

Contract N°: PH-046-2015

FRAMEWORK SERVICE CONTRACT

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

And the State Institute for Drug Control, Czech Republic, represented by Zdeněk Blahuta, Director, hereinafter referred to as the "Service Provider".

Article 1 Nature of contract

1.1 The Service Provider, subject to the agreed terms and conditions set forth below, shall provide the Council/EDQM with collaborators to act as GMP inspectors hereinafter referred to as "Inspector" in either the capacity of Team Leader or as an accompanying inspector within the framework of the Procedure for the Certification of Suitability to the Monographs of the European Pharmacopoeia.

1.2 This framework contract shall be concluded for a period of three years from the date of signature. It shall be renewed tacitly for one additional period of 2 years, unless one of the Contracting Parties denounces it to the other Party in writing three months before the date of expiry.

Article 2 Service and Deliverables

2.1 The services and deliverables furnished to EDQM will be supervised by the Certification Division at the EDQM. The services to be provided are as follows:

- The Inspector shall carry out GMP inspections for companies in relation to a certificate of suitability within the framework of the EDQM inspection programme, either as a Team Leader or as an accompanying inspector.
- The Inspector shall take part in the elaboration of the EDQM inspection report, which shall include the inspection results, a list of findings and recommendations, as per EDQM Standard Operating Procedures (SOPs).
- The Inspector shall take part in the follow-up activities which include the review of corrective actions proposed by the companies and the drafting of a corresponding report, as per EDQM Standard Operating Procedures (SOPs).
- The Inspector may be asked to take on the role of Team Leader and shall act in accordance with EDQM Standard Operating Procedures (SOPs).

Handwritten signature

Article 3 Language and length of documents

3.1 Any written documents prepared by the Inspector under the contract shall be written in English.

Article 4 Intellectual property rights

4.1 The Service Provider and the Inspector 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 2.1 (in particular the inspection report which contains the inspection results and a list of findings and recommendations). Such rights shall include in particular the right to use, reproduce, represent, publish, adapt, translate and distribute – or to have used, reproduced, represented, published, adapted, translated and distributed - in any country, in any language, in any form and on any kind of support, including on a CD-ROM or the internet, the deliverables, or any part thereof, submitted by the Inspector under the contract.

The Council/EDQM reserves to exercise the above-mentioned intellectual property rights for any purpose falling within its activities and in particular to Certification Activities.

4.2 The Service Provider and the Inspector guarantee that use by the Council/EDQM of the items supplied under the contract and referred to in Article 2.1 will 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 will compensate it in full for any damage it may suffer in consequence.

4.3 The Council/EDQM authorises the Service Provider and the Inspector and his supervisory authority to use deliverable(s) referred to under Article 2.1 above in the context of the activities of his/her supervisory authority in the domain of GMP inspections and their follow-up as the Council/EDQM accepts that this sharing of inspection reports is in the best interests of public health in Europe.

Article 5 Loyalty and discretion

5.1 In the performance of the present contract, the Inspector will be expected to sign a confidentiality agreement and a declaration of interests as set out in Appendix 1.

5.2 The Inspector will furthermore, not seek or accept instructions from any government or any authority external either to the Council/EDQM and/or to his/her own supervisory authority. The Inspector 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.

5.3 The Service Provider and the Inspector shall observe the utmost discretion in all matters concerning the contract, and particularly any service matters or data that have been or are to be recorded that come to the Inspector's attention in the performance of the contract.

Unless obliged to do so under the terms of the contract, or expressly authorised to do so by the Secretary General of the Council, the Service Provider and the Inspector shall refrain at all times from communicating to any person, legal entity, government or authority external to the Council/EDQM and/or to his/her own supervisory authority 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 and the Inspector seek to gain private benefit from such information. Neither the expiry of the contract nor its termination by the Council/EDQM shall lift these obligations.

Article 6 Health and social cover

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

Article 7 Disclosure of the terms of the contract

7.1 The Service Provider is informed and gives an authorisation of disclosure of all relevant terms of the contract, 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 contract/projects, the nature and purpose of the contract/projects, name and locality of the Service Provider and amount of the contract/project.

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

Article 8 Use of the Council and EDQM's name

8.1 Neither the Service Provider nor the Inspector shall use 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

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

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

Article 10 Other obligations of the Service Provider and the Inspector

10.1 In the performance of the present contract, the Service Provider and the Inspector undertake to comply with the applicable principles, confidentiality and rules and values of the Council/EDQM¹.

10.2 The Staff Regulations and the rules concerning temporary staff members shall not apply to the Inspector.

10.3 Nothing in this contract may be construed as conferring on the Inspector the capacity of a Council of Europe staff member or employee.

Article 11 Fees, expenses and mode of payment

11.1 In the framework of this contract, the Council/EDQM shall address an invitation letter to the Inspector each time the Council/EDQM requires the Inspector to undertake inspection activities as mentioned under Article 2. The invitation letter shall stipulate detailed information on the Inspector's participation to a specific inspection programme, including the period and the place of the inspection. The invitation letter shall stipulate each task to be provided by the Inspector during the inspection as well as the number of days allocated to each task. The precise number of allocated days may be adapted depending on the inspection workload, and agreed beforehand.

11.2 In return for the fulfillment by the Inspector of his obligations under the contract and the invitation letter, the Council/EDQM shall pay the Service Provider a net flat daily rate of €400 (FOUR HUNDRED EUROS) for each of the following tasks set out below. These tariffs are final and not subject to review.

