

FRAMEWORK AGREEMENT ON COLLABORATIVE STUDIES

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

And the State Institute for Drug Control, Šrobárova 48, 100 41 Prague 10,
Czech Republic, represented by Irena Storová, Director, hereinafter
referred to as "the Service Provider".

Article 1 Nature of services

1.1 The Service Provider undertakes, on the conditions, within the limits and in the manner laid down by common agreement hereafter excluding any accessory verbal agreement, to participate in inter-laboratory studies called "collaborative studies" to ensure the highest level of objectivity in the establishment of reference standards or standard methods of the European Pharmacopoeia. It is understood that the Service Provider will not have to develop nor to transfer its own method(s) in the context of this framework.

1.2 For each study the Service Provider will be asked to undertake some or all of the following activities:

The Council / EDQM will provide the samples and the related study protocol;

The Service Provider will carry out any collaborative study with the Council / EDQM in accordance with the protocol and, when applicable, with the rules and standards of the OMCL Network;

The Service Provider will provide the Council / EDQM with a final report after the completion of a study or will provide the Council / EDQM with all raw data after the completion of the studies required for the statistical evaluation and preparation of the final report;

The final report documents reporting sheets for each study shall include the information/results required by the protocol and shall be properly authorised and signed;

The Service Provider is informed that his data will be included in the collaborative study report which forms, where applicable, the establishment report of the CRS/BRP/BRR.

1.3 Each request to participate in a collaborative study will be made via an official Purchase Order from the Council / EDQM with reference to this framework agreement. The Purchase Order shall outline the specific study concerned, the specific tasks/techniques to be undertaken and the deadline for submitting the results of the study.

Article 2 Duration

2.1 This framework agreement shall come into force on 1st March 2021 and shall continue in full force and effect for a period of three years from the date of signature. It shall be renewed tacitly for one additional period of 2 years.

2.2 Either party may terminate this agreement on reserve that the other party is given two months notice of the intention to terminate the agreement. Any notice shall be deemed to have been duly given if sent by recorded delivery post or facsimile transmission (confirming the same by post) to the signatories of this agreement.

Article 3 Property rights

3.1 Information and samples supplied by the Council/EDQM

Any information supplied to the Service Provider by the Council / EDQM to complete the services referred to in Article 1 remains the property of the Council / EDQM. The Council / EDQM may, however, on prior application by the Service Provider, authorise the Service Provider to use the information supplied. When giving the Service Provider such authority, the Council / EDQM will inform the Service Provider of any conditions to which such use may be subject. That said, under no condition will the Council / EDQM authorise the Service Provider to publish or share the information provided by the Council / EDQM under the framework of this agreement.

Samples provided by the Council/EDQM are to be used solely in the context of the collaborative study and for no other purpose.

3.2 Deliverables

3.2.1 The Service Provider cedes to the Council / EDQM, on an exclusive basis and for an unlimited period of time all rights in the deliverables referred to in Article 1. Such rights shall include in particular the right to use, reproduce, represent, publish, adapt in any form and on any kind of support, the deliverables, or any part thereof, submitted by the Service Provider under the agreement.

3.2.2 The Council / EDQM reserves to exercise the above-mentioned rights for any purpose falling within its activities, in particular for the establishment of monographs and reference standards.

3.2.3 The Service Provider guarantees that use by the Council / EDQM of the items supplied under the agreement and referred to in Article 1 will not infringe the rights of third parties. However, should the Council/ EDQM incur liability as the result of any such infringement, the Service Provider will compensate it in full for any damage it may suffer in consequence. Notwithstanding the provision in Article 3.1 above, the Service Provider

may use the results obtained in providing the deliverables identified in Article 1 in the context of the Service Provider's legal framework and in particular in the context of the Service Provider's quality management system on condition that the Council / EDQM is informed by the Service Provider in advance via the nominated contact person. While the Council/EDQM authorises the Service Provider to make public that they participated in collaborative studies organised by the EDQM, the Council / EDQM, may on request authorise the Service Provider to publish its own results obtained in providing the deliverables under the framework of this agreement. When giving the Service Provider such authority, the Council / EDQM will inform the Service Provider of any conditions to which such use may be subject. That said, under no condition will the Council / EDQM authorise the Service Provider to publish or share the results obtained in providing the deliverables identified in Article 1 of this agreement.

Article 4 Loyalty and discretion

4.1 The Service Provider undertakes to comply with the Council / EDQM's directives for the completion of the work, to observe absolute discretion regarding all service matters and to refrain from any word or act that may be construed as committing the Council / EDQM.

4.2 The Service Provider 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 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, the Service Provider shall refrain at all times from communicating to any person, legal entity, government or any third party authority external to the Council / EDQM any information which has not been made public and which has come to the Service Provider's notice as a result of dealings with the Council / EDQM. Nor shall the Service Provider 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.

Article 5 Data protection

Without prejudice to the other provisions of this contract, the Parties undertake, in the execution of this contract, to comply at all times with the legislation applicable to each of them concerning the processing of personal data.

