**REQUEST FOR PROPOSALS FOR FORMULATION DEVELOPMENT OF AN INVESTIGATIVE MEDICINAL PRODUCT INTENDED FOR CLINICAL RESEARCH USE.**

Case ZO-08-2018

Commencing a research task within project no, POIR.01.01.01-00-0123/16 entitled ***"Development of Selective Endometriosis Therapy Based on Mesoprogestins"*** we invite to submit a tender for **FORMULATION DEVELOPMENT OF AN INVESTIGATIVE MEDICINAL PRODUCT INTENDED FOR CLINICAL RESEARCH USE**.

1. **CONTRACTING ENTITY:**

Evestra Onkologia Sp. z o.o., seated in Łódź at ul. Jana Muszyńskiego 2 lok. 3. 22, 90-151 Łódź, KRS 0000544596, NIP 5311691730, REGON: 360861230, e-mail: [zamowienia@evestraonkologia.pl](mailto:mwierzbicki@evestraonkologia.pl);

1. **PROCEDURE TYPE:**

The procedure is in the form of a request for proposals according to the competitiveness rule, pursuant to art. 70¹ - 705 of the act of 23rd April 1964 – the Civil Code (i.e. Off. J. of 2014, item 121).

1. **GENERAL INFORMATION:**

The order is co-financed from the Smart Development Operating Programme 2014-2020 within the project no. POIR.01.01.01-00-0123/16 entitled ***"Development of Selective Endometriosis Therapy Based on Mesoprogestins"*** The project key objective is to validate a new active substance on in vitro and in vivo models and to perform clinical trials for further development of a new form of endometriosis therapy.

1. **DESCRIPTION OF THE SUBJECT OF THE PROCUREMENT:**

The Contracting Authority currently is aiming to develop a new endometriosis treatment option – antiprogestin EC313 and is looking for a subcontractor for formulation and analytical methods development as well as clinical trial material manufacturing. Target is to develop three different strengths of tablets (1 mg, 5 mg and 25 mg) with a scoring line to be able to cover all strengths needed for the clinics. The Contractors shall present the offer - formulation development package that will include analytical method development for the drug product as well as formulation and process development. In the final offer following activities must be included:

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**0. Project Initiation**

Provide project management and timelines. Identify and order necessary reference standards, columns, excipients and API

**1. Cleaning Verification**

Considering the NCE nature of the active compound a cleaning verification needs to be performed. For analysis of verification samples a method for cleaning verification should be developed and validated based on the Contractor acceptance criteria.

**2. Raw material testing – Drug Substance + Excipients**

**2.1. Method Transfer – Drug Substance**

The Contractor will provide analytical methods for assay, related substances and residual solvents determination for the drug substance. Company will set up these methods in their labs and perform the necessary tests

**2.2 Raw material analysis**

The API should be delivered by Contracting Authority (EVESTRA ONKOLOGIA). API should be released by Contractor based on the provided drug substance supplier specification and after performed method transfer. Excipients should be tested according to the relevant monographs. Raw materials (i.e. excipients and packaging materials) which must be specifically purchased for the project by the Contractor. Material costs as well as the costs for release analysis should be invoiced separately. Where applicable, the Contractor should use raw materials (i.e. excipients and packaging materials) from their own commercial stocks. These raw materials should be invoiced separately. For manufacture of lab-scale, non-GMP batches, the Contracting Authority requires identity testing of ingredients. In case API and ingredients are used for GMP-manufacturing, a full release analysis is required.

**2.3. Method Development and Validation**

The Contractor should provide Method development for assay, related substances as well as the development of a suitable dissolution model (including determination of sink conditions). This phase of the project shall start from the methods available for the characterisation of the API. Method validation, if applicable at this stage of development, should be performed for phase I clinical trial readiness. The aforementioned should include writing the protocol, conducting the analysis and writing the report.

**2.3.1. Method Development**

* Assay
* Related substances
* Dissolution

**2.3.2. Method Validation**

The following methods should be validated according to ICH Q2 guidelines. Validation should be performed by Contractor including writing the protocol, conducting the validation sample analysis and writing the report. The separate reports for each parameter should be delivered as the report of this point as well as constitute attachment to clinical trial material. Extent of validation activities should target method readiness for clinical phase I supplies.

