**REQUEST FOR PROPOSALS TO CONDUCT 13-WEEK TOXICITY STUDY IN FEMALE CYNOMOLGUS MONKEYS, FOR A NEW CHEMICAL ENTITY (SMALL MOLECULE) ACCORDANCE WITH REGULATORY ICH M3 (R2)**

Case ZO-02-2020

Commencing a job 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** **13-week Toxicity Study in Female Cynomolgus Monkeys,for a New Chemical Entity (Small Molecule) with accordance with regulatory the ICH M3 (R2), for IND/IMPD submission.**

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 (Journal of Laws of 2020, item 1740, as amended.).

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 trial for further development of a new form of endometriosis therapy.

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

The subject of the procurement includes services for **13-week Toxicity Study in Female Cynomolgus Monkeys with accordance with regulatory ICH M3 (R2), suitable to support clinical trial applications for a new chemical entity (small molecule)** which is the subject of the project entitled: "Development of Selective Endometriosis Therapy Based on Mesoprogestins" A detailed scope of the procurement has been included in Attachment no. 3 hereto.

2. The Contractor shall develop a time attachment for test, which shall in particular include:

1. Conducting the experiment according to schedule provided. The Contractor will develop the schedule of study including, above all:
2. maximum time to deliver the active substance
3. period for methods' validation (if applicable),
4. experimental part, including *in life*,
5. time necessary for draft report delivery time;

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| NOTE: the time attachment should only include information of use in case of performing a given task within the procured service. **A time attachment template constitutes Attachment no.4 hereto.** |

1. In case if the tasks are performed, before commencing the task(s), the Contractor shall be obliged to deliver to the Contracting Entity information regarding:

a) a need for certain data (acquired from previous tasks) to be transferred by the Contracting Entity, providing their type and delivery date;

b) a need to perform tests by the Contracting Entity or another entity which are necessary for the performance of the task, providing their type and completion date.

c) the amount of API required with schedule of deliveries

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 test 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 – constituting the summary of in life phase;
4. Final report – giving a detailed description of the results obtained and all the information necessary to submit a dossier for the study in question as an annex to the consent to the Phase I clinical trial (CTA).
5. 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 anne018, item 666, hereinafter referred to as the "Law") created within the procurement by Contractor's employees or subcontractors.
6. 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:
7. recording on any medium, regardless of system and format standards;
8. multiplication by any technique, including for editorial and publishing purposes;
9. making publicly available in Poland and abroad;
10. using, introducing, displaying, transferring and storing in any format, system or standard;
11. entering into computer memory and a multimedia network, including the Internet;
12. placing on digital platforms;
13. making available in such a manner that anyone can access them in a place and time of their choice;
14. dissemination in the form of print, digital recording, multimedia transmission.
15. The Contracting Authority allows to award orders according to the competitiveness rule, pursuant to art. 67 pkt. 1 ppkt. 6 i 7 of the act of 29rd January 2004 – Public procurement law (consolidated text Journal of Laws 2019, item 1843), with a value not exceeding 50% of the basic contract.
16. Procurement Classification according to Common Procurement Vocabulary (CPV): 73.10.00.00 – 3 Research, experiment and development services.
17. **DELIVERY DATE:**

The order shall be completed till **28th of February 2022**. The Contracting Authority does not set any intermediate deadlines for the implementation of individual tasks.

1. **PROCEDURAL INFORMATION:**
2. Contractors who meet the following criteria can apply:
3. in respect of competencies or authorisations to perform specific activities, the Contracting Entity has set no specific conditions.

This condition shall be assessed based on a submitted declaration on meeting the criteria for participation in the proceedings.

1. in respect of technical capacity, the Contracting Entity has set the following minimum criteria:
2. 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 test;

This condition shall be assessed based on a submitted declaration on having a dedicated laboratory.

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

This condition shall be assessed based on a submitted declaration on meeting the criteria for participation in the proceedings.

1. the following shall not cause exclusion from the procedure:
2. circumstances listed in Guidelines Chapter 6 sect. 6.5.1 item 8;
3. 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.

This condition shall be assessed based on documents listed in item 2 point 1).