Where the Service Provider, pursuant to its obligations under this contract, processes personal data on behalf of the Council/EDQM, it shall:

- i. Process personal data only in accordance with written instructions from the Council/EDQM;
- ii. Process personal data only to the extent and in such manner as is necessary for the execution of the contract, or as otherwise notified by the Council/EDQM;
- iii. 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;

- iv. Take reasonable steps to ensure the reliability of the Service Provider's employees having access to the personal data and to ensure that they have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality and thus agree to comply with the data protection obligations set out in this contract;
- v. Obtain written consent from the Council/EDQM prior to any transfer of possession or responsibility for the personal data to any subcontractors. If the Council/EDQM chooses to authorise subcontracting, the same data protection obligations as set out in this contract shall be imposed on the subcontractor by way of a contract. The Service Provider shall remain fully liable to the Council/EDQM for the performance of that subcontractor's obligations.
- vi. Notify the Council/EDQM within five working days if it receives:
 - a request from a data subject to have access (including rectification, deletion and objection) to that person's personal data; or
 - a complaint or request related to the Council/EDQM's obligations to comply with the data protection requirements.
- vii. Provide the Council/EDQM with full assistance in relation to any such request or complaint and assist the Council/EDQM to fulfil its obligation to respond to the requests for rectification, deletion and objection, to provide information on data processing to data subjects and to notify personal data breaches;
- viii. Allow for and contribute to checks and audits, including inspections, conducted or mandated by the Council/EDQM or by any authorised third auditing person. The Service Provider shall immediately inform the Council/EDQM of any audit not conducted or mandated by the Council/EDQM;
- ix. Not process nor transfer personal data outside the jurisdiction of a Council/EDQM of Europe Member State without the prior authorisation of the Council/EDQM and provided that an adequate level of protection is guaranteed by law or by ad hoc or approved standardised safeguards (such as binding corporate rules) in the jurisdiction of the recipient;
- x. Make available to the Council/EDQM all information necessary to demonstrate compliance with the obligations under the contract in connection with the processing of personal data and the rights of data subjects;

Upon the Council/EDQM's request, delete or return to the Council/EDQM all personal data and any existing copies, unless the applicable law requires storage of the personal data.

Article 6 Health, social and travel insurance

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

Article 7 Disclosure of the terms of the agreement

7.1 The Service Provider is informed and gives an authorisation of disclosure of all relevant terms of the agreement, including identity and price, for the purposes of internal and external audit and to the Committee of Ministers and to the Parliamentary Assembly of the Council 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 of Europe or its donors. The Service Provider authorises the publication, in any form and medium, including the websites of the Council of Europe or its donors, of the title of the agreement/projects, the nature and purpose of the agreement/projects, name and locality of the Service Provider and amount of the agreement/project.

7.2 Whenever appropriate, specific confidentiality measures shall be taken by the Council / EDQM to preserve the vital interests of the Service Provider.

Article 8 Use of the Council of Europe / EDQM's name

The Service Provider shall not use either the Council's or EDQM's name, flag or logo without prior authorisation of the Secretary General of the Council and the EDQM Director.

Article 9 Fiscal obligations of the Service Provider

The Service Provider undertakes to observe all applicable rules and to comply with her fiscal obligations in:

- submitting a payment request to the Council / EDQM in conformity with the legislation of her country of fiscal residence;

- declaring all fees received from the Council / EDQM for tax purposes as required in her country of fiscal residence.

Article 10 Other obligations of the Service Provider

- 10.1 In the performance of the present contract, the Service Provider undertakes to comply with the applicable principles, rules and values of the Council/EDQM*.
- 10.2 The Staff Regulations and the rules concerning temporary staff members shall not apply to the Service Provider.
- 10.3 Nothing in this contract may be construed as conferring on the Service Provider the capacity of a Council/EDQM staff member or employee.

Article 11 Fees, expenses and mode of payment

11.1 The Council / EDQM will pay the Service Provider a net fiat amount based on tariffs mentioned below and this will be specified in each Purchase Order.

Study	Determination	Sum (Euro)
Chemical Assay CRS	related substances by LC, GC or CE plus Water (KF or Coulometry) or LOD	500*
Microbiological Assay CRS	microbiological potency plus Water (KF or Coulometry) or LOD	700*
BRP/BRR	Biological assays	1,000*

* may be adapted in case the Service Provider has to purchase expensive consumables and this will be mentioned in the Purchase Order.

11.2 The Service Provider declares not be subject to VAT; consequently, the amount invoiced shall be net fixed amount.

11.3 On acceptance of the deliverable, the Council / EDQM will invite the Service Provider to send a payment request in triplicate in conformity with the legislation of his/her country of fiscal residence mentioning the total amount in Euros to be paid. A model payment request is attached in the Appendix 1 to this agreement. This model can be modified as appropriate to conform to legislation of the country of fiscal residence.

11.4 Payments shall be made into the bank account of the Service Provider as indicated in Article 18. This sum shall be payable within 60 calendar days upon receipt and acceptance of the payment request by the Council / EDQM.

