a biotechnological process authorised in the Czech Republic and/or another EU Member State, but in off-label use as referred to under Art. 5, 6, 8, 9, 86, and 87 of the Clinical Trial Regulation	a) With the Czech Republic acting as the reporting Member State; b) Repeated submission of the application with the Czech Republic acting as the reporting Member State; Art. 13 of the Clinical Trial Regulation.	108 000 CZK
K-017	Authorisation of a clinical trial on a medicinal product produced by a biotechnological process (including advanced therapy products) authorised in the EU, but in off-label use, and/or on a medicinal product produced by other than a biotechnological process authorised in the Czech Republic and/or another EU Member State, but in off-label use as referred to under Art. 5, 6, 8, 9,	a) With the Czech Republic acting as the Concerned Member State; b) National clinical trial; c) Repeated submission of the application with the Czech Republic acting as the Concerned Member State; Art. 13 of the Clinical Trial Regulation; d) Repeated submission of the application	87 300 CZK

	86, and 87 of the Clinical Trial Regulation	concerning a national clinical trial; Art. 13 of the Clinical Trial Regulation; e) Subsequent addition of a Member State concerned, with the Czech Republic acting as the reporting Member State; Art. 14 of the Clinical Trial Regulation; f) Subsequent addition of the Czech Republic as another Member State concerned; Art. 14 of the Clinical Trial Regulation.	
K-018	Low-intervention clinical trials – authorisation of a clinical trial on a medicinal product authorised in the Czech Republic and/or another EU Member State, used in compliance with the summary of the product characteristics or routine medical practice documented as required by Art. 5, 6, 8, 9, 86, and 87 of the Clinical Trial Regulation	a) With the Czech Republic acting as the reporting Member State; b) Repeated submission of the application with the Czech Republic acting as the reporting Member State; Art. 13 of the Clinical Trial Regulation.	75 600 CZK
K-019	Low-intervention clinical trials – authorisation of a clinical trial on a medicinal product authorised in the Czech Republic and/or another EU Member State, used in compliance with the summary of the product characteristics or routine medical practice documented as required by Art. 5, 6, 8, 9, 86, and 87 of the Clinical Trial Regulation	a) With the Czech Republic acting as the Concerned Member State; b) National clinical trial; c) Repeated submission of the application with the Czech Republic acting as the Concerned Member State; Art. 13 of the Clinical Trial Regulation; d) Repeated submission of the application concerning a national clinical trial; Art. 13 of the Clinical Trial Regulation; e) Subsequent addition of a Member State concerned, with the Czech Republic acting as the reporting Member State; Art. 14 of the Clinical Trial Regulation; f) Subsequent addition of the Czech Republic as another Member State concerned; Art. 14 of the Clinical Trial Regulation.	57 600 CZK
K-020	Clinical trials – cluster trial as referred to under Art. 5, 6, 8, 9, 86, and 87 of the Clinical Trial Regulation		38 700 CZK
K-021	Substantial modification associated with assessment report part I (assessment of each part of the documentation affected by the substantial modification to part I of the assessment report requires a separate reimbursement of costs – e.g. the protocol, Investigator´s Brochure, pharmaceutical documentation) as referred to under Art. 16, 17, 18, 19, 21, 22, 23, 86, and 87 of the Clinical Trial Regulation	a) With the Czech Republic acting as the reporting Member State; b) National clinical trial.	30 600 CZK
K-022	Substantial modification associated with assessment report part I (assessment of each part of the documentation affected by the substantial modification to part I of the assessment report requires a separate reimbursement of costs (e.g. the protocol, Investigator´s Brochure, pharmaceutical documentation) as referred to under Art. 16, 17, 18, 19, 21, 22, 23, 86, and 87 of the Clinical Trial Regulation	With the Czech Republic acting as the Concerned Member State.	21 600 CZK
Assessment of a clinical trial application dossier – assessment report part II			
K-023	Application for clinical trial authorisation – documentation for assessment report part II as referred to by Art. 4, 5, 7, 8, 9, 86, and 87 of the	With 1 trial site in the Czech Republic.	44 100 CZK