1. Apart to the statement regarding the fulfilment of the conditions for participation in the proceedings and the lack of grounds for exclusion constituting Annex No. 2 to the Inquiry, the Contractor shall submit:
2. In order to confirm the lack of grounds for exclusion from the proceedings due to the liquidation or bankruptcy and also existence of a conflict of interests, the Contractor shall submit a current copy of the register relevant for the organizational and legal form of the register;
3. In order to confirm compliance with the condition set out in item 1 point 2, the Contractor submits a declaration regarding the disposal of resources necessary to perform the contract based on the template including in the attachment no 2A.
4. The Contractor can only place one offer for the entire subject of the procurement within a given task.

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.
3. The Contractor shall place the offer by sending an email to [zamowienia@evestraonkologia.pl](mailto:zamowienia@evestraonkologia.pl) entitled:

***"Offer for* 13-week Toxicity Study in Female Cynomolgus Monkeys, with accordance with regulatory ICH M3 (R2), suitable to support clinical trial applications for a new chemical entity (small molecule)*.***

***Do not open before 08th of December 2020"***

1. **The Contracting Entity allows Contractors to submit motions and enquire about the contents hereof until 23th of November 2020.** 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.
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: <https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/ogloszenia/15684>
3. Individuals authorised to contact Contractors:
4. for substantive issues:

* dr hab. Katarzyna Błaszczak-Świątkiewicz

email: [kblaszczak@evestraonkologia.pl](mailto:kblaszczak@evestraonkologia.pl)

b) for formal issues:

- dr Maciej Wierzbicki,

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

- 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 9 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 reserves the right to request the contractor to provide explanation regarding the content of the submitted offer in case of doubts to its compliance with the description of the contract, scope and other data affecting the offered contract.
5. In case of the suspicion of offering the contract below market value (ie the value of the offer is 30% lower than the established estimated value or the average value of all submitted offers) the Contracting Authority reserves the right to call the contractor to provide relevant explanations. The contracting authority will reject the offer if the contractor fails to provide explanation or if the explanation given are insufficient.
6. The Contracting Entity can invalidate the proceedings without providing any reason or terminate the proceedings without an outcome during each phase.
7. **PRINCIPLES OF PERSONAL DATA PROCESSING:**

In accordance with Article 13(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 Data Protection Regulation) (OJ L 119, 04.05.2016, p. 1), hereinafter referred to as "the GDPR", I hereby inform you that:

1. the administrator of your personal data is Evestra Onkologia Sp. z o.o., with its registered office in Łódź at ul. Jana Muszyńskiego 2 lok. 3.22, post office 90-151 Łódź, KRS 0000544596, NIP 5311691730, REGON: 360861230,
2. Your personal data will be processed on the basis of Article 6(1)(c) of the GDPR for the purpose of this procurement procedure,
3. the recipients of your personal data will be persons or entities to whom the documentation of conduct in accordance with the requirements of the horizontal guidelines will be made available,
4. Your personal data will be stored. for a period of 4 years from the date of completion of the contract award procedure, and if the duration of the contract exceeds 4 years, the storage period covers the entire duration of the contract,
5. your obligation to provide personal data directly to you is a statutory requirement in connection wit your participation in a public procurement procedure; the consequences of not providing certain data result from the PUBLIC TENDER Act,
6. in relation to your personal data, decisions will not be taken by automated means, applying to Article 22 of the GDPR,
7. You have:
8. the right of access to your personal data pursuant to Article 15 of the GDPR;
9. The right to rectify your personal data pursuant to Article 16 of the GDPR;
10. the right under Article 18 of the OROD to require the controller to restrict the processing of personal data, except in the cases referred to in Article 18(2) of the GDPR;
11. the right to lodge a complaint with the President of the Office for the Protection of Personal Data if you consider that the processing of your personal data concerning you is in breach of the provisions of the GDPR.
12. You are not entitled to it:
13. In conjunction with Article 17(3)(b), (d) or (e), the right to erasure of personal data;
14. the right to transfer personal data as referred to in Article 20 of the GDPR,
15. The right to object to the processing of personal data pursuant to Article 21 of the GDPR as the legal basis for the processing of your personal data is Article 6(1)(c) of the GDPR.
16. **OFFER VALIDITY TERM:**

