

Agreement No.: CN-3047

FRAMEWORK COOPERATION AGREEMENT FOR THE ASSESSMENT OF CEP APPLICATIONS

Between the Secretary General of the Council of Europe represented by XXX, Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM), hereinafter referred to as the “Council/EDQM”,

and State Institute for Drug Control (SUKL), Šrobárova 48, 106 41 Praha 10, Czech Republic, represented by Irena Storova, Director, hereinafter referred to as the “Service Provider”.

Article 1 Nature of the agreement

The Service Provider, subject to the agreed terms and conditions set forth below, shall provide the Council/EDQM with collaborators to act as assessors, hereinafter referred to as “Assessors”, within the framework of the Procedure for the Certification of Suitability to the Monographs of the European Pharmacopoeia. This cooperation agreement is based on the pursuit of common assessment goals.

Article 2 Services and deliverables

The services and deliverables supplied by the Service Provider will be supervised by the Certification of Substances Department (DCEP) of the EDQM. The services to be provided are as follows:

- The Assessor shall carry out assessments of applications for certificates of suitability (new, revisions and renewals) and contribute to the development of an external assessment.
- The Assessor shall take part in the elaboration of the EDQM assessment report, as per EDQM Standard Operating Procedures (SOPs).
- Other duties performed by the Assessor in the frame of the Certification Procedure, such as participation in meetings (including, but not limited to Technical Advisory Board meetings), trainings, preparation or review of guidance documents, etc. shall be excluded from the terms of this agreement and shall not be subject to payment of any fee by the Council/EDQM.

Article 3 Language of documents

All documents prepared by the Assessor under the agreement shall be written in English.

Article 4 Intellectual property rights

- 4.1 The Service Provider and the Assessor concede to the Council/EDQM, on a non-exclusive basis and for an unlimited period of time, all intellectual property rights on the deliverables referred to in Article 2 (in particular the assessment report and assessment documents). In particular, such rights shall include the right to use, reproduce, represent, publish, adapt, translate and distribute in any country, in any language, in any form and on any kind of medium (including on electronic support devices and via the internet), the deliverables, or any part thereof, submitted by the Assessor under the agreement. The Council/EDQM reserves the right to exercise the above-mentioned intellectual property rights for any purpose related to its activities and in particular to its Certification Activities.
- 4.2 The Service Provider and the Assessor guarantee that use by the Council/EDQM of the deliverables supplied under the agreement and referred to in Article 2 shall not infringe the intellectual property rights of third parties. However, should the Council/EDQM incur liability as the result of any such infringement of intellectual property rights, the Service Provider shall compensate the Council/EDQM in full for any damage suffered as a consequence.
- 4.3 The Council/EDQM authorises the Service Provider and the Assessor to use deliverable(s) referred to under Article 2 above in the context of the activities of the Service Provider in the domain of assessments as the Council/EDQM accepts that this sharing of assessment reports is in the best interests of public health in Europe.

Article 5 Data protection

Each Party is a Data Controller with respect to processing of personal data in relation to the Agreement.

- 5.1 Without prejudice to the other provisions of this agreement, the Parties undertake, in the execution thereof, to comply at all times with the legislation applicable to each of them concerning the processing of personal data, and to process personal data only to the extent and in such manner as is necessary for the execution of the agreement.
- 5.2 The Parties shall implement appropriate technological measures to protect personal data against accidental loss, destruction, damage, alteration or disclosure. These measures shall be appropriate to the harm, which might result from any authorised or unlawful processing, accidental loss, destruction, or damage while having regard to the nature of the personal data which is to be protected.
- 5.3 Each Party undertakes to provide the other Party with full assistance in relation to a data subject access request (including requests for rectification or deletion of personal data and objection to data processing) or to a complaint related to the latter Party's obligations to comply with the data protection requirements, in order to facilitate that Party's fulfilment of its obligation to respond to such requests and complaints.

- 5.4 Upon the other Party's request, each Party undertakes to delete or return to the other Party all personal data and any existing copies, unless the applicable law requires storage of the personal data.