	Clinical Trial Regulation		
K-024	Application for clinical trial authorisation – documentation for assessment report part II as referred to by Art. 4, 5, 7, 8, 9, 86, and 87 of the Clinical Trial Regulation	With 2 trial sites in the Czech Republic.	51 300 CZK
K-025	Application for clinical trial authorisation – documentation for assessment report part II as referred to by Art. 4, 5, 7, 8, 9, 86, and 87 of the Clinical Trial Regulation	Any additional trial site in the Czech Republic for initial submission of a clinical trial application.	5 400 CZK
K-026	Application for clinical trial authorisation – documentation for assessment report part II as referred to by Art. 4, 5, 7, 8, 9, 86, and 87 of the Clinical Trial Regulation	Any additional trial site in the Czech Republic for an ongoing clinical trial.	10 800 CZK
K-027	Substantial modification associated with assessment report part II – an update to the Patient Information Sheet, Informed Consent Form as referred to under Art. 16, 20, 21, 22, 23, 86, and 87 of the Clinical Trial Regulation		11 700 CZK
K-028	Substantial modification associated with assessment report part II – change to the investigator or principal investigator or another substantial modification associated with assessment report part II as referred to under Art. 16, 20, 21, 22, 23, 86, and 87 of the Clinical Trial Regulation		7 200 CZK
Provision of SUSAR (suspected unexpected serious adverse reaction) reporting from clinical trials to the EudraVigilance CT database by the Institute upon sponsor's request			
K-029	Sponsor's request for SUSAR reporting by the Institute as referred to under Art. 42, paragraph 3 and Art. 86 and 87 of the Clinical Trial Regulation		3 150 CZK
K-030	Entry of a report in the EudraVigilance CT database – per year as referred to under Art. 42, paragraph 3 and Art. 86 and 87 of the Clinical Trial Regulation		8 100 CZK

B. Pricelist for the reimbursements of costs of laboratory analyses of pharmaceuticals and excipients conducted within the powers of the Institute - Regulation No. 128/2019 Coll
http://www.sukl.eu/modules/payment2/

Item	Test	Amount of reimbursement
PREPARATORY AND AUXILIARY ACTIVITIES		
1.	Receipt of a sample for analysis and drafting of the testing plan	820 CZK
2.	Pre-analysis preparatory works	1 120 CZK
3.	Validation of biological methods	3 190 CZK
PHYSICAL AND CHEMICAL TESTS		
4.	Clarity and degree of opalescence of liquids – per examined unit	70 CZK
5.	Degree of coloration of liquids – per examined unit	70 CZK
6.	Potentiometric determination of pH	1 330 CZK
7.	Density and relative density	1 820 CZK
8.	Refractive index	1 330 CZK
9.	Optical rotation	1 820 CZK
11.	Viscosity – using a rotation viscosimeter	2 620 CZK
13.	Distillation range	1 010 CZK

14.	Boiling point	1 010 CZK
15.	Determination of water by distillation	1 010 CZK
16.	Melting point – capillary method	
16a.	For a labelled substance	1 010 CZK
16b.	For an unlabelled substance	1 995 CZK
17.	Drop point	1 010 CZK
18.	Freezing point	1 010 CZK
19.	Substance content by potentiometric titrations in hydrous or anhydrous environment	2 670 CZK
20.	Substance identity by infrared spectrometry	4 660 CZK
21.	Substance identity by Raman spectrometry	4 660 CZK
22.	UV-VIS by spectrophotometry	3 300 CZK
23.	Substance identity, purity, and content by thin-layer chromatography	
23a.	Qualitative determination – for each system	1 870 CZK
23b.	Semi-quantitative determination – for each system	2 870 CZK
24.	Substance identity, purity, and content by gas chromatography	
24a.	Simple determination	9 330 CZK
24b.	Complex determination	10 650 CZK
25.	Substance identity, purity, and content by high-performance liquid chromatography	
25a.	Simple determination	8 305 CZK
25b.	Complex determination	12 300 CZK
26.	Substance identity by high-performance liquid chromatography with mass detection	21 000 CZK
27.	Exclusion chromatography	
27a.	Exclusion chromatography of albumin	16 560 CZK
27b.	Exclusion chromatography of immunoglobulins	21 000 CZK
28.	Zone electrophoresis of albumin and immunoglobulins	6 660 CZK
29.	Specific electrical conductivity	1 330 CZK
30.	Ion and group identity testing	790 CZK
31.	Smell	330 CZK
32.	Ammonium (limit test)	790 CZK
33.	Arsenic (limit test)	3 300 CZK
34.	Calcium (limit test)	790 CZK
35.	Chlorides (limit test)	790 CZK
36.	Fluorides (limit test)	790 CZK
37.	Magnesium (limit test)	790 CZK
38.	Magnesium and alkaline-earth metals (limit test)	790 CZK
39.	Heavy metals (limit test)	790 CZK
40.	Iron (limit test)	790 CZK
41.	Phosphates (limit test)	790 CZK
42.	Potassium (limit test)	790 CZK
43.	Sulphates (limit test)	790 CZK
44.	Sulphated ash	3 990 CZK
45.	Total ash	3 990 CZK
46.	Loss by drying	2 660 CZK
47.	Free formaldehyde	
47a.	Method A	790 CZK
47b.	Method B	2 660 CZK