* Assay
* Related substances
* Dissolution

**2.4. Lab scale batches – non GMP**

**2.4.1. Manufacturing of lab scale batches (10 batches for dry blend and one batch for 1 unit for wet granulation should be priced)**

Lab scale batches should be produced with the aim to develop a formulation and a manufacturing process that is robust enough for later scale up purposes. The targeted tablet strengths are 1, 5 and 25 mg. The targeted tablet size and weight should be agreed together with The Contracting Authority prior to project start but it is assumed that the same tablet size for three strengths should be targeted.

This phase of the project should start with a dry blend process. Fluid bed granulation should be considered as an alternative option in case the dry blending comes out to be not appropriate for the discussed compound. The pricing should include both options.

Approximately 8-12 batches should be produced. Focus should be set on the lowest and highest strength first as these are considered to be the worst case in regards to uniform distribution of API respectively flow ability of the powder blend. Once a formulation and a process is identified for both strengths a confirmatory batch should be produced for the middle strength.

**2.4.2. Analysis of lab scale batches – tablet core for 10 batches**

The Contracting authority requires carrying out out the following analysis of the product:

* Physical characteristics (uniformity of mass, hardness, disintegration, friability)
* Mass Uniformity of tablet halves
* Assay EC313
* Related Substances
* Uniformity of dosage units according to Ph.Eur.2.9.40 and USP <905>
* Dissolution profile (5, 10, 15, 30, 45 min) // n=6
* Water content (for wet granulation)

**2.4.3. Manufacturing of lab scale batches – film coating (5 batches should be priced)**

A film coating composition and manufacturing process should be developed for the EC313 tablet. Development of the coating process should be done with one of the tablet strengths. For the others then one confirmatory batch should be produced.

**2.4.4. Analysis of lab scale batches – FCT (5 batches should be priced)**

Contractor should carry out the following analysis of the product:

* Physical characteristics (uniformity of mass, hardness, disintegration, friability)
* Mass Uniformity of tablet halves
* Dissolution profile (5, 10, 15, 30, 45 min) // n=6
* LOD

**2.4.5.** **Primary Packaging of Lab Scale Batches (3 batches**

Selected batches should be manually packed into agreed packaging material (multi-dose containers) and included in a technical stability study.

**2.5. Technical stability study (3 units for first sample should be priced + 15 units for additional samples)**

Packed samples of selected lab scale batches should be tested in a technical stability test program. 1 batch per strengths is expected to be tested in this study. Results from this step should also be used to support the clinical batch. Required storage conditions and testing times are indicated in the table below. The data generated shall be summarized in a tabular overview.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Stability Testing Schedule (months)** | | | | | |
| **0** | **1** | **3** | **6** | **9** | **12** |
| **Long Term Conditions**  **(25°C/60% r.h.)** | T0 | X | X | X | (X) | (X) |
| **Intermediate Conditions**  **(30°C/65%r.h.)** | (X) | (X) | (X) | (X) | (X) |
| **Accelerated conditions**  **(40˚C/75% r.h.)** | X | X | X |  |  |

**T0** Covered by lab scale batch analysis

**X**: Appearance, physical characteristics, mass uniformity of tablet halves, assay and related substances, dissolution profile, (LOD)

After each time point a stability overview can be issued on request.

**2.6. Prototype formulation selection (1 batch should be priced)**

In collaboration with Evestra formulation and manufacturing process should be selected and taken as basis for the production of the clinical trial material. Contractor should issue a report justifying the selection. A draft specification should be agreed with the Contracting Authority.

**2.7. Clinical Batch Manufacturing – GMP**

**2.7.1. Manufacturing of Clinical Batches - Tablet Core (3batchesshould be priced)**

Based on the finalized manufacturing process 1 batch per strength should be produced under GMP conditions. Batch size shall rely on the selected process (vide: lab scale batches).

**2.7.2. Analysis of Clinical Batch (3 batches should be used)**

Contractor should carry out the following analysis on the product:

* Appearance
* Physical characteristics (uniformity of mass, hardness, disintegration, friability)
* Identity EC313 (two methods)
* Mass Uniformity of tablet halves
* Uniformity of dosage units according to Ph.Eur.2.9.40 and USP <905>
* Related Substances
* Dissolution (5, 10, 15, 30, 45 min) // n=6
* (LOD)

**2.7.3. Manufacturing of Clinical Batches – film coating (3 batches should be priced)**

A film coating should be performed under GMP conditions. If wet granulation batches is finally used, coating of sub-batches would need to be performed.

