

## APPENDIX NO. 1 A

to procedure No. EM-V-2021-1093-41114-7653

**CONTENT OF THE REQUEST FOR QUOTATION****1. NAME AND ADDRESS OF THE ORDERING PARTY**

Polpharma Biologics Spółka Akcyjna  
ul. Trzy Lipy 3  
80-172 Gdańsk

**2. ORDER AWARD PROCEDURE AND TYPE OF ORDER**

The procedure will be conducted by way of a request for quotation in accordance with the competition principle set out in the Guidelines on the eligibility of expenditures under the European Regional Development Fund and the Cohesion Fund for the years 2014-2020 in its version of 21 December 2020. The Public Procurement Law Act of 11 September 2019 shall not apply to this Request for Quotation, polish reference of Journal of Laws (Dz. U. z 2019 r. poz. 2019, z późn. zm).

**3. PLACE AND MANNER OF SUBMISSION OF BIDS**

3.1. Bids must be submitted by electronic mail to the e-mail address [ewelina.mascianica@polpharmabiologics.com](mailto:ewelina.mascianica@polpharmabiologics.com) or published at the [bazakonkurencyjnosci.gov.pl](http://bazakonkurencyjnosci.gov.pl) website, in a non-editable file format e.g. pdf.

3.2. Bids submitted by electronic mail:

- Where more than one bid is submitted, the first of the bids submitted shall be taken into consideration for the evaluation. The title of the message with a bid should contain number EM-V-2021-1093-41114-7653.
- Before the bid submission time limit, the Supplier shall have the right: • to withdraw the bid by a written notification sent in accordance with the bid submission procedure • to change the bid.
- The notification of changes must be made in accordance with the same rules as the bid, with information on the update of the bid.

3.3. Bids submitted through the Competitiveness Base website:

- According to the bidder's instruction in BK2021, [https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web\\_instruction](https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web_instruction)

3.4. The date and time of the receipt of the bid to the Ordering Party shall determine the time limit met.

3.5. Bids submitted after the time limit shall not be considered.

3.6. The Ordering Party does not foresee the public opening of offers.

**4. MANNER OF COMMUNICATION OF THE ORDERING PARTY WITH THE CONTRACTORS, AUTHORISED PERSONS**

- 4.1. No oral and telephone information, explanations or answers shall be granted to the requests addressed to the Ordering Party.
- 4.2. The Contractor may request the Ordering Party to clarify the content of this Request for quotation. Any questions relating to this request shall be submitted by e-mail to the address indicated above or through the competition base through the “question” tab [<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>]. The Ordering Party is obliged to provide explanations, provided that the request for clarification of the content has been received by the Ordering Party no later than until the end of the day on which half of the time period for the submission of tenders expires. After the indicated date, the Ordering Party may leave the question without a reply. The extension of the time period for the submission of tenders shall not affect the time limit for lodging the above-mentioned request.
- 4.3. The content of requests (without disclosure of their source), together with the explanatory notes, shall be uploaded by the Ordering Party to the [www.bazakonkurencyjnosci.gov.pl](http://www.bazakonkurencyjnosci.gov.pl) website and shall communicate it to the Contractors who submitted the request.

## 5. DESCRIPTION OF THE SUBJECT OF THE ORDER

- 5.1. Announcement category: Other deliveries
- 5.2. Brief description of the contract subject matter:

1. 13mm Flurotec injection stopper
2. 20mm Flurotec lyo stopper
3. 13mm Clean Certified Sterilised Flip Off seal
4. 20mm Flip Off seal

- 5.3. Place of contract fulfillment: Voivodeship: pomorskie Poviát: gdański City: Gdańsk
- 5.4. Purpose of the contract:

Continuation of research on the “Development of an innovative form of medicine containing a monoclonal antibody for use in the treatment of non-specific enteritis” Task 1.1 “R&D projects for enterprises” under 1<sup>st</sup> Priority axis: “Support for the conduct of R&D work by enterprises” of the Smart Growth Operational Programme, 2014-2020.

- 5.5. The contract subject matter

### PRODUCT DESCRIPTION:

1. 13mm Flurotec injection stopper, art. 1358, 4023/50 grey bromobutyl rubber, B2-40, Westar Select RS ready to sterilise packed in Sterilisable bags of 2,000 pieces. Part number INJ13TB3WSRS -or equivalent (\*).

Quantity: 1 package

2. 20mm Flurotec lyo stopper, art. 1346, 4023/50 grey, B2-TR, NovaPure RS. Part number 7002-5023-or equivalent (\*).