48.	Identification and control of residual solvents	10 650 CZK
49.	Residual ethylene oxide and dioxane	10 650 CZK
50.	Acid value	1 995 CZK
51.	Ester value	1 995 CZK
52.	Hydroxyl value	1 995 CZK
53.	Iodine value	1 995 CZK
54.	Peroxide value	1 995 CZK
55.	Saponification value	3 130 CZK
56.	Determination of nitrogen by sulphuric acid digestion	6 660 CZK
57.	Chelatometric titrations	1 670 CZK
58.	Water semi-microdetermination	3 300 CZK
59.	Phenol in immunosera and vaccines	1 700 CZK
60.	Oxidising substances	1 670 CZK
61.	Total protein	2 670 CZK
62.	Disintegration of tablets and capsules (without determination)	
62a.	Disintegration in water	660 CZK
62b.	*Disintegration is gastric juice*	1 670 CZK
62c.	*Disintegration in duodenal juice*	3 000 CZK
63.	Disintegration of rectal and vaginal formulations (without determination)	660 CZK
64.	Dissolution test for solid pharmaceutical forms (without determination)	
64a.	Short-term dissolution	1 670 CZK
64b.	Long-term dissolution	7 995 CZK
65.	Dissolution test for transdermal patches (without determination)	7 995 CZK
66.	Uniformity of mass of single dose preparations – per weighted amount	170 CZK
67.	Friability of uncoated tablets	660 CZK
68.	Resistance to crushing of tablets	340 CZK
69.	Ethanol content in liquid formulations	10 650 CZK
70.	Test for methanol and 2-propanol in liquid formulations	10 650 CZK
71.	Test for extractable volume of parenteral formulations	340 CZK
72.	Uniformity of mass of individual doses in multiple-dose packaging	170 CZK
73.	Uniformity of dose units	170 CZK
74.	Volumetric determination of substances	
74a.	Titration	1 670 CZK
74b.	Re-titration	3 130 CZK
74c.	Titration in heterogeneous environment	3 130 CZK
74d.	Titration in anhydrous environment (without isolation)	3 130 CZK
75.	Weighing of individual doses of medicines – per weighted amount	170 CZK
76.	Macroscopic description, appearance	340 CZK
MICROBIOLOGICAL AND BIOLOGICAL TESTS		
77.	Sterility	
77a.	Sterility – direct inoculation to substrates (products without antimicrobial effects)	1 995 CZK
77b.	Sterility – direct inoculation to substrates (products with antimicrobial effects)	2 320 CZK
77c.	Sterility – membrane filtration method	3 640 CZK
77d.	Sterility of antibiotics – membrane filtration method	3 640 CZK
78.	Microbiological quality of non-sterile products and substances for pharmaceutical use (TAMC, TYMC, tests for specified microorganisms)	