Article 6 Loyalty and Confidentiality

- 6.1 For the purposes of this agreement, the Assessor shall be expected to sign a confidentiality agreement and complete a declaration of interests as set out in Appendix 1.
- 6.2 Furthermore, the Assessor shall not seek or accept instructions from any government or any authority external either to the Council/EDQM and/or his/her own competent authority. The Service Provider and the Assessor undertake to comply with the Council/EDQM's directives for the completion of the work, to observe the utmost discretion regarding all service matters and to refrain from any word or act that may be construed as committing the Council/EDQM.
- 6.3 The Service Provider and the Assessor shall observe the utmost discretion in all matters concerning the agreement, and particularly any service matters or data that have been or are to be recorded that come to the Service Provider's and the Assessor's attention in the performance of the agreement. Unless obliged to do so under the terms of the agreement, or expressly authorised to do so by the Secretary General of the Council of Europe, the Service Provider and the Assessor shall refrain at all times from communicating to any person, legal entity, government or authority external to the Council/EDQM any information which has not been made public and which has come to the Service Provider's and Assessor's notice as a result of dealings with the Council/EDQM. Nor shall the Service Provider and Assessor seek to gain private benefit from such information. Neither the expiry of the agreement nor its termination by the Council/EDQM shall lift these obligations.
- 6.4 Moreover, authorised representatives of the Council/EDQM who, in performing their duties, are informed of means of production or any other information pertaining to the Provider, shall be subject to the obligation of confidentiality.

Article 7 Health and social insurance coverage

The Service Provider shall undertake all measures required under national law to arrange for health and social insurance during the entire agreement. The Service Provider acknowledges and accepts in this regard that the Council/EDQM shall not assume any responsibility for any health or social risks concerning illness, maternity or accident, which might occur during the performance of work under the agreement.

Article 8 Disclosure of the terms of the agreement

- 8.1 The Service Provider is informed and gives an authorisation of disclosure of all relevant terms of the agreement, including identity, for the sole purposes of internal and external audit and to the Committee of Ministers and to the Parliamentary Assembly of the Council/EDQM with a view to these latter discharging their statutory functions, as well as

for the purpose of meeting the publication and transparency requirements of the Council/EDQM or its donors. The Service Provider authorises the publication, in any form and medium, including the websites of the Council/EDQM or its donors, of the title of the agreement, the nature and purpose of the agreement, name and locality of the Service Provider and amount of the agreement. Whenever appropriate, specific confidentiality measures shall be taken by the Council/EDQM to preserve the vital interests of the Service Provider.

Article 9 Use of the Council and EDQM's name

Neither the Service Provider nor the Assessor shall use the name, flag or logo of the Council of Europe or the Council/EDQM without prior permission from the Secretary General of the Council and the Director of the EDQM.

Article 10 Fiscal obligations of the Service Provider and Assessor

The Service Provider and the Assessor undertake to observe all applicable rules and to comply with his/her fiscal obligations in:

- submitting a payment request to the Council/EDQM in conformity with the legislation of his/her country of fiscal residence;
- declaring all fees received from the Council/EDQM for tax purposes as required in his/her country of fiscal residence.

Article 11 Other obligations of the Service Provider and the Assessor

11.1 During the performance of the present agreement, the Service Provider and the Assessor undertake to comply with the applicable principles, rules and values of the Council/EDQM¹, and with the related confidentiality requirements.

11.2 The Staff Regulations and the rules concerning temporary staff members shall not apply to the Assessor.

11.3 Nothing in this agreement shall be construed as conferring on the Assessor rights enjoyed by a Council of Europe staff member or employee.

Article 12 Fees, expenses and mode of payment

12.1 In the framework of this agreement, the Council/EDQM shall address an invitation letter to the Assessor each time the Council/EDQM requires assessment services as mentioned under Article 2. The invitation letter shall stipulate detailed information on his

¹ See the web site of the Council of Europe www.coe.int, in particular Rule No. 1292 of 3 September 2010 on the protection of human dignity at the Council of Europe, and Instruction No. 47 on the use of the Council of Europe's Information System.

participation to the assessment programme, including the period and the place of the assessment.