Quantity: 1 package

3. 13mm Clean Certified Sterilised Flip Off seal art. 5417 with plain white matt PP button. Packed in double heat-sealed PE bags of 1,000 pieces. Part number FOT13W5417CCS (5921-9810)- or equivalent (\*).

Quantity: 2 packages

4. 20mm Flip Off seal art. 5115 with plain matt white PP button. Packed in heat-sealed PE bags of 500 pieces. Part number FOT20W5115- or equivalent (\*).

Quantity: 4 packages

Product expiry date: not less than 80% of the total expiry date of the product.

The Buyer does not accept other sizes of packages than indicated in the description of the contract subject matter.

(\*) Due to the continuation of studies, the description of the contract subject matter, due to technical reasons of an objective nature, contains the catalogue number and the name of the product manufacturer – the products are used for methods developed and operating on the products concerned.

5.6. CPV code:

38437000-7

Contract execution schedule:

One-off delivery by 30.07.2021

5.7. Lista dokumentów/oświadczeń wymaganych od Wykonawcy:

5.7.1.Required documents:

- declaration of the lack of capital and personal links with the Ordering Party (in accordance with the attachment to the request for quotation) together with the bid,
- CoA together with the first delivery of the products.

5.7.2.Please provide, at the Ordering Party's request, material safety data sheets for the ordered reagents, in accordance with applicable provisions. The supplier undertakes to: provide the SDS in Polish with the first delivery of a given reagent. If a material safety data sheet is not required, please provide information in accordance with Article 32 of the REACH Regulation. This information should be provided no later than on the date of first delivery. The lack of required documents is regarded as non-compliance with the delivery obligation and it will be the basis for the suspension of payments.

5.7.3.Given the uniqueness, singularity and strictly defined methodology of the projects, research and experimentation and the need to maintain continuity and repetition of the research carried out by the Ordering Party, a Supplier offering products that are

equivalent to the products described in this request for quotation shall, at the beneficiary's request, be obliged to:

- demonstrate, on the basis of technical documentation/a material safety data sheet for a reagent /etc. and on the basis of a written declaration, that each of the equivalent products offered by the Supplier meets the requirements allowing the Buyer to continue its research without the need to perform additional activities (procedures), including e.g. calibration of devices,
- demonstrate (by means of a written declaration contained in the submitted bid) that the equivalent products offered will not result in increased costs arising from the need to buy additional products and consumables,
- assume (in the form of a written declaration) liability for damage to the equipment resulting from the use of the offered and delivered equivalent products, on the basis of an opinion issued by an authorised service of the equipment manufacturer.

## 6. GROUNDS FOR EXCLUSION FROM PARTICIPATION IN THE PROCEEDINGS

6.1. Entities which have personal or capital ties with the Ordering Party are excluded from the procedure. Capital or personal ties shall mean interconnectedness between the Ordering Party or persons authorised to incur obligations on behalf of the Ordering Party, or persons performing activities related to the preparation and execution of the procedure of selection of the contractor on behalf of the Ordering Party, and the Bidder, in particular:

- Participation in the company as a partner of a civil law partnership or commercial partnership,
- Holding at least 10% of stocks or shares,
- Being a member of a supervisory or management corporate body, a holder of general commercial power of attorney, an authorized representative;
- Being married, in a relationship of direct kinship or affinity, in a collateral relationship of the second degree or collateral affinity of the second degree, or in the relationship of adoption, care or guardianship.

*Method of evaluating whether there are no grounds for exclusion:*

*Verification shall be based on the Contractor's statement on the absence of such personal or capital ties with the Ordering Party in accordance with Appendix No. 2 to the Request for Quotation.*

6.2. The Buyer has the right to reject a bid if it is incomplete or incompatible with the request for quotation.

## 7. DESCRIPTION OF OFFER PREPARATION

7.1. Preparation of the bid:

- each supplier may submit only one bid,
- the bid should be made in Polish or English,
- the bid must contain:
  - the net price or net value calculated for the purpose of the request for quotation,
  - the date of performance of the subject matter of the contract (presented in days/weeks),
  - declaration of the lack of capital and personal links with the Ordering Party (in accordance with the attachment to the request for quotation),

- the expiry date of the offer is not less than 60 days. The period begins to run from the date of submission of the bid. The Supplier will remain bound by the final bid with the Buyer throughout the contract execution period.
- offer together with Appendices must be signed by the persons authorised to represent the Contractor in accordance with the representation arising from the relevant register or on the basis of the power of attorney granted. If the person(s) signing the bid (representing the Contractor) acts on the basis of a power of attorney, that power of attorney must be attached to the bid (permissible form: scan or electronic signature).
- If the prices in the bid are denominated in a currency different than the Polish zloty, they will be converted using the average selling rate announced by the National Bank of Poland (NBP) applicable on the bid issue date.
- The absence of any of the above elements will result in rejection of the bid (having considered the one-off possibility for supplementing the submitted documents).