**2.7.4. Analysis of FCT scale batches – FCT (3 batches should be priced)**

Contractor should carry out the following analysis of the product:

* Physical characteristics (uniformity of mass, hardness, disintegration, friability)
* Mass Uniformity of tablet halves
* Dissolution profile (5, 10, 15, 30, 45 min) // n=6
* LOD

**2.7.5 Primary Packaging of Clinical Batches (3batchesshould be priced)**

The Contractor should perform filling of the clinical trial bulk material in agreed primary packaging material (multi dose containers) under GMP conditions

**2.8. ICH Stability Testing (analytical testing: 3 batches be priced plus option additional 20 units should be priced; Microbiological testing: 6 units should be priced)**

Packed samples of the clinical batches should be included in an ICH stability test program. Storage conditions and testing times are indicated in the table below. The data generated should be summarized in a report.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **0** | **1** | **3** | **6** | **9** | **12** | **18** | **24** | **36** |
| **Long Term Conditions**  **(25°C/60% r.h.)** | T0 | X | X | X | X | X,M | (X) | (X,M) | (X,M) |
| **Intermediate Conditions (30°C/65%r.h.)** | - | (X) | (X) | (X) | (X) |  |  |  |
| **Accelerated conditions**  **(40˚C/75% r.h.)** | X | X | X,M | - | - | - |  | - |

**X**: Appearance, physical characteristics, mass uniformity of table halves, assay and related substances, dissolution profile, (water content)

**T0:** Covered by release testing; **( ):** optional

**M:** Microbiology

After each time point a stability overview can be issued on request.

**2.9. QP Batch Certification of CGMP Batches (3 batches should be priced)**

In case a QP release e.g. for the performance of clinical trial is needed supporting release documentation should be supplied to the Contracting Authority by Contractor.

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1. The Contractor, in consultation with the Contracting Authority, shall prepare a schedule of realization of the object of the order.
2. The Contractor shall bear all the costs associated with the performance of the subject matter of the contract, in particular: the costs of developing the formulation and analytical methods, the cost of producing the materials for clinical trials (GMP compliant laboratory series, GMP-compliant clinical series, drug testing, packaging costs, remuneration for transferring copyrighted research results to the Contracting Authority.

**NOTE**: Purchasing materials for the subject matter of the order should be monitored for their safety certificates and confirmation that they are non-infectious products that can be used for GMP work.

1. The Contractor shall be obliged to allow Contracting Entity's representatives (upon Contracting Entity's request) participation in the tests in the capacity of observers.
2. The Contractor shall deliver full documentation on the tests in a hard copy and in an electronic format (on a medium), sent in an MS Office editable format, in the English language:
3. Interim reports - a description of the methodology of its preparation and execution, the conditions prevailing in the laboratory, the results in the form of numerical data and the recorded images and their analysis, provided after the completion of the test for each of the materials tested;
4. Final report - Detailed description of the results obtained, charts and tables in a format for reading and editing in the Ms Office package.
5. The Contractor shall prepare a final presentation (MS Power Point) presenting the course of tests, achieved results and conclusions
6. As of the date of Contracting Entity's approval of each of the Interim Reports and within the fee, the Contractor shall transfer to the Contracting Entity copyright to the pieces (hereinafter referred to as the "Pieces") in the understanding of the Copyright and Related Rights Law (i.e. Off. J. of 2016, item 666, hereinafter referred to as the "Law") created within the procurement by Contractor's employees or subcontractors.
7. The assignment of the copyright and related rights to the Pieces shall be unlimited in time and territory, upon all known fields of exploitation, and in particular shall include the following exploitation fields:
8. recording on any medium, regardless of system and format standards;
9. multiplication by any technique, including for editorial and publishing purposes;
10. making publicly available in Poland and abroad;
11. using, introducing, displaying, transferring and storing in any format, system or standard;
12. entering into computer memory and a multimedia network, including the Internet;
13. placing on digital platforms;
14. making available in such a manner that anyone can access them in a place and time of their choice;
15. dissemination in the form of print, digital recording, multimedia transmission.

10. Procurement Classification according to Common Procurement Vocabulary (CPV): 73.10.00.00 – 3 Research, experiment and development services.