- 12.2 In return for the fulfilment by the Assessor of his/her obligations under the agreement and the invitation letter, the Council/EDQM shall pay the Service Provider a flat fee amount of €400 (FOUR HUNDRED EUROS) per day, as compensation for request to the Service Provider. This tariff is final and not subject to review.
- 12.3 The Service Provider declares not to be subject to VAT, consequently, the amount invoiced shall be net flat amount.
- 12.4 No later than the end of the civil year for work completed before the 4th trimester of that year, the Service Provider shall send a payment request by email to finances@edqm.eu, stating the net flat amount, exclusive of VAT, to be paid in euro, and established in accordance with the legislation in force in his/her country of fiscal residence. A payment request template can be found in Appendix 2. The template can be modified to comply with the legislation in force in the Service Provider's country.
- 12.5 Payment is due within 60 calendar days after the payment request is received and provided it has been confirmed that the work has been satisfactorily completed.
- 12.6 If the Assessor is required to travel for the purposes of the agreement, the Council/EDQM also undertakes to reimburse the Service Provider for any subsistence allowances the latter has had to pay to the Assessor. Travel expenses will be prepaid by the Council/EDQM (business class for flights lasting more than 7 hours). Subsistence allowances (including expenses incurred by travelling within the locality visited) will be reimbursed at the standard Council of Europe rate (€175 per day in 2021).
- 12.7 In the cases when the Assessor has to undertake travel under the agreement, the entire trip (travelling time and stay) shall be covered by an insurance policy taken out with Chartis (policy No. 2.004.761). Chartis Assistance operates a 24/7 hotline (+ (32) 3 253 69 16) that can be called in case of need. This insurance policy covers the risks to which the Assessor may be exposed whilst travelling or staying at EDQM (including any medical expenses related to unexpected illnesses or accidents and other expenses related to repatriation, death, cancellation of accommodation or flights and theft or loss of personal belongings). The insurance policy covers people up to their 76th birthday.

Article 13 Breach of the agreement

- 13.1 In the event that the Assessor does not satisfy the conditions laid down in this agreement or those resulting from any modifications duly accepted in writing by both parties, in accordance with the provisions of Article 15 below, or the services provided as referred to under Article 2 do not reach a satisfactory level, the Council/EDQM shall consider there to have been a breach of agreement and may consequently refuse to pay to the Service Provider the amounts referred to in Article 12 above.
- 13.2 In the cases described in paragraph 13.1 above, the Council/EDQM reserves further, at any moment and further to prior notification to the Service Provider, the right to terminate

the agreement. In case of termination, the Council/EDQM shall pay only the amount corresponding to the services actually and satisfactorily provided at the time of termination of the agreement and shall request reimbursement of the sums already paid for services not provided.

- 13.3 The outstanding sums shall be paid to the Council/EDQM's bank account within 60 calendar days from the notification in writing by the Council/EDQM to the Service Provider regarding the outstanding sums to be paid.

Article 14 Duration and termination

- 14.1 This framework agreement enters into force on the date of signature by both parties and is applicable for 4 years from that date. It shall be renewed tacitly for one additional period of 2 years.
- 14.2 This framework agreement may be terminated by either party upon three months' written notice. Notice will be considered to have been given if it has been sent by registered letter or by fax (and confirmed by letter) to the signatories of the agreement. If notice is sent by post, a receipt showing that the letter has been sent to the right address, with the postage paid, and in accordance with the procedure described above is considered sufficient proof that notice has been given and received. If notice is given by fax, a transmission verification report showing that the text was sent legibly and in full to the right phone number with no error messages is considered sufficient proof that notice has been served and received, on condition that a copy of the transmission verification report is also sent to the other party by registered letter according to the procedure described above.