7.2. A bid may additionally contain:

- the name and address of the Supplier,
- number of the request for quotation,
- the product name and catalogue number,
- a net list price,
- terms and conditions of payment (expressed in days),

7.3. the Buyer does not allow submission of partial bids,

7.4. The Supplier shall bear all costs associated with the preparation and submission of a bid. The Buyer does not provide for reimbursement of the costs of participation in the procedure.

7.5. The Supplier will pay the Ordering Party contractual penalties for delay in the delivery of the subject matter of the contract, for each commenced day of delay, unless the delay is attributable to the Buyer. The Supplier agrees to have the amounts of contractual penalties deducted directly upon payment of the VAT invoice concerning the delivery.

7.6. Bids submitted after the time limit will not be taken into consideration.

## 8. DESCRIPTION OF THE CRITERIA TO BE FOLLOWED BY THE AWARDING ENTITY IN THE SELECTION OF THE OFFER

8.1. In assessing the offers, the Ordering Party shall follow the following criteria:

- Price — 80%,
- Delivery time — 20%,

8.2. The offer score shall be based on the following formula:

$$L = C + D$$

where:

- L - offer score
- C - number of points obtained in the “Price” criterion
- D - number of points obtained in the “Delivery time” criterion

8.3. The number of points (C) in the “Price” criterion shall be calculated according to the formula:

$$C = \frac{C_N}{C_B} * 80 \text{ points}$$

where:

- C - number of points in the “Price” criterion
- P<sub>LN</sub> - lowest total net price of the offer from among the offers which were not rejected
- P<sub>TN</sub> - total net price of the examined offer

Price means a net contract value or, if partial bids are accepted, a net position value.

Bids submitted in a currency other than PLN shall be converted into PLN using the average selling rate announced by the National Bank of Poland (NBP) applicable on the bid issue date.

**8.4.** The number of points (*D*) in the “Delivery time” criterion shall be granted as follows:

$$D = \frac{D_N}{D_B} * 20 \text{ points}$$

where:

- D - number of points for the “Delivery time” criterion
- D<sub>N</sub> - shortest delivery time offered
- D<sub>B</sub> - delivery time offered

Delivery time — means the time of delivery expressed in business days or calendar days, calculated from the date of submission of the contract. The use of a term “day(-s)” only or the provision of a total number only will be understood as calendar days. The delivery time will be converted into calendar days as follows:

- 1–5 business days = 1–5 calendar days,
- 6–10 business days = 8–12 calendar days (i.e. number of business days +2 days),
- 11–16 business days = 15–20 calendar days (i.e. number of business days +4 days),

and, according to that conversion, for other time limits expressed in business days.

The use of other forms of determining the Delivery Date (e.g. by specifying the date of delivery of products) will result in rejection of the bids in the procedure.

8.5. The Buyer will select the most advantageous bid on the basis of the bid evaluation criteria specified in this request for quotation. The Contractor can obtain a maximum of 100 points. The calculations shall be made to two decimal places. The Buyer will publish information about the outcome of the procedure in the Competitiveness Base website.

8.6. The Ordering Party reserves the right to enter into negotiations with a selected Bidder whose offer will gain the best score and meet the formal criteria.

## 9. PROCEDURE FOR EVALUATION OF OFFERS AND ANNOUNCEMENT OF RESULTS

9.1. In the course of evaluation of submitted Bids, the Ordering Party may request Bidders to clarify (if it does not affect competitiveness) the contents of the Bids submitted by them, excluding items with evaluation criteria. The time limit for providing clarifications will be indicated in a message sent to the Bidder (at least 2 business days from the receipt of a request for clarification).



- 9.2. In the course of evaluation of submitted Bids, the Ordering Party may request Bidders to supplement the documents (if it does not affect competitiveness). It may also address requests for the correction of obvious errors and accounting errors. The time limit for providing supplementations will be indicated in a message sent to the Bidder (at least 2 business days from the receipt of a request).
- 9.3. Failure to clarify and/or supplement documents within a time limit set by the Ordering Party and in the required form will be the basis for rejecting the Bid.
- 9.4. If the Bidder who has submitted the most advantageous bid does not enter into an Agreement, the Ordering Party reserves the right to sign the Agreement with the Bidder with the second best score, without reopening the Tendering Procedure.
- 9.5. The Ordering Party does not provide for the possibility of lodging protests and appeals.

