Agreement No.: CN-2368

CENTRALLY AUTHORISED MEDICINAL PRODUCTS
PRODUCT TESTING FRAMEWORK CO-OPERATION AGREEMENT

BETWEEN

The Council of Europe – European Directorate for the Quality of Medicines & HealthCare (EDQM),
represented by XXX,
hereinafter referred to as "the Council/EDQM",

AND

The State Institute for Drug Control (ŠÚKL) - Czech Republic,
represented by Irena Storová, Director,
hereinafter referred to as "the OMCL",

hereinafter referred to as "the Parties".

PREAMBLE

Regulation (EC) n° 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA) stipulates that EMA "shall be responsible for co-ordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products" (Article 55). In particular, EMA shall undertake the co-ordination of the monitoring, under practical conditions of use, of medicinal products which have been authorised within the Union (Article 57.1(c)), and the "co-ordination of the supervision of the quality of medicinal products placed on the market by requesting testing of compliance with their authorised specifications by an Official Medicines Control Laboratory or by a laboratory that a Member State has designated for that purpose" (Article 57.1(r)).

The Council/EDQM is the hosting organisation of the European Network of Official Medicines Control Laboratories including EEA member states (EEA OMCLs Network) and is in a position to co-ordinate the work of the above-mentioned laboratories with regard to the common activities of the OMCL network. The EMA and the Council/EDQM have, therefore, concluded a co-operation agreement entrusting the Council/EDQM with the task of co-ordinating the organisation and execution of the individual Testing Programmes (sampling and testing) of Centrally Authorised medicinal products and/or APIs of such products by OMCLs in conformity

with the procedures and templates for the sampling and testing of Centrally Authorised Products agreed between the EMA, EDQM and the OMCL Network.

Article 1 NATURE OF SERVICES AND DELIVERABLES

- **Annual Programme:** yearly sampling and testing programme performed during the duration of the agreement on Centrally Authorised Products selected each year using a risk-based approach by the EMA Secretariat, in collaboration with the EMA Scientific Committees and agreed with the Council/EDQM and CAP Advisory Group. Ad hoc Testing of Centrally Authorised Products, carried out on request from the CHMP and the CVMP, is excluded from the programme.

- **Generics Programme:** 5-year sampling and testing programme performed on Centrally Authorised Generic Products with the same or similar dosage form and containing the same INNs for which there is a developed common test method from previous testing experience in the OMCL network selected by the EMA Secretariat, in collaboration with the EMA Scientific Committees and agreed with the Council/EDQM and CAP Advisory Group.

- **Biosimilars Programme:** 5-year sampling and testing programme performed on Centrally Authorised Biosimilar Products associated to a pre-agreed list of Biosimilar Products Groups selected by the EMA secretariat, in collaboration with the EMA Scientific Committees, Council/EDQM and CAP Advisory Group. The list of Biosimilar Products Groups will be agreed by EMA and Council/EDQM in writing and can only be modified by written agreement. For each Biosimilar Products Group, activities can include development of common test methods (product sampling and testing), which can take place over the course of several years, as well as preparation of the report (in particular, regarding the scientific discussion and the conclusions of the study) in collaboration with the scientific programme manager in charge at the EDQM before they are delivered to the EMA.

- **Parallel Distribution Programme:** yearly sampling and testing programme performed on Centrally Authorised Products that are subject to parallel distribution. Each year a number of Centrally Authorised Products will be randomly sampled from the parallel distribution chain and tested.

- **Ad Hoc API Programme:** yearly sampling and testing programme performed on Active Pharmaceutical Ingredients upon request by a member state or EMA whenever samples are available from a manufacturing site where there is a suspicion of GMP non-compliance.

1.1 In the framework of the procedures for each of the individual sampling and testing Programmes of Centrally Authorised medicinal products and/or APIs of such products, the OMCL is responsible for testing the samples provided by the Council/EDQM and shall deliver the test reports in accordance with the data sheets supplied (where applicable) – as detailed in the Individual CAP testing template – and with the test protocol (Standard Operating Procedures [SOPs] included, where applicable). Each

request to participate in a product testing will be made via an official Purchase Order from the Council/EDQM with reference to this framework agreement. The Purchase Order will be sent by email together with the completed Individual CAP testing template as included in Appendix 1. The OMCL shall acknowledge receipt and acceptance of the work by returning by email the Individual CAP testing template signed by the authorised person.

1.2 The deadline for submitting the report to the Council/EDQM will be specified in the Individual CAP testing templates. After receipt of the data sheets and test samples, the OMCL will duly communicate to the Council/EDQM using the acknowledgement of receipt.

The OMCL shall, without delay, inform the Council/EDQM of any actual or anticipated difficulty in meeting this deadline. Where necessary, the Council/EDQM may appoint another OMCL during the course of testing.