1. **DELIVERY DATE:**

The order shall be completed in **20 months from the date of the start of research activities**, whereby this date refers to the entire procurement. Completion dates of particular tasks can be different.

1. **PROCEDURAL INFORMATION:**

1. Contractors who meet the following criteria can take part in proceedings:

*1) within the scope of the condition relating to the competence or the right to perform specific activities, provided that the obligation to hold them results from separate provisions, the Contracting Authority shall establish the following minimum requirements:*

*a) The contractor is obliged to show that he has a current authorization to conduct activities in the scope of development and / or manufacture of medicinal products in the GMP standard.*

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| **This condition shall be assessed based on a submitted copy Certificate of GMP compliance** |

2) in respect of technical capacity, the Contracting Entity has set the following minimum criteria:

1. *in respect of available resources necessary for the due performance of the procurement, the Contractor shall be obliged to show it has a dedicated laboratory with equipment which allows for the performance of the tests with GMP standard;*

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| **This condition shall be assessed based on a submitted statement** |

3) in respect of professional capacity, the Contracting Entity has set the following minimum criteria:

*a) experience, the contractor must show that within the last three years before the deadline for submission of tenders in the proceedings, and if the period of activity is shorter - during that period he completed at least one service consisting in developing the experimental formulation of the medicinal product.*

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| **Evaluation of the fulfilment of the above condition will be made on the basis of the list of performed services** |

*b) in respect of staff capable of performing the task, the Contractor shall show that it can delegate at least two individuals to work on the procurement who have higher education, experience and qualification necessary to perform the experiments included in the submitted tender.*

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| **This condition shall be assessed based on a submitted list of individuals delegated by the Contractor to perform the order.** |

4) in respect of economic or financial situation necessary for the due performance of the procurement, the Contracting Entity has set no special condition.

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| **Evaluation of the fulfilment of the above condition will be made by means of the "fulfilment / non fulfilment" method based on the submitted statement concerning the fulfilment of conditions for participation in the procedure.** |

5) the following shall not cause exclusion from the procedure:

1. circumstances listed in Guidelines Chapter 6 sect. 6.5.1 item 8;
2. liquidation or no bankruptcy declared, excluding contractors who after being declared bankrupt executed a composition agreement approved by a legally valid court decision, if the agreement does not provide for satisfaction of creditors by liquidation of the bankrupt's assets.

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| **This condition shall be assessed based on documents listed in item 2 point 1, lett. a) and b)).** |

1. Apart from the declaration on meeting the criteria to participate in the proceedings which constitutes Attachment no. 3 hereto, the Contractor shall submit:
2. In order to confirm no grounds to exclude from the proceedings due to a conflict of interests, the Contractor shall submit:
3. a declaration according to a specimen which constitutes Attachment no. 2 hereto – regardless of its organisational and legal status;
4. In order to confirm the fulfilment of the condition described in pt. 1 pt. 1, the Contractor shall submit a copy of the GMP certificate or other equivalent document confirming possession of competence or authority to carry out activities in the scope covered by the subject of the order.
5. In order to confirm the fulfilment of the condition specified in pt. 1 pt. 3 lit. a), the Contractor shall submit a list of completed services containing information on the subject, the date of execution

In order to confirm the fulfillment of the condition specified in pt. 1 pt. 3 point b), the Contractor shall submit a list of persons initially assigned to the performance of the contract,.

**The value of the offer should include all costs related to the implementation of the subject of the order, with the reservation that the Employer allows changes in the value of remuneration resulting from the need to purchase materials, raw materials, etc. to carry out the activities provided for in the order**

The Contractor may submit only one tender for the whole scope of the contract.

The offer should be made in the Polish or English language, in a permanent way which guarantees that the content can be read.