Article 15 Modifications

The provisions of this agreement cannot be modified without the written agreement of both parties. This agreement may not be transferred, in full or in part, in exchange for payment or free of charge, without the written permission of the Council/EDQM and the Service Provider.

Article 16 Case of force majeure

- 16.1 In the event of a force majeure, the parties shall be released from the application of the agreement without any financial compensation. Force majeure is defined as unforeseeable circumstances beyond the control of either of the parties, including but not limited to the following: major weather problems, earthquake, strikes affecting air travel, attacks, a state of war, health risks.
- 16.2 In the event of such circumstances each party shall be required to notify the other party accordingly in writing, within a period of 5 days.

Article 17 Disputes

- 17.1 Any dispute between the Council/EDQM and the Service Provider as regards the application of this agreement shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration (as laid down in Rule No 481 of the Secretary General – appendix 3) by an Arbitration Board. Such a Board shall be composed of two

arbitrators each selected by one of the parties, and of a presiding arbitrator, appointed by the other two arbitrators; in the event of no presiding arbitrator being appointed under the above conditions within a period of six months, the President of the Tribunal de Grande Instance of Strasbourg shall make the appointment.

17.2 However, the parties may submit the dispute for decision to a single arbitrator selected by them by common agreement or, failing such agreement, by the President of the Tribunal de Grande Instance of Strasbourg.

17.3 The Board or, where appropriate, the arbitrator referred to herein shall determine the procedure to be followed. If the parties do not agree upon the law applicable the Board or, where appropriate, the arbitrator shall decide ex aequo et bono having regard to the general principles of law and to commercial usage.

17.4 The arbitral decision shall be binding upon the parties and there shall be no appeal from it.

Article 18 Address and bank details of parties

COUNCIL OF EUROPE / EDQM	SUKL
<i>Address:</i> 7, Allée Kastner CS 30026 67081 Strasbourg France	<i>Address:</i> Šrobárova 48 106 41 Praha 10 Czech Republic
<u>Bank details:</u>	<u>Bank details:</u>
<i>Bank:</i> SOCIETE GENERALE Strasbourg, France	<i>Bank:</i> CESKA NARODNI BANKA Praha, Czech Republic
<i>IBAN:</i> XXX	<i>IBAN:</i> XXX
<i>SWIFT Code:</i> XXX	<i>SWIFT code:</i> XXX

Article 19 Date, place and signatures of the parties

On behalf of the Council/EDQM

On behalf of the Service Provider

Signature:

Signature:

Name: XXX

Name: Irena Storova

Position: Director

Position: Director

Date: 9.7.2021

Date: 28.7.2021

APPENDIX 1



Declaration of Interests and confidentiality undertaking of the European Directorate for the Quality of Medicines & HealthCare (EDQM) Group of Experts, Working parties, Committees and staff.

Instructions

The document consists of three parts:

- 1- your Personal Details,
- 2- the Declaration of Interests and
- 3- the Confidentiality Undertaking.

All parts must be duly completed. You are responsible for the accuracy and completeness of the submitted information.

1. Personal Details

Enter your full name, your organisation/company name, country of organisation/company, the e-mail address on which you would like to be contacted regarding this declaration and the identification of the EDQM Group(s) / Committee(s) / Meeting(s) you are willing to take part.

Your e-mail address will be kept confidential and will not be published.

2. Declaration of Interests

This section asks you to declare any interests in a concerned commercial entity (*) that you currently have or have had within the past 3 years. If you have interests to declare, please tick 'Yes' to the relevant questions. All questions in this section must be answered. Your declaration will not be accepted if any fields are left empty.

You may also provide information on interests over 3 years ago. This information could be useful in the context of increased transparency regarding previous interests. If this should be the case, please declare under §2.6.

(*) The expression "Concerned commercial entity" is used throughout this document and includes any commercial business, industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related of the meeting or work.

3. Confidentiality Undertaking

Read carefully the confidentiality undertaking agreement. Signing this Declaration of Interests and confidentiality undertaking implies that you adhere to the information declared in this part.