Data sheets, test samples and all required reference substances relevant to the CAP testing will be sent by the Council/EDQM to OMCL. The approximate date of shipment will be specified in the Individual CAP testing templates. This deadline will be met provided that there is no delay during the sampling phase of the product concerned.

If a temperature monitoring device is included together with the materials sent by the Council/EDQM, this needs to be returned to the Council/EDQM within 48 hours after reception of the materials. In the case of failure by the OMCL to return the device to the Council/EDQM using a courier company according to the instructions provided by the Council/EDQM, the corresponding cost shall be subtracted from the Council/EDQM total financial contribution.

1.3 The testing report shall be of the highest possible scientific quality, prepared in accordance with the procedures and guidelines adopted by the EU/EEA OMCL network for centrally authorised products (current versions available on CAPnet). The data sheets provided by the Council/EDQM shall be completed and accompanied where necessary by graphs and printouts of the instrument used. Furthermore, it shall be ensured that testing is performed under a quality assurance system, which is in compliance or moving progressively towards compliance with the standard ISO/IEC 17025:2017, and for which assessment by external bodies can be documented.

1.4 All written documents shall be produced in one of the Council of Europe two official languages (English or French).

1.5 Subcontracting of CAP Sampling and Testing Program by the testing OMCL to third parties shall only be allowed on an exceptional basis (for specific individual test parameters) and on prior approval of the Council/EDQM. When subcontracting activities are approved by the Council/EDQM, this must follow the rules of good practice as laid down in ISO/IEC 17025:2017 as well as the rules defined under this Product Testing Agreement.

Article 2 INTELLECTUAL PROPERTY

2.1 The OMCL accepts that the Council/EDQM uses proprietary information of the Marketing Authorisation Holder (MAH) and, therefore, does not transfer any intellectual property rights to the OMCL in respect of this information.

2.2 The OMCL cedes to the Council/EDQM on an exclusive basis and for an unlimited period of time all rights in the deliverables referred above in Article 1 and as detailed in the official purchase orders and the Individual CAP testing templates. Such rights shall include in particular the right to use, represent, adapt, translate on any kind of support, the deliverables, or any part thereof, submitted by the OMCL under the agreement, and shall be used within the framework of the current EU regulations on medicines.

2.3 The Council/EDQM reserves its prerogative to exercise the above-mentioned rights for purposes falling within its activities in the framework of the Agreement between the Council of Europe and EMA.

2.4 The OMCL accepts that the Council/EDQM is under an obligation to share such intellectual property rights with the EMA.

2.5 The OMCL guarantees that the rights of third parties shall not be infringed upon further to the use by the Council/EDQM or by EMA of the deliverable(s) of the agreement referred to in Article 1 above and as detailed in the official purchase orders and the Individual CAP testing templates. However, in such instance as the Council/EDQM or EMA incur any liability as the result of any such infringement, the OMCL shall keep the Council/EDQM wholly indemnified from any ensuing prejudice, in particular from any claims made by EMA vis-à-vis the Council/EDQM.

2.6 Notwithstanding the provisions above, the Council/EDQM authorises the OMCL to use the deliverables referred to in Article 1 above and as detailed in the official purchase orders and the Individual CAP testing templates for the purposes of its own regulatory activities.

Article 3 LOYALTY AND CONFIDENTIALITY

3.1 The OMCL shall not seek or accept instructions from any government or any authority external either to the Council/EDQM and/or to its own supervisory authority. The OMCL undertakes to comply with the Council/EDQM 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 OMCL 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 OMCL attention in the performance of the Agreement.

3.3 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 OMCL shall refrain at all times from communicating to any person, legal entity, government or authority external to the Council/EDQM and/or to its own supervisory authority any information which has not been made public and which has come to the OMCL notice as a result of dealings with

the Council/EDQM. In particular, the OMCL must not disclose the documentation transferred by the Council/EDQM, including the Materials obtained from the Market Authorisation Holder nor the results of testing, to any third party other than members of the EU/EEA OMCL network without prior authorisation of the Council/EDQM. Nor shall the OMCL 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 CONTRIBUTIONS, EXPENSES AND MODE OF PAYMENT

4.1 Contributions for testing are based on the rules for the calculation of funding for co-ordination and analysis of centrally authorised products as established by agreement between the Council/EDQM and EMA.

4.1.1 The Council/EDQM shall provide the testing OMCL with an appropriate contribution for the testing and reporting referred to in Article 1 and as detailed in the official purchase orders and Individual CAP testing templates. The financial contribution of the Council/EDQM to the testing OMCL is defined in Appendix 2. The contribution will be paid as follows:

The total amount of the product testing contribution (100%), as specified in the official purchase orders shall be settled within 60 days of receipt of the report complying with the criteria for quality of test reports agreed by the EU/EEA OMCL Network.