The Contractor shall be bound by the submitted tender for a period of 90 days. The 90-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 **08th of December 2020 15:00 hrs (CET)** – date and hour of reception by the Contracting Entity shall be binding.
3. The tenders shall be sent 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. Provisions of point 9 Chapter VI shall apply
4. The Contracting Entity does not provide for a public opening of tenders. 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.
5. **ASSESSMENT CRITERIA:**
6. The Contracting Entity shall evaluate the tenders according to the following tender assessment criterion:
7. 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. change the scope of the contract due to perform additional experiments uncovered by the contract in order to ensure an appropriate level of credibility of the results and guarantee the interoperability of services covered by the basic contract, the value of each change will not exceed 50% of the basic contract;
3. reducing the fee amount due to limitation or exclusion of a part of the procurement by the Contracting Entity;
4. extension of the price of the contract, if additional experiments are required to ensure the results credibility;
5. extension of the price of the contract, if additional animals are required to ensure the results credibility;
6. reducing of the price of the contract, due to limitation of animals for study
7. change of the Contract term, in case the Project deadline varies;
8. extension of the Contract term due to organisational issues on the part of the Contracting Entity or technical issues;
9. changes of the price of the contract due to changes to the number of animals subject to tests provided for in the Contract;
10. changes of the price (extension or reducing the price) resulting from applying or excluding GLP conditions
11. changes in individuals in charge of contacts and supervision over the contract.
12. occurrence of any events as a result of force majeure;
13. changes in a co-financing contract the Contracting Entity shall execute with an Intermediate Body;
14. **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 2020, item 1740, as amended) 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-02-2020

**Contracting Entity:**

**Evestra Onkologia Sp. z o.o.**

**ul. Jana Muszyńskiego 2 lok. 3.22**

**90-151 Łódź**

**TENDER FORM**

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 05.11.2020 at <https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/ogloszenia/15684> and on the Contracting Entity's website, I am submitting a tender within the proceedings **13-week Toxicity Study in Female Cynomolgus Monkeys, with accordance with regulatory ICH M3 (R2), suitable to support clinical trial applications for a new chemical entity (small molecule)**, run in the form of a request for proposal.

I am offering the performance of the order within task no. ………………………… for the price of: PLN ……………………………………………… gross (say: …………………………………………………........................................................................................)

The tender value includes all and any costs related to the performance of the order, including remuneration for transferring to the Ordering Party the economic copyrights to the results of research and any studies covered by the scope of the contract.

I declare that the order shall be completed till .............. (i.e. within ......... weeks from actual commencement).

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 I have qualified staff experienced in running tests on animals.

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

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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 90 days from the deadline for tenders' submission.

I declare that I have fulfilled the information obligations provided for in Art. 13 or article. 14 of the GDPR towards natural persons from whom I have obtained personal data directly or indirectly in order to apply for a public contract in this procedure [If the contractor does not provide personal data other than directly related to him or there is an exception to the application of the information obligation, pursuant to Art. 13 sec. 4 or article. 14 sec. 5 GDPR, the contractor does not submit the content of the declaration - removal of the content of the declaration, e.g. by deleting it].

The tender together with attachments counts ……… pages.

\* - delete not applicable

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

Place, date: signature of the authorised signatory

Attachment no. 2 to the Request for proposal

Case ZO-02-2020

**DECLARATION ON MEETING PARTICIPATION CRITERIA**

**FOR THE PROCEEDINGS AND NO GROUNDS FOR EXCLUSION**

**DUE TO A CONFLICT OF INTEREST**

On submission of the tender for **13-week Toxicity Study in Female Cynomolgus Monkeys, with accordance with regulatory ICH M3 (R2), suitable to support clinical trial applications for a new chemical entity (small molecule)**, I declare that the Contractor:

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

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

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

(RESIDENCE ADDRESS / SEAT ADDRESS)

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

(PHONE, FAX, E-MAIL)

**meets** the conditions for participation in respect of knowledge and experience, financial status, and technical and human potential;

**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, unless the lower shares results from legal regulations or has not been defined by the governing body of the operational program
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 of the authorised signatory

\* - delete not applicable

Attachment no. 2A to the Request for proposal

Case ZO-02-2020

**DECLARATION ON MEETING PARTICIPATION CRITERIA**

Submitting offer in the procedure for the performance of tests in the scope of 13-week Toxicity Study in Female Cynomolgus Monkeys, with accordance with regulatory ICH M3 (R2), suitable to support clinical trial applications for a new chemical entity (small molecule), guidelines Contractor declares:

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

(CONTRACTOR'S NAME AND SURNAME/FULL NAME)

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

(RESIDENCE ADDRESS / SEAT ADDRESS)

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

(PHONE, FAX, E-MAIL)

has / does not have \* technical resources necessary for the proper performance of the subject of the order, in particular: a dedicated laboratory with equipment.