1: PERSONAL DETAILS

First name:

Last name:

Institution / Company:

Country:

Contact e-mail address:

Identification of EDQM Group/Committee/Meeting:

I do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in concerned commercial entity are those listed below:

*Please specify the interests that you currently have (at the time of completion of the form) or have had within the past **3** years.*

2: DECLARATION OF INTERESTS

2.1. Employment in a concerned commercial entity

No

Yes

→If NO, please go to section 2.2.

EMPLOYMENT¹

Period²: Current Past

From Month: From Year: To Month: To Year:

Name of concerned commercial entity³:

EMPLOYMENT¹

Period²: Current Past

From Month: From Year: To Month: To Year:

Name of concerned commercial entity³:

1 Please indicate any form of occupation, part time or full-time, paid or unpaid, in a concerned commercial entity.

2 Please select the appropriate response (Current or Past).

For current ongoing activities, indicate starting date (month/year).

Note: current is interpreted as at the time of completion of this form. Should you engage in future activities of this nature, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the specified time, please indicate starting and end date (month / year).

3 Also includes supply or service companies which contribute to the research, development, manufacturing, control, marketing and/or distribution in the concerned commercial entity.

2.2. Consultancy* No Yes

* Any activity where you provide(d) consultancy services/business advice to a concerned commercial entity regardless of contractual arrangements or any form of remuneration.

→If NO, please go to section 2.3.

CONSULTANCY¹

Period²: Current Past

From Month: From Year: To Month: To Year:

Name of the concerned commercial entity:

CONSULTANCY¹

Period²: Current Past

From Month: From Year: To Month: To Year:

Name of the concerned commercial entity:

1 Please indicate any activity in which you provide or have provided consultancy services/business advice regardless as to whether or not you received a fee for this activity.

2 Please select the appropriate response (Current or Past). Please indicate activities which are currently ongoing. Indicate starting date (month / year).

Note: current is interpreted as at the time of completion of the form. Should you engage in future activities of this nature, you will need to update your Declaration of Interest form accordingly. For activities that are no longer ongoing and that have been completed within the specified time, please indicate starting and end date (month / year).

2.3. Financial Interests* No Yes

*Financial interests relate to:

Any current economic stake in concerned commercial entity including:

- Holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of the concerned commercial entity(ies). The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements would not need to be declared provided that they are diversified (i.e. not exclusively based on the concerned sector) and they are independently managed (i.e. the individual has no influence on their financial management).
- Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a product owned by the individual or of which the individual is directly a beneficiary.
(current is interpreted as at the time of completion of this form).

→If NO, please go to section 2.4.

Financial Interests, including holding of shares in a concerned commercial entity and receipt of any other fees / honoraria

Name of concerned commercial entity	Financial Interest
1.	
2.	
3.	

Patent Ownership

Name of concerned commercial entity	Subject Matter
1.	
2.	

2.4. Grant / Funding to Institution/Organisation* No Yes

*Refers to any funding received from a concerned commercial entity by the organisation/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activity whether or not it is related to research work.

→If NO, please go to section 2.5.

Grant or Other Funding

Name of concerned commercial entity	Subject Matter
1.	
2.	
3.	

2.5. Close Family Member Interests* No Yes

* Means known interests from first-line members of your family (i.e. spouse or partner, children and parents).

Interest of Close Family Member¹

Name of concerned commercial entity	Type of Interest Declared
1.	
2.	
3.	

¹ Please indicate known interests currently held by first-line members of your family (i.e. spouse or partner, children and parents). In order to maintain privacy, neither the relationship nor the name need be declared. Interests to be declared include all current Direct Interests (i.e. Employment, Consultancy, Current Financial interests or current Patent Ownership).

2.6. Any other matters that might be of interest for transparency purposes* No Yes

* Means any other matters that might be of interest for transparency purposes e.g. working for or providing expert advice to another standardisation body (ISO, CEN, etc.) or to non-European pharmacopoeias, a former employment in a concerned commercial entity, etc.