## 10. CONDITIONS FOR AMENDING THE AGREEMENT

- 10.1. The Ordering Party reserves the possibility to make substantial changes to the provisions of the concluded agreement as compared to the content of the offer on the basis of which the Contractor was selected, in the following scope and situations:
  - 10.1.1. amending the provisions of the European Union law or of the national law in the scope in which they affect the implementation of the Agreement (in particular changes of the VAT rates);
  - 10.1.2. extending the time limit for execution of the Agreement due to the necessity to perform additional works, the performance of which is necessary for the proper performance of the Agreement, and the performance of which the Ordering Party, acting with due diligence, could not have foreseen earlier, subject to item 10.1.6 below;
  - 10.1.3. extending the time limit for execution of the Agreement due to force majeure, together with all the consequences arising in connection with the extension of that time limit;
  - 10.1.4. changing the parameters of the subject of the Agreement, not leading to a change in nature of the Agreement – technological changes, in particular: the necessity to execute the Agreement using other technical/technological or material solutions other than the ones indicated in the Request for Quotation, where the application of the envisaged solutions would result in non-performance or defective performance of the Agreement, subject to item 10.1.7. below;
  - 10.1.5. the amendments relate to the performance of additional deliveries or services of the Contractor, not covered with the Agreement, if they became necessary, and all the following conditions have been met:
    - the change of the Contractor cannot be made due to economic or technical reasons, in particular regarding the interchangeability or interoperability of the equipment, services or installations, ordered under the basic subject of the Agreement,
    - the change of the Contractor would cause a significant inconvenience or substantial increase of costs for the Ordering Party,
  - the value of any subsequent change does not exceed 50% of the value of the original subject of the net Agreement;
  - 10.1.6. the amendment does not lead to a change in the nature of the Agreement and the following cumulative conditions are met:
    - the necessity to amend the Agreement is due to circumstances which the Ordering Party, acting with due diligence, could not have foreseen,
    - the value of the amendment does not exceed 50% of the value of the original subject of the net Agreement;

10.1.7. The Contractor is to be replaced by the new contractor:

- as a result of merger, division, conversion, bankruptcy, restructuring or acquisition of the Contractor or its enterprise, if the new contractor fulfils the conditions for participation in the proceedings, there are no grounds for the exclusion and it does not entail any other substantive changes to the Agreement,
- as a result of the assumption of the Contractor's obligations by the Ordering Party towards its subcontractors.

10.1.8. amending the Agreement shall not lead to a change in its nature, and the total value of changes is less than EUR 214,000 and shall at the same time be less than 10% of the value of the original subject of the net Agreement.

10.2. The Ordering Party also envisages the possibility to make minor changes to the provisions of the concluded Agreement in relation to the content of the offer, on the basis of which the Contractor was selected.

10.3. Amendments to the Agreement shall be made in the form of an annex signed by both parties, and the possibility of introducing them shall be subject to the acceptance by the Ordering Party.

## 11. OTHER INFORMATION

11.1. The Buyer reserves the right to:

- cancel or terminate the procedure at any stage without stating the reason,
- choose not to select any of the bids submitted,
- extend the time limit for submitting bids.
- amend or supplement documents constituting part of the request for quotation which will become an integral part thereof;

A Bidder will have no claims for compensation against the Ordering Party on any of the grounds referred to above.

11.2. Protection of Personal Information:

With regard to personal data contained in the bids, the Ordering Party, upon the time of submission of the bid, shall become the controller of that data within the meaning of Article 4 (7) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR). The Ordering Party shall process that data for the purpose of evaluating the bids, concluding the Agreement with the selected Contractor and for the execution of the concluded Agreement, i.e. pursuant to Article 6, section 1, letter b) of the GDPR.

The Ordering Party shall share the personal data contained in the bids submitted, on the basis of the applicable law, to the authorised bodies and institutions authorised to inspect projects co-financed by the budget of the European Union. That data will be provided, in particular, to the intermediate body, ie. the National Research and Development Centre and the competent Minister for development shall be the data controller pursuant to Article 71, section 1. Information on the range of data processing by the competent authorities is available at: <https://www.funduszeuropejskie.gov.pl/strony/o-funduszach/ogolne-zasady-przetwarzania-danych-osobowych-w-ramach-funduszy-europejskich/>

The Ordering Party shall process personal data within the period it is required by the applicable law to keep all documentation related to the project co-financed by the EU budget.



## 12. APPENDICES

12.1. Appendices to this Request for Quotation are the following:

- 1) declaration of the lack of capital and personal links with the Ordering Party (Appendix No 2)