Task	Basis
Team leader - inspection	Per inspection day
Team leader – follow-up*	Per follow-up day
Accompanying inspector - inspection	Per inspection day
Accompanying inspector – follow-up	Per follow-up day
Bonus inspections far east countries**	1 day per inspection week

** may be adapted in case the Inspector does not write the report and/or the Final summary report, or does not evaluate the company's answer*

*** This bonus will be mentioned exactly in the invitation letter and it may be adapted according to difficulties or length of campaigns. These countries include China, India, South Korea, Japan etc.*

¹ See www.coe.int in particular Instruction 44 on the protection of human dignity of the Council of Europe and Instruction 47 on the use of the Council of Europe's information system.

11.3 Not later than 3 months after the completion of work, the Service Provider shall submit a payment request in triplicate mentioning the net flat amount to be paid in Euros in conformity with the legislation of her country of fiscal residence. The request for payment should not include VAT. A model payment request is attached in the Appendix 2 to this contract. This model can be modified as appropriate to conform to such financial legislation.

11.4 This sum shall be payable within 60 calendar days upon receipt of the invoice and acceptance that the work has been satisfactorily completed.

11.5 In the event of the Inspector being required to travel for the purposes of the contract, the Council/EDQM also undertakes to reimburse the Inspector's subsistence allowances to the Service Provider.

Travel expenses will be pre-paid (business class for flights of more than 7 hours).

Subsistence expenses (including travel expenses within the locality visited) will be reimbursed at the standard Council of Europe rate (€ 175 a day in 2015). They will be mentioned in the invitation letter.

11.6 In the cases when the Inspector has to undertake travel under the contract, the duration of the Inspector's travel and stay will be covered by an insurance policy with the insurers, Chartis (Policy n° 2.004.761). The following help line Chartis Assistance 24 Hours can be called in case of need: + (32) 3 253 69 16. The said insurance will cover specific risks related to travel and stay of the Inspector (including medical costs related to unforeseen illness or accident, repatriation, death, cancellation of journey or flight, theft or loss of personal possessions). The insurance policy provides cover for persons up to their 76th birthday.

Article 12 Breach of contract

12.1 In the event that the Inspector does not satisfy the conditions laid down in this contract or those 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 under Article 2.1 do not reach a satisfactory level, the Council/EDQM shall consider there to have been a breach of contract and may consequently refuse to pay to the Service Provider the amounts referred to in Article 11 above.

12.2 In the cases described in Article 12.1 above, the Council/EDQM reserves further, at any moment and further to prior notification to the Inspector, the right to terminate the contract. 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 contract and shall request reimbursement of the sums already paid for services not provided.

12.3 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 13 Modifications

The provisions of this contract cannot be modified without the written agreement of both parties. This contract may not be transferred, in full or in part, for money or free of charge, without the Council/EDQM's prior authorisation in writing.

Article 14 Case of force majeure

14.1 In the event of force majeure, the parties shall be released from the application of this contract without any financial compensation. 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 contract.

14.2 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 15 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 contract 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 Appendix 3).

Article 16 Address and bank details of parties

COUNCIL OF EUROPE / EDQM

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

Bank details:

Bank: SOCIETE GENERALE
Strasbourg, France

IBAN FR7630003023600055003425676

SWIFT Code: SOGEFRPPBRG

SERVICE PROVIDER:

THE STATE INSTITUTE FOR DRUG CONTROL

Address: Šrobárova 48
100-41 Prague
Czech Republic

Bank details:

Bank: CZECH NATIONAL BANK

IBAN: CZ9407100000350000623101

SWIFT Code: CNBACZPP

Article 17 Date, place and signatures of the parties

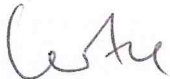
Done in two copies

On behalf of the Council / EDQM

Name: Susanne KEITEL

Position: Director

Date: 11/4/15

Signature: 

On behalf of the Main Pharmaceutical Inspectorate

Name: Zdeněk Blahuta

Position: Director

Date: 29.4.2015

Signature: 

Státní ústav pro kontrolu léčiv
Šrobárova 48
100 41 Praha 10
(100)

Company name	Nature (shareholder)	Is it current (Yes/No)	Is it from the past 3 years (give the date)
Financial interest			
Others			

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly (within 1 month) notify the EDQM and complete a new form detailing the changes.

Date and signature:



APPENDIX 1

DECLARATION OF CONFIDENTIALITY, DECLARATION OF INTERESTS AND ACCEPTANCE OF THE CODE OF PRACTICE FOR THE CERTIFICATION PROCEDURE

Participants in the Certification procedure are required to complete the following declaration undertaking confidentiality and listing their personal interests in the pharmaceutical and associated industries that are current or from the past 3 years.

I,
(Title)(First Name and Name)

Understand that I may be invited to participate either directly or indirectly in EDQM activities and hereby undertake to participate in the Certification work in accordance with the Code of Practice.

I undertake to respect full confidentiality of information as described in the Code of Practice.

I do hereby declare on my honour that, to the best of my knowledge, I have no interests in the pharmaceutical and associated industries *.

I do hereby declare on my honour that, to the best of my knowledge, I have the following interests (as defined in the Code of Practice) in the pharmaceutical and associated industries *.

	Company name	Nature (shares/fee,...)	Is it current (Yes/No)	Is it from the past 3 years (give the dates)
Financial interest				
Others				

* delete as appropriate

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly (within 1 month) notify the EDQM and complete a new form detailing the changes.

Date and signature:

Wp

REQUEST FOR PAYMENT

ADDRESS:

Date:

9/10

Cell

APPENDIX 3

Rule No. 481 of 27 February 1976 on the arbitration procedure of any disputes between the Council and service providers

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 a 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

Georg KAHN-ACKERMANN
Secretary General