Employment or consultancy work for a non-European pharmacopoeia

No Yes

If YES, please specify which pharmacopoeia:

- International Pharm. USP Chinese Pharm. Indian Pharm.
 Other: _____

Any other matters that might be of interest for transparency purposes

Further to the interests (direct and indirect) declared above, I do hereby declare on my honour that I do not have any other interests or facts that should be made known to the EDQM and the public.

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify the EDQM and complete a new Declaration of Interests detailing the changes. This declaration does not discharge me from my

obligation to declare any potential conflicting interest(s) at the start of any EDQM Activity or meeting/session in which I participate.

3: CONFIDENTIALITY UNDERTAKING

In view of the following definitions:

“EDQM Activities” encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the EDQM, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on guidance development.

“Confidential Information” means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EDQM Activities.

“Confidential Documents” mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EDQM activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

Note: the confidentiality status does not apply where the individual has a legitimate access to the data from sources other than the EDQM confidential documents or where EDQM provides public access to a document (for example: Technical Guides, Rules of Procedure, Guide for Work).

I understand that I may be invited to participate either directly or indirectly in certain EDQM activities and hereby undertake:

- ✓ to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality,
- ✓ not to disclose (or authorise any other individual to disclose) in any way to any third party any Confidential Information or Confidential Document,
- ✓ not to use (or authorise any other individual to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EDQM activities,
- ✓ to dispose of Confidential Documents as confidential material as soon as I have no further use for them and take all measures to protect them especially when handled in public area (e.g. airport, train etc.).

I also understand that in case I do involve other persons in the work for the EDQM where this is useful for the conduct of the work, I am responsible for ensuring that these persons are aware of the confidential nature of the information and document/data provided and that the results of the work shall be used by the EDQM only.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being made available to public in case of request.

Full name:

Date:

Signature:

APPENDIX 2
REQUEST FOR PAYMENT

NAME:
ADDRESS:

Payment request Reference:
Council of Europe Agreement No.: **CN-3047**
Date:

Description of Item	Amount €
	Total net of VAT in Euro

APPENDIX 3

Rule No. 481 of 27 February 1976 laying down the arbitration procedure for disputes between the Council and private persons concerning goods provided, services rendered or purchases of immovable property on behalf of the Council.

The Secretary General of the Council of Europe,

Having regard to the Statute of the Council of Europe, of 5 May 1949, and in particular its Articles 11 and 40,

Having regard to the General Agreement on Privileges and Immunities of the Council of Europe signed on 2 September 1949, and in particular its Articles 1, 3, 4 and 21, as well as the Special Agreement relating to the seat of the Council of Europe signed on 2 September 1949,

Considering that it is appropriate to determine the arbitration procedures for any disputes between the Council and private persons regarding supplies furnished, services rendered or immovable property purchased on behalf of the Council,

Having regard to the decision of the Committee of Ministers of the Council of Europe at the 253rd meeting of the Deputies,

Decides

Article 1

Any dispute relating to the executives or application of an agreement covered by Article 21 of the General Agreement on Privileges and Immunities of the Council of Europe shall be submitted, failing a friendly settlement between the parties, for decision to an Arbitration Board composed of two arbitrators each selected by one of the parties, and of a presiding arbitrator, appointed by the other two arbitrators : in the event of no presiding arbitrator being appointed under the above conditions within a period of six months, the President of the Tribunal de Grande Instance of Strasbourg shall make the appointment.

Article 2

However, the parties may submit the dispute for decision to a single arbitrator selected by them by common agreement or, failing such agreement, by the President of the Tribunal de Grande Instance of Strasbourg.

Article 3

The Board referred to in Article 1 or, where appropriate, the arbitrator referred to in Article 2 shall determine the procedure to be followed.

Article 4

If the parties do not agree upon the law applicable the Board or, where appropriate, the arbitrator shall decide *ex aequo et bono* having regard to the general principles of law and to commercial usage.

Article 5

The arbitral decision shall be binding upon the parties and there shall be no appeal from it.

Strasbourg, 27 February 1976

XXX
Secretary General