

Warsaw, 09/08/2024
place and date

PRICE INQUIRY NO. SEMA/40/2024/API
conducted in the market research mode

In connection with the implementation of the project entitled "Development and development of an innovative solution - a generic drug from the group of GLP-1 receptor agonists in the treatment of type 2 diabetes", co-financed from the state budget as part of competitions conducted by the Medical Research Agency, Zakłady Farmaceutyczne Polpharma SA, invites you to submit offers regarding **purchase and delivery of the active substance Semaglutide (C₁₈₇H₂₉₁N₄₅O₅₉, CAS 910463-68-2), described in detail in section III.**

I. NAME AND ADDRESS OF THE ORDERING PARTY

Zakłady Farmaceutyczne Polpharma SA
street Pelpińska 19, 83-200 Starogard Gdański

II. CONTRACT AWARD PROCEDURE

1. This contract is not subject to the provisions of the Public Procurement Law of September 11, 2019 (uniform text: Journal of Laws of 2019, item 2019).
2. The procedure is carried out as an intentional and cost-effective market assessment study, while maintaining the following principles:
 - (a) achieving the best possible results using available resources;
 - b) selecting the best possible means and methods to achieve previously defined goals;
 - c) ensuring transparency, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF THE INQUIRY

III.1. The subject of this price inquiry is the purchase and delivery of the active substance **semaglutide**, (C₁₈₇H₂₉₁N₄₅O₅₉, CAS 910463-68-2) obtained exclusively by chemical synthesis (Solid Phase Peptide Synthesis). .

III.2. CPV CODE: 24950000-8 Specialized chemical product.

III.3. Scope of the request for quotation:

III.3.1. **providing 42 grams of Semaglutide** converted into a form without water and sodium, along with a certificate of analysis.

The ordering party prefers to deliver 3 different series with a total weight of 42g.

The Ordering Party allows the delivery of 1, 2 or 3 series in one delivery.

(acceptable delivery: 1 series of 42g or 2 series of 24g or 3 series of 14g)

III.3.2. **The active substance Semaglutide should meet the following requirements:**

1. Manufacturing under GMP

2. Water content not more than 10% (mass/mass)

3. Sodium cation content not more than 4% (weight/weight)



- 4. Total content of all related substances not more than 1.5%
- 5. No contamination with substituted residue 25Trp(4-hydroxybenzyl)
- 6. Content of marked oligomers not more than 0.3%
- 7. Production series not older than 9 months at the time of delivery

- III.3.3. the offered price should include all costs related to the delivery of the subject of the contract, including transport, insurance, etc.,
- III.3.4. The Ordering Party reserves the right to change the quantity of the ordered material: active substance semaglutide within $\pm 5g$,

III.4. Partial offers or different offer variants will not be accepted.

IV. DATE AND PLACE OF DELIVERY

- IV.1. **Delivery date of the subject of the contract: no later than September 30th, 2024.**
- IV.2. The order will be placed with the supplier immediately after the procedure is completed and the winning offer is selected.
- IV.3. Place of delivery: CIP Warsaw, Zakłady Farmaceutyczne Polpharma SA, Research and Development Department, ul. Barska 31, 02-315 Warsaw.

V. REQUIREMENTS FOR THE CONTRACTOR

- V.1. The procedure is open to any Contractor who meets all of the following requirements:
 - V.1.1. Possessing knowledge and at least 3 years of experience in the production of active substances belonging to the class of therapeutic peptides produced using SPPS, under the GMP quality system,
 - V.1.2. Having at least 3 years of experience in preparing registration documentation for an active substance belonging to the class of therapeutic peptides,
 - V.1.3. **Declaration** availability of full ASMF/DMF documentation,
 - V.1.4. **Declaration** providing an open part of the ASMF/DMF quality documentation after placing the order, or related documents such as material specification, description of substance control methods used, detailed description of impurities, their source, stress tests, minimum stability period of 6 months under accelerated conditions (minimum 2 batches) and proof of substance compliance
 - V.1.5. **Declaration** compliance of the active substance with the quality requirements specified in ICH Q6A, ICH Q11, monograph EP 2034 Substances for pharmaceutical use, monograph USP1503 Quality attributes of synthetic peptide drug substances,
 - V.1.6. **Declaration** confirming that the compliance of the offered substance with the active substance of the reference drug has been assessed in accordance with current FDA recommendations *ANDAs for Certain Highly Purified Synthetic Peptides Drug Products That Refer to Listed Drugs of rDNA Origin*,
 - V.1.7. **42 grams of Semaglutide come from certified series that** fully represent the final process material, but may be manufactured under non-GMP conditions. The offer should include a certificate along with a declaration that the material comes from the final production process.