Article 12 Breach of the agreement

12.1 In the event that the Service Provider does not satisfy the conditions laid down in this agreement or these resulting from any modifications duly accepted in writing by both parties, in accordance with the provisions of Article 13 below, or the services provided as referred to

¹ See www.coe.int and, in particular, Instruction No.44 of 7 March 2002 on the protection of human dignity of the Council of Europe.

under Article 1 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 11 above.

122 In the cases described in paragraph 12.1 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.

123 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 13 Modifications

The provisions of this agreement cannot be modified without the written agreement of both parties.

Article 14 Changes in the Service Provider's situation or standing

14.1 The Service Provider shall inform the Council/EDQM without delay of any changes in their address or legal domicile or in the address or legal domicile of the person who may represent them.

14.2 The Service Provider shall inform also inform the Council/EDQM without delay:

- i. if they are involved in a merger, takeover or change of ownership or there is a change in their legal status;
- ii. where the Service Provider is a consortium or similar entity, if there is a change in membership or partnership.
- iii. if they are sentenced by final judgment on one or more of the following charges: participation in a criminal organisation, corruption, fraud, money laundering;
- iv. if they are in a situation of bankruptcy, liquidation, termination of activity, insolvency or arrangement with creditors or any like situation arising from a procedure of the same kind, or is subject to a procedure of the same kind;
- v. if they have received a judgment with res judicata force, finding an offence that affects their professional integrity or serious professional misconduct;
- vi. If they do not comply with their obligations as regards payment of social security contributions, taxes and dues, according to the statutory provisions of their country of legal domicile;
- vii. If they are or are likely to be in a situation of conflict of interests.

Article 15 General obligation to provide advice

The Service Provider recognises that it is subject to a general obligation to provide advice, including, but not limited to, an obligation to provide any relevant information or recommendations, to the Council/EDQM. In this context, the Service Provider shall supply to the Council/EDQM all the advice, warnings and recommendations necessary particularly in terms of quality of services and compliance with professional standards. The Service Provider also undertakes to inform the Council/EDQM as soon as it becomes aware, during the execution of the Contract, of any initiatives and/or adopted laws and regulations, policies, strategies or action plans or any other development related to the object of the Contract.

Article 16 Case of force majeure

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.

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 Communication between the parties

17.1 Communications shall be done through the contact details indicated below:

COUNCIL OF EUROPE / EDQM

STATE INSTITUTE FOR DRUG CONTROL

Person/function/Department:

Person/function/Department:

XXX

XXX

Address: 7, Allée Kastner
ES 30026
67081 Strasbourg
France

Address: Šrobárova 48
100 41
Prague 10
Czech Republic

Telephone: XXX

Telephone: XXX

Email: XXX

Email: XXX

17.2 Any communication is deemed to have been made when it is received by the receiving party, unless the Agreement refers to the date when the communication was sent.

17.3 Electronic communication is deemed to have been received by the receiving party on the day of successful dispatch of that communication, provided that it is sent to the addressees listed in paragraph 17.1 above. Dispatch shall be deemed unsuccessful if the sending party receives a message of non-delivery. In this case, the sending party shall immediately send again such communication to any of the other addresses listed in paragraph 17.1 above. In case of unsuccessful dispatch, the sending party shall not be held in breach of its obligation to send such communication within a specified deadline, provided the communication is dispatched by another means of communication without further delay.

17.4 Mail sent to the Council/EDQM using the postal services is considered to have been received by the Council/EDQM on the date on which it is registered by the department identified in paragraph 17.1 above.

17.5 Formal notifications made by registered mail with return receipt or equivalent, or by equivalent electronic means, shall be considered to have been received by the receiving party on the date of receipt indicated on the return receipt or equivalent.

Article 18 Address, and bank details of the parties

COUNCIL OF EUROPE / EDQM	STATE INSTITUTE FOR DRUG CONTROL
Address: 7, Allée Kastner ES 30026 67081 Strasbourg France	Address: Šrobárova 48 100 41 Prague 10 Czech Republic
Bank details:	Bank details:
Bank: SOCIETE GENERALE Strasbourg, France	Bank: Czech National Bank Na Příkopě 28 115 03 Praha 1
IBAN: XXX	IBAN :XXX
SWIFT Code:	SWIFT Code: XXX

Article 19 Disputes

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 2) 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.

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.

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.

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

Article 20 Date, place and signatures of the parties

Done in two copies

On behalf of the Council/EDQM

On behalf of the Service Provider

Signature:

Signature:

Name: XXX

Name Irena Storová

Position: Director of the EDQM

Position: Director

Date: 25.1.2021

Date: 5.2.2021

APPENDIX 1 - MODEL PAYMENT REQUEST

NAME:

ADDRESS:

Invoice No.:

Contract No.: **CN-2954**

Date:

Description of Item	Amount €
Total net amount	

APPENDIX 2

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 execution or application of a contract 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 to 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 arbitrator's decision shall be binding upon the parties and there shall be no appeal from it.

Strasbourg, 27 February 1976

XXX

Secretary General