

Agreement No : CN-2030

FRAMEWORK AGREEMENT ON COLLABORATIVE STUDIES

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

And Zooprophyllaxis & Research Institute for the Latium and Tuscany Regions M.ALEANDRI, represented by Ugo Della Marta, Chief Executive Officer, 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 document/data 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 Property rights

2.1 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.

2.2 Deliverables

2.2.1 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.

2.2.2 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.

2.2.3 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 2.1 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 3 Loyalty and discretion

3.1 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.

3.2 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 4 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 5 Disclosure of the terms of the agreement

5.1 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.

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

Article 6 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 7 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 8 Other obligations of the Service Provider

The Staff Regulations shall not apply to the Service Provider.

Article 9 Fees, expenses and mode of payment

9.1 The Council / EDQM will pay the Service Provider a net flat 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.*

9.2 Within 60 days of receipt of the deliverable(s) the Council / EDQM will confirm whether the work has been satisfactorily completed. On acceptance of the deliverable, the Council / EDQM will invite the Service Provider to send a payment request mentioning "the net flat amount to be paid" in Euros, in conformity with the legislation of his/her country of fiscal residence. A model payment request is attached in the Annex 1 to this agreement. This model can be modified as appropriate to conform to legislation of the country of fiscal residence.

9.3 This sum shall be payable within 60 calendar days upon receipt and acceptance of the payment request by the Council / EDQM.

Article 10 Breach of agreement

10.1 In the event that the Service Provider 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 12 below, or the services provided as referred to 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 9 above.

10.2 In the cases described in paragraph 10.1 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.

10.3 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 11 Duration

11.1 This framework agreement shall come into force on the date of its signature by both Parties 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.

11.2 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.

To prove service of any notice it shall be sufficient to show in the case of service delivered by post that the same was duly addressed, prepaid and posted in the manner set out above. In the case of notice given by facsimile transmission, it shall be sufficient to show that it was despatched in a legible and complete form to the correct telephone number without any error message and provided that a confirmation copy is sent to the other party by registered post in the manner set out above.

Article 12 Modifications

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

Article 13 Case of force majeure

Force majeure is defined as including the following: major weather problems, earthquake, strikes affecting air travel, attacks, a state of war, health risks or events that would require the Council / EDQM or the Service Provider to cancel the agreement. In the event of such circumstances each party shall be required to notify the other party accordingly in writing, within a period of 7 calendar days.

Article 14 Disputes

In accordance with the provisions of Article 21 of the General Agreement on privileges and immunities of the Council of Europe, all disputes 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 (attached in Annex 2).

Article 15 Address, contact points and bank details of the parties

COUNCIL OF EUROPE/ EDQM

Address: 7, Allée Kastner,
CS 30026
FR - 67081 Strasbourg
France

Contact: Karl-Heinz BUCHHEIT

Telephone: +33 3 90 21 48 55

E-Mail: karl.buchheit@edqm.eu

Bank details:

Bank: SOCIETE GENERALE,
Strasbourg, France

IBAN: FR7630003023600055003425676

SWIFT Code: SOGEFRPPBRG

Zooprophylaxis & Research Institute for the Latium and Tuscany Regions M.ALEANDRI

Address: Via Appia Nuova N. 1411
00178 ROMA
ITALY

Contact: Gian Luca Autorino

Telephone: +390679099449

E-Mail: gianluca.autorino@izslt.it

Bank details:

Bank: BPER BANCA
Albano Laziale (Rm), Italy

IBAN: IT48C0538738860000002430983

SWIFT Code: BPMO1T22XXX

Article 16 Date, place and signatures of the parties

Done in two copies

On behalf of the Council/EDQM

Signature:

Name: Susanne Keitel
Position: Director of the EDQM

Date:



On behalf of the Service Provider

Signature:

Name: Ugo Della Marta
Position: Chief Executive Officer

Date:

ANNEX 1
PAYMENT REQUEST

NAME:

ADDRESS:

Council of Europe Agreement No.: CN-2030

Council of Europe Purchase Order No:

Payment Request Reference No:

Date:

Description of Item		Amount €
The net flat amount to be paid (Euros)		

ANNEX 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 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

Georg KAHN-ACKERMANN

Secretary General