Assessment procedure:

The Ordering Party will consider the Contractor to have met the condition if the Contractor presents a declaration of compliance with the conditions for participation in the procedure (Appendix 2 to the Price Inquiry) by entering YES or NO and all the required information. Entering the NO option will result in rejection of the offer.

The Ordering Party reserves the right to verify compliance with the conditions on site at the Contractor's or to request the submission of appropriate documentation.

- V.2.** Offers submitted by Contractors who demonstrate that they meet certain requirements will be forwarded to the offer examination and evaluation stage. Compliance with the above requirements will be assessed on the basis of the "meets-does not meet" criterion. Bids submitted by Contractors who do not meet any of the above requirements will be rejected.
- V.3.** Entities in which the following circumstances occur are excluded from the tender:
- as described in Article 7(1) 1 of the Act of April 13, 2022 on special measures to counteract support for aggression against Ukraine and on the protection of national security,
 - as described in Article 5k of Council Regulation (EU) No. 833/2014 of 31 July 2014 on restrictive measures in view of Russia's actions destabilizing the situation in Ukraine.

Method of verifying the grounds/lack of grounds for exclusion:

Verification will be carried out on the basis of the Contractor's declaration in accordance with Appendix No. 1.

VI. PLACE AND DATE FOR SUBMITTING OFFERS

VI.1. The deadline for submitting offers is August 20, 2024.

– Offers can be sent electronically (in the form of electronically signed documents or a document scan) to the following address: dominika.radzanowska@polpharma.com

VI.2. The offer will be deemed properly submitted if the complete offer is delivered to the above e-mail address within the deadline specified in this section.

VI.3. The offer should be signed by persons authorized to represent the bidder pursuant to entries in the relevant registers or pursuant to a power of attorney. The power of attorney should be attached to the offer.

VI.4. Offers submitted after the deadline will not be considered.

VII. EVALUATION CRITERIA

VII.1 The Ordering Party will apply the following criteria for evaluating offers:

- Price – 100%

VII.2 Offer points will be calculated according to the following formula:

$$O_P = P_C$$

Where:

- OP - point evaluation of the offer
P.C - number of points obtained in the "Price" criterion

VII.3The number of points (PC) in the "Price" criterion will be calculated according to the formula:

$$P_C = \frac{C_N}{C_B} * 100 \text{ pkt}$$

Where:

- P.C - number of points for the "Price" criterion
- CN - among the non-rejected offers, the lowest total net price of the offer
- CB - total net price of the examined offer

For evaluation purposes, offers submitted in a currency other than PLN will be converted into PLN at the average NBP exchange rate as of the closing date for the submission of offers.

VII.4The offer from among the non-rejected offers that obtains the highest number of points in total will be considered the most advantageous offer. A maximum of 100 points can be obtained by the Seller. Calculations will be made with an accuracy of two decimal places.

VIII. DESCRIPTION OF THE METHOD OF PREPARING THE OFFER

- VIII.1.** The contractor must prepare an offer in accordance with the template included in Appendix 1 and Appendix 2 to the Quotation Request. The offer must be accompanied by certificates in accordance with the requirements of point. V.1.7
- VIII.2.** Making more than one offer will result in rejection of all offers.
- VIII.3.** Offers may be modified or withdrawn before the deadline for submission of offers.
- VIII.4.** Contractors are obliged to carefully read the information contained in the request for quotation.
- VIII.5.** The bidder submitting an offer remains bound by it for a period of 60 calendar days from the date of expiry of the deadline for submitting offers.
- VIII.6.** In case of any matters related to this request for quotation, please contact the Ordering Party by e-mail at the following e-mail address: dominika.radzanowska@polpharma.com

IX. HOW BUYERS COMMUNICATE WITH SELLERS AND PERSONS AUTHORIZED TO CONTACT

- IX.1.** In the proceedings, declarations, applications, notices and information are provided by the Buyer and the Seller in Polish or English
- IX.2.** All notices, declarations, applications and information