4.2 On acceptance by the Council/EDQM that the work has been satisfactorily completed, the Council/EDQM shall invite the OMCL to submit a payment request mentioning “the net fixed amount to be paid” in Euros, in conformity with the legislation of his/her country of fiscal residence. The sum(s) shall be payable within 60 calendar days upon receipt of the payment request.

4.3 The OMCL declares not be subject to VAT; consequently, the amount invoiced shall be net fixed amount.

4.4 Following further consideration from the EMA and as per the binding agreement signed between the Council/EDQM and the EMA for the years 2019 to 2024, an extension of the contribution can be granted to the testing OMCL to cover exceptional costs, such as the purchase of reagents or consumable materials of special grade, not usually available in a normal OMCL environment.

4.4.1 The amounts of the extensions to the financial contribution are defined in Appendix 2. When applicable, the amounts of these extensions will be specified on the official purchase orders and the Individual CAP testing templates. These shall be:

(a) Payable only when i) a complete report of acceptable quality is submitted to the Council/EDQM and ii) evidence of these exceptional costs incurred is duly documented (invoices and explanatory note) and presented to the Council/EDQM. Documented evidence shall be provided at the latest when delivering the testing report.

(b) Paid to the OMCL within 60 days of receipt of a complete report complying with the criteria for acceptance of test reports agreed by the EU/EEA OMCL Network, and of receipt of the documented evidence for the exceptional costs.

4.5 For Generics Programmes, Biosimilar programmes and Parallel Distribution Programme:

In case of re-test using the MAH method, due to an out-of-specification result obtained by testing according to the INN-Test Protocol, an extension of the contribution can be granted to the testing OMCL to cover exceptional costs, such as the purchase of reagents or consumable materials of special grade, not usually available in a normal OMCL environment. The corresponding amount shall be paid to the OMCL as per the rules defined in 4.1.

4.6 An additional exceptional payment may be foreseen under special circumstances, e.g. coverage of animal testing, following previous written agreement by the EMA. The corresponding amount shall be paid to the OMCL as per the rules defined in Article 4.

Article 5 DURATION

5.1 This framework agreement shall come into force on 1 January 2019 and shall continue in full force until 31 December 2024.

5.2 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 registered mail with acknowledgement of receipt or equivalent, or by equivalent electronic means, to the signatories of this contract.

5.3 Formal notifications made by registered mail with acknowledgement of 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 acknowledgement of receipt or equivalent.

Article 6 RISKS

The OMCL shall undertake all necessary measures to arrange for health and social insurance for its staff during the entire period of the performance of work under this Agreement. The OMCL acknowledges and accepts in this regard that the Council/EDQM shall not assume any responsibility for any health and social risks concerning illness or accident of the OMCL staff which might occur during the performance of work under this Agreement. The Council of Europe Staff Regulations shall not apply to the OMCL staff.

Article 7 LIABILITY

The Council/EDQM shall not be liable for any indirect, special or consequential damage of any kind in connection with or arising out of this Agreement or the testing of the samples provided. In no event shall the Council/EDQM cumulative liability to the OMCL for any other damage exceed the contribution paid by the Council/EDQM under this Agreement.

Article 8 USE OF THE NAME OF THE COUNCIL OF EUROPE AND THE EDQM

The OMCL shall not use the Council of Europe or the EDQM names or logos without prior authorisation of the Secretary General of the Council of Europe.

Article 9 DISCLOSURE OF THE TERMS OF THE AGREEMENT

The OMCL 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 OMCL 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 location of the OMCL and amount of the contract/project.

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

Article 10 BREACH OF THE AGREEMENT

10.1 In the event that the OMCL does not satisfy the conditions laid down in this Agreement or those resulting from any modifications duly accepted in writing by both parties, or the services provided 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 OMCL the amounts referred to in Appendix 2.

10.2 The Council/EDQM reserves the right to withdraw up to 50% of the financial contribution in case of:

- undue delays in the provision of the testing report by the OMCL;
- the quality criteria set out by the EU/EEA OMCL Network are not met for the testing report;
- the testing protocol including the timelines requested by the Council/EDQM has not been followed.

10.3 In the cases described above, the Council/EDQM reserves further, at any moment and further to prior notification to the OMCL, the right to terminate this Agreement forthwith. 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 this Agreement and shall request reimbursement of the sums already paid for services not provided.

10.4 In exceptional circumstances and after having consulted the advisory group of the EU/EEA OMCL Network for Centrally Authorised Products, the Council/EDQM may ask the OMCL to refund the Council/EDQM for the first payment of the financial contribution (see official purchase order and respective Individual CAP testing template) already transferred to the OMCL.