1. The Contracting Entity recommends the tender to be prepared using forms which constitute attachments hereto or exactly according to the Offer Form which constitutes Attachment no. 1 hereto.
2. The Contracting Entity recommends numbering all the pages in the tender and securing them against getting disassembled by stapling or binding - for offers submitted in writing.
3. The Contractor shall place the offer in a non-transparent envelope with a note:

***“REQUEST* FOR PROPOSALS FOR FORMULATION DEVELOPMENT OF AN INVESTIGATIVE MEDICINAL PRODUCT INTENDED FOR CLINICAL RESEARCH USE.**

***Do not open before ............................. "***

1. **The Contracting Entity allows Contractors to submit motions and enquire about the contents hereof.** To this end, the Contracting Entity has established the following forms of communication with Contractors: electronic, to the address: zamowienia@evestraonkologia.pl. A written form shall always be acceptable. Enquiries should be submitted by October 11, 2017. Inquiries that should be received by the Ordering Party after the expiry of the above deadline should not be considered.
2. Any information regarding the proceedings shall be published by the Contracting Entity on its own website and in the competitiveness base under the address: bazakonkurencyjności.funduszeeuropejskie.gov.pl
3. Individuals authorised to contact Contractors:
4. for substantive issues:

- Prof. Klaus Nickisch

e-mail: knickisch@evestraonkologia.pl

- dr Ze'ev Shaked,

e-mail: zshaked@evestraonkologia.pl;

- Dr Maciej Wierzbicki,

e-mail: [mwierzbicki@evestraonkologia.pl](mailto:mwierzbicki@evestraonkologia.pl) ;

b) for formal issues:

- Robert Kochański, MA

e-mail: [rkochanski@evestraonkologia.pl](mailto:robertkochanski@evestraonkologia.pl) ;

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| **All electronic correspondence should be addressed CC: zamowienia@evestraonkologia.pl** |

1. The Contracting Entity may introduce changes in the terms and conditions of the proceedings. Provisions of point 12 shall apply respectively.
2. The Contracting Entity shall correct the offer in respect of obvious spelling errors, calculation mistakes considering calculation consequences resulting from the changes and other mistakes which make the offer incompliant with the request, provided this does not introduce essential changes in the offer.
3. The Contracting Entity shall request the contractor to remedy any deficiencies in the offer, and in particular the documents named in item 2.
4. The Contracting Entity can invalidate the proceedings without providing any reason or terminate the proceedings without an outcome during each phase.
5. **The agreement should be concluded subject to the approval of the National Centre for Research and Development and it's approval of further research.**

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| **PLEASE NOTICE!** |
| According to art. 13 para. 1 and 2 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46 / EC (general regulation on data protection) (OJ L 119, 04.05.2016, page 1), hereinafter "RODO", I inform that: |
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| 1. the administrator of your personal data is Evestra Onkologia Sp. z o.o., ul. Jana Muszyńskiego 2 lok. 3.22, 90-151 Łódź, |
| 1. Your personal data will be processed on the basis of art. 6 par. 1 lit. c RODO for the purpose related to the public procurement procedure to carry out the development of an experimental medicinal product formulation for use in a clinical trial, case mark ZO-08-2018 |
| 1. recipients of your personal data will be persons or entities to whom the documentation of proceedings based on art. 8 and art. 96 para. 3 of the Act of January 29, 2004 - Public Procurement Law (Journal of Laws of 2017, item 1579 and 2018), hereinafter the "Act"; |
| 1. Your personal data will be stored, in accordance with art. 97 ust. 1 of the Act, for a period of 4 years from the date of completion of the procurement procedure, and if the duration of the contract exceeds 4 years, the storage period covers the entire duration of the contract; |
| 1. the obligation to provide your personal data directly to you is a statutory requirement set out in the provisions of the Act, related to participation in the public procurement procedure; the consequences of failure to provide specified data result from the Act; |
| 1. f. in relation to your personal data, decisions will not be taken in an automated manner, application to art. 22 RODO; |
| 1. you have: |
| * + 1. based on Article. 15 RODO the right of access to your personal data relating to; |
| * + 1. based on Article. 16 RODO right to rectify your personal data; |
| * + 1. based on Article. 18 RODO the right to request the administrator to restrict the processing of personal data, subject to the cases referred to in art. 18 para. 2 RODO; |
| * + 1. the right to file a complaint to the President of the Office for Personal Data Protection, if you decide that the processing of your personal data concerning you violates the provisions of the GDPR; |
| 1. you are not entitled to: |
| 1. in connection with art. 17 sec. 3 lit. b, d or e RODO right to delete personal data; |
| 1. the right to transfer personal data referred to in art. 20 RODO; |
| 1. based on Article. 21 RODO right to object to the processing of personal data, as the legal basis for the processing of your personal data is art. 6 par. 1 lit. c RODO. |

1. **OFFER VALIDITY TERM:**

The Contractor shall be bound by the submitted tender for a period of 60 days. The 60-day period shall commence on the elapse of the deadline for tender submission.