78a.	Non-aqueous oral formulations	3 300 CZK
78b.	Aqueous oral formulations	3 300 CZK
78c.	Rectal formulations	3 300 CZK
78d.	Oral, gingival, dermal, nasal, aural formulations	3 300 CZK
78e.	Vaginal formulations	3 300 CZK
78f.	Transdermal patches	3 300 CZK
78g.	Inhalation formulations	3 300 CZK
78h.	Pharmaceutical forms containing natural substances	3 300 CZK
78i.	Substances for pharmaceutical use	3 300 CZK
79.	Microbiological quality of herbal medicinal products for oral use	
79a.	Herbal medicinal products – category A	3 300 CZK
79b.	Herbal medicinal products – category B	3 300 CZK
79c.	Herbal medicinal products – category C	3 300 CZK
80.	Effectiveness of antimicrobial conservation substances	9 890 CZK
81.	Bacterial endotoxins	2 670 CZK
82.	Anti-A and anti-B hemagglutinins – indirect method – (indirect Coombs test)	4 670 CZK
83.	Immunochemical methods	
83a.	Methods with labelled antigen or labelled antibody (ELISA)	6 660 CZK
83b.	Immunoprecipitation methods – Ouchterlony	6 660 CZK
83c.	Immunoprecipitation methods – Mancini	3 990 CZK
84.	Tetanus vaccine adsorbed efficacy (*in vivo* test)	115 400 CZK
85.	Identity test, thermal stability tests, efficacy on tissue cultures	
85a.	Monovaccine	9 000 CZK
85b.	Divaccine	12 950 CZK
85c.	Trivaccine	21 580 CZK
86.	Cytotoxicity on tissue cultures	19 530 CZK
87.	Precallicrein activator assay	10 910 CZK

C. Reimbursements for services associated with the provision of information and services of the specialised library

Item	Service description	Service reimbursement	Unit
1	**Copy services**		
1a	*A4 copy – one side*	2.00 CZK	piece
1b	*A4 copy – both sides*	4.00 CZK	piece
1c	*A3 copy – one side*	4.00 CZK	piece
1d	*A3 copy – both sides*	8.00 CZK	piece
1e	*Scanning - A4 format*	2.00 CZK	piece
2	**Procurement of technical data carriers**		
2a	*CD/DVD*	10.00 CZK	piece
3	**Sending of information to the applicant**		
3a	*Mailing services*	As per the current pricelist of Czech Post	
4	**Extraordinarily extensive information retrieval pursuant to the Act on Free Access to Information**		
4a	*Information retrieval*	272.00 CZK	Price for each (even if incomplete) hour
5	**Inter-library loan service (MVS)**		

5a	*Book unit loan from the library*	Free of charge	
5b	*Copy from the database*	20.00 CZK	Price for each set (even if incomplete) of 10 pages of the original
6	**Literature research, information from specialised databases**		
6a	*Conduct of research*	80.00 CZK	Price for each (even if incomplete) half-hour
6b	*Fee for output*	See items 1-3	

D. Reimbursement for other services

Item	Item name	Reimbursement of the service in CZK ex. VAT*	
		per 1 hr. (even if incomplete)	Per 1 day (8 hr. max.)
1	**Assembly hall rental**	1000.00 CZK	6 500.00 CZK
2	**Kitchenette rental**	400.00 CZK	4 000.00 CZK

*Basic VAT rate (21%) added to the total amount of rental.

E. Medical devices

Expert activities the application for which is generated through SÚKL´s website

Code	Expert activity category (pursuant to Section 94, paragraph 1 of Act on Medical Devices)	Amount of cost reimbursement
110	Drafting of expert positions or opinions	1800 CZK/hour

The applicant shall be obliged to generate the document "Proof of payment for reimbursement of costs of expert services performed upon request" for the amount which corresponds to the anticipated time necessary for the conduct of the expert activity, using the following formula:

Reimbursement of costs in CZK = **h * s**,

where:

h = number of hours of work (each, even if incomplete, hour)

s = costs of 1 hour of work amounting to **1800 CZK**

The applicant shall be always obliged to generate the "Proof of payment for reimbursement of costs of expert services performed upon request" **at least** for the amount equal to the payment for:

- 4 hours where applications for expert position or opinion or opinion on clinical investigation are concerned;
- 4 hours where applications for assessment of whether the product is a medical device are concerned;
- 2 hours where applications for assessment of whether the medical device has been correctly classified are concerned.

Expert activities the application for which is generated via RZPRO

Code	Expert activity category (pursuant to Section 94, paragraph 2 of Act on Medical Devices)	Amount of cost reimbursement
210	Expert activities associated with the issue of authorisation of the conduct of a medical device clinical investigation	15 000 CZK
211	Expert activities associated with the issue of authorisation of changes to the conditions of a medical device clinical investigation	1 500 CZK