10.5 The outstanding sums shall be paid to the Council/EDQM bank account within 60 calendar days from the notification in writing by the Council/EDQM of the OMCL regarding the outstanding sums to be paid.

Article 11 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, for money or free of charge, without the Council/EDQM prior authorisation in writing.

Article 12 FORCE MAJEURE

12.1 In the event of force majeure, the parties shall be released from the application of this Agreement without any financial compensation. Force majeure is defined as any event that can neither be anticipated nor controlled by the Parties and which would require the Council/EDQM or the OMCL to terminate the Agreement.

12.2 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 13 DISPUTES

In accordance with the General Agreement on Privileges and Immunities of the Council of Europe, all disputes between the Council/EDQM and the Institute relating to or arising in connection with this Agreement shall be submitted to arbitration as laid down in the rule No. 481 of the Secretary General of the Council of Europe (Appendix 3), if a mutual agreement of the two parties cannot be reached.

Article 14 ADDRESS AND BANK DETAILS OF PARTIES

COUNCIL/EDQM	**SÚKL**
7 allée Kastner - CS 30026	Šrobárova 48
67081 Strasbourg Cedex	100 41 Prague 10
FRANCE	CZECH REPUBLIC
Bank: SOCIETE GENERALE	Bank: ČESKÁ NÁRODNÍ BANKA (ČNB)
IBAN: XXX	IBAN: CZ94 0710 0000 3500 0062 3101
Swift: code: SOGEFRPPBRG	Swift code : CNBACZPP

Article 15 DATE, PLACE AND SIGNATURES OF PARTIES

For the COUNCIL/EDQM:	For the OMCL:
Signature:	Signature:
Name: XXX	Name: Irena Storová
Position: XXX	Position: Director
Date:	Date:

APPENDIX 1

INDIVIDUAL CAP TESTING TEMPLATE

Agreement No.:	**CN-2368**
OMCL Name – Country:	State Institute for Drug Control (ŠÚKL) - Czech Republic
Name of authorised person:	
Purchase Order No.:	
Name of the product/INN:	
EU marketing authorisation number:	
Project number:	
Reference of the data sheets supplied to the OMCL:	
Deadline for report submission by the OMCL (from the receipt of the sample):	
Week of shipment of data sheets, test samples and all required reference substances relevant to the testing[1]:	
Payment *(As per Appendix 2)*:	
• **Contribution for testing** • **Total**	**0,00 €** **0,00 €**
Additional information:	

Reception date at the OMCL:

Signature of authorised person:

APPENDIX 2

[1] Provided that there is no delay during the sampling phase of the product concerned.

FINANCIAL CONTRIBUTION FEES FOR PRODUCT TESTING
as established in the 2019–2024 Co-operation Agreement between EMA and Council/EDQM for
Sampling and Testing of Centrally Authorised Products

Type of product	**Fee**
Annual CAP programme	
Chemical/pharmaceutical product	
Product testing	**€2900** *(per product)*
Extension covering exceptional costs *(when applicable)*	**€1700** *(per product)*
Biological/veterinary immunological product	
Product testing	**€6600** *(per product)*
Extension covering exceptional costs *(when applicable)*[1]	**€3400** *(per product)*
Additional exceptional payment[2]	Product dependent. Value to be agreed upon by EMA on a case-by-case basis.
Generics CAP programme	
Product testing	**€6000** *(per testing OMCL, for each Generic INN Group tested)*
Extension covering additional costs *(when applicable)*	**€1700** *(per testing OMCL, for each Generic INN Group)*
Retest in case of out of specification results with MAH method *(when applicable)*	**€1450** *(per testing OMCL, for each Generic INN Group tested)*
Biosimilars CAP programme	
Product testing	**€6600** *(per testing OMCL, per Biosimilar Products Group)*
Method development fee	**€10 000** *(per Biosimilar Products Group)*
Extension covering additional costs *(when applicable)*	**€3400** *(per testing OMCL, per Biosimilar Products Group)*

[1] Purchase of reagents or consumable material of special grade, usually not available in a standard OMCL environment.
[2] E.g. coverage of animal testing.

Retest in case of out of specification results with MAH method *(when applicable)*	**€1450** *(per testing OMCL, per Biosimilar Products Group)*
Parallel Distribution Programme	
Authenticity Product testing	**€800** *(per product)*
Testing of additional parameters *(when applicable)*	**€2100** *(per product)*
Ad Hoc API Programme	
Chemical API	
API testing	**€2900** *(per API)*
Extension covering additional costs *(when applicable)*	**€1700** *(per API)*
Biological/veterinary immunological API	
API testing	**€6600** *(per API)*
Extension covering additional costs *(when applicable)*	**€3400** *(per API)*

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 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

XXX

Secretary General