1. **DEADLINE FOR THE SUBMISSION OF TENDERS:**
2. Tenders shall be submitted till **19th of September 2019 12:00 hrs** – date and hour of reception by the Contracting Entity shall be binding.
3. Tenders in writing shall be submitted in the Contracting Entity's seat or sent to the following address: Evestra Onkologia Sp. z o.o., ul. Jana Muszyńskiego 2 lok. 3. 22, 90-151 Łódź, Poland.
4. The Contracting Entity allows **sending the tender in an electronic format** to the following address:[zamowienia@evestraonkologia.pl](mailto:zamowienia@evestraonkologia.pl) . If the tender is sent in an electronic form, the Contractor shall safeguard the tender so that its content cannot become acquainted with before the elapse of the deadline for tender submission. In this case it is highly recommended that the email is titled: **“Offer, case ZO-08-2018”**
5. .According to the transparency rule of the proceedings, the Contracting Entity, upon a request from the Contractor, shall make the minutes from tenders' opening available.
6. **ASSESSMENT CRITERIA:**
7. The Contracting Entity shall evaluate the tenders according to the following tender assessment criterion:
8. Financial criterion (price) – weight 100%;

The Contracting Entity shall score by dividing the value of the cheapest tender by the analysed offer value and then multiplying the outcome by the weight, according to the following formula: **WP= (WONC /WOB) x weight,** where WP – score value in the financial criterion, WONC – value of the cheapest tender, WOB – value of the analysed tender.

**NOTE:**

**Should the contractor provide prices in currencies other than PLN, the Contracting Entity shall use an NBP exchange rate of the date of publication of the request for proposal in the Competitiveness Base of the Ministry of Development. Exchange rate tables are available at:**  [**http://www.nbp.pl/home.aspx?f=/Kursy/kursy.htm**](http://www.nbp.pl/home.aspx?f=/Kursy/kursy.htm) **;**

**Should a tender be submitted which generates a tax obligation on the part of the Contracting Entity, according to the regulations on tax on goods and services, in order to evaluate such an offer, the Contracting Entity shall add the value added tax to the price provided therein which must be accounted for according to the said regulations. When submitting the tender, the Contractor shall advise the Contracting Entity whether its offer shall generate a tax obligation on the part of the Contracting Entity providing the name (type) of goods or services whose supply shall involve the tax and their net value. Should a tender be submitted which generates a tax obligation on the part of the Contracting Entity, according to the regulations on tax on goods and services, the price of the best or cheapest price shall be increased by the value added tax to the price provided therein which must be accounted for by the Contracting Entity according to the said regulations. Therefore, in such an instance, the price provided in the tender by such a contractor as "gross price" must not include VAT which the Contracting Entity shall be obliged to account for.**

1. **AMENDMENT OF THE CONTRACT:**

The Contracting Entity may amend the contract between the Contracting Entity and a Contractor, in case of:

1. changes which result from updating commonly applicable law;
2. reducing the fee amount due to limitation or exclusion of a part of the procurement by the Contracting Entity;
3. extension of the performance term of the contract, if registration or other procedures with respective authorities are extended in time;
4. change of the Contract term, in case the Project deadline varies;
5. changes in remuneration resulting from justified technical reasons on the part of the Employer and / or the Contractor
6. change of final remuneration depending on the experimentally chosen method (dry blending vs. fluid bet granulation)
7. extension of the Contract term due to organisational issues on the part of the Contracting Entity;
8. The need to purchase raw materials by the Contrator for the tests provided under the subject matter of the contract;
9. changing the number of units in particular research tasks,
10. changes in individuals in charge of contacts and supervision over the contract.
11. occurrence of any events as a result of force majeure;
12. changes in a co-financing contract the Contracting Entity shall execute with an Intermediate Body;
13. **FINAL PROVISIONS:**

The procedure shall be governed by the Polish law. In any matters not stipulated herein, provisions of the act of 23rd April 1964 – the Civil Code (i.e. Off. J. of 2014, item 121) and provisions of current Guidelines on Eligibility of Expenses within the European Regional Development Fund, European Social Fund and Cohesion Fund for the years 2014-2020.