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

signature and Company stamp

\* - delete inappropriate

Attachment no. 3 to the Request for proposal

Case ZO-02-2020

**PRICE CALCULATION / SCOPE OF THE ORDER**

Request for Proposals to

Conduct 13-week Toxicity Study in Female Cynomolgus Monkeys,

Suitable to Support Clinical Trial Applications for a New Chemical Entity (Small Molecule)

(the study shall be planned exactly with accordance to regulatory ICH M3 (R2))

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study | Requirements | Nett price | Vat rate | Gross price |
| **EC313 13-week toxicity study in mature monkey (Cynomolgus monkey) with 4 week recovery period according to the guidelines (oral dosage)\*\*\*** | * Conducted under GLP\* * Oral administration * 3 doses of test compound * 20 animals  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Groups** | **Treatment** | | **Treatment**  **phase** | **Recovery phase** | | 1 | | control | 2 | - | | 2 | | low dose | 4 | 2 | | 3 | | mid dose | 4 | 2 | | 4 | | high dose | 4 | 2 |  * N=4 animals per tested group * **The price shall detail the histopathology (incl. report)** * The price should include the cost of animals – Ordering and delivery from the Animal Provider (including all health and other required standards) * The price should include analysis, report / documentation and any other obligatory costs * The price should include storage of all data over 5 years\*\* * The price should not include any additional costs beyond the costs required to carry out the procedure in accordance with the requirements of the guidelines * Service provider should indicate the turnover time in weeks (starting from animal quarantine until delivery of final report) |  |  |  |

\* The Contracting Entity reserves the rights to change the conditions of study into GLP with an adjusted price, accordingly.

\*\* This is optional. In the end, the data will have to be preserved for 5 years. But it is necessarily to be stored at the CRO.

\*\*\* ICH guideline ICH S5(R3 (annex 1, chapter 1.1.2.) is recommended

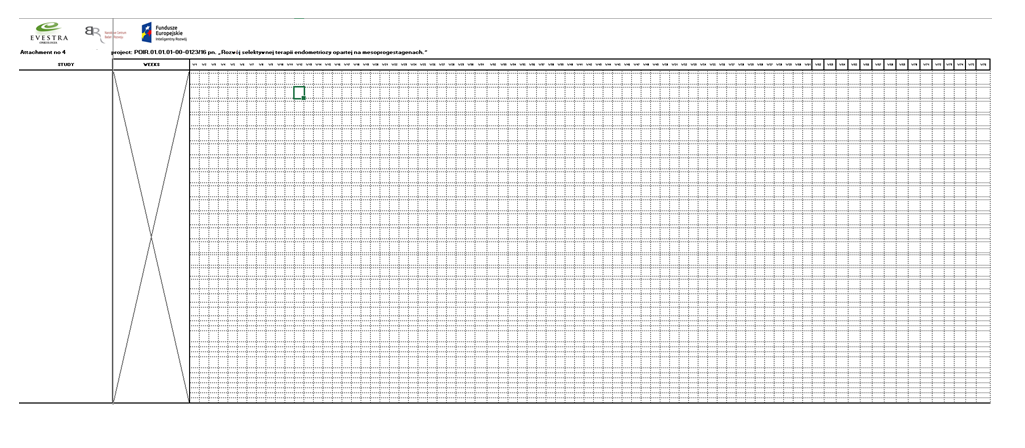
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| --- | --- |
| Evestra Onkologia Sp. z o.o.  ul. Muszyńskiego 2 lok. 3.22,  90-151 Łódź  [biuro@evestraonkologia.pl](mailto:biuro@evestraonkologia.pl) | KRS: 0000544596  NIP: 5311691730  Regon: 360861230 |

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siganture of authorised person

Attachment no. 4 to the Request for proposal

Case ZO-02-2020

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