Attachment no. 1 to the Request for proposal

Case ZO-08-2018

**TENDER FORM\***

**(copy for each task)**

Acting for and on behalf of the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

in response to the request for proposal published on 17th of August 2018 at bazakonkurencyjności.funduszeeuropejskie.gov.pl and on the Contracting Entity's website, I am submitting a tender within the proceedings for **REQUEST FOR PROPOSALS FOR FORMULATION DEVELOPMENT OF AN INVESTIGATIVE MEDICINAL PRODUCT INTENDED FOR CLINICAL RESEARCH USE** proceeded in form of a request for proposal.

I am offering the performance of the order for the price of: PLN ……………………………………………… gross (say: …………………………………………………........................................................................................)

The tender value includes all and any costs related to the performance of the order.

I declare that I have experience needed for the due performance of the order.

I declare that I have infrastructure needed for the performance of the order.

I declare that there were no events that could cause a failure to comply with the market regulator, and all corrective measures are recommended and if you apply, have been implemented.

I declare that I shall complete the order without / with subcontractors\* (if yes, provide the scope of the order which shall be subcontracted).

…………………………………………………………………………………………………………………………………………………………

I declare that I have obtained all and any information needed for the due performance of the order.

I shall be bound by this offer for a period of 60 days from the deadline for tenders' submission.

The tender together with attachments counts ……… pages.

…......................................... ………………………………………………………………………

Place, date: signature and Company stamp

Attachment no. 2 to the Request for proposal

Case ZO-08-2018

**DECLARATION ON**

**NO GROUNDS FOR EXCLUSION**

**DUE TO A CONFLICT OF INTEREST**

On submission of the tender for **FOR FORMULATION DEVELOPMENT OF AN INVESTIGATIVE MEDICINAL PRODUCT INTENDED FOR CLINICAL RESEARCH USE**, I declare that the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

**is not affiliated** to the Contracting Entity, personally or in terms of equity, by mutual relations between the beneficiary and individuals authorised to bind the beneficiary or individuals performing on behalf of the beneficiary actions related to preparation and running the proceedings for choosing a contractor and the contractor, which in particular includes:

1. being a partner to a civil partnership or another partnership
2. holding at least 10% of shares,
3. acting as member of a supervisory or management board, proxy, attorney
4. being married, in consanguinity or affinity in a straight line, in second degree of kinship or affinity of the second degree in collateral line or by adoption, guardianship or custody

….....................................................................................

signature and Company stamp

\* - delete inappropriate

Attachment no. 3 to the Request for proposal

Case ZO-08-2018

**DECLARATION ON MEETING PARTICIPATION CRITERIA**

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

**does meet** the conditions for participation in proceedings;

….....................................................................................

signature and Company stamp

\* - delete inappropriate

Attachment no. 4 to the Request for proposal

Case ZO-08-2018

**LIST OF INDIVIDUALS INITIALLY DELEGATED TO WORK ON THE ORDER**

On submission of the **REQUEST FOR PROPOSALS FOR FORMULATION DEVELOPMENT OF AN INVESTIGATIVE MEDICINAL PRODUCT INTENDED FOR CLINICAL RESEARCH USE**, I declare that the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

(PHONE, FAX, E-MAIL)

shall delegate the following individuals to work on the order:

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Name and surname or position** | **EDUCATION / EXPERIENCE / QUALIFICATIONS** | **SCOPE OF DELEGATED WORKS** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

..............................................................

signature and Company stamp

Attachment no. 5 to the Request for proposal

Case ZO-08-2018

**LIST OF COMPLETED SERVICES**

On submission of the **REQUEST FOR PROPOSALS FOR FORMULATION DEVELOPMENT OF AN INVESTIGATIVE MEDICINAL PRODUCT INTENDED FOR CLINICAL RESEARCH USE**, I declare that the Contractor:

…............................................................................................................................................................

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

seated in / residence address \*\*…........................................................................................................

(RESIDENCE ADDRESS / SEAT ADDRESS)

…............................................................................................................................................................

**D**uring the last three years before the deadline for submission of tenders in the proceedings, the following services corresponding to their type of object were completed:

|  |  |  |
| --- | --- | --- |
| **No.** | **SCOPE** | **TIMELINE** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

..............................................................

signature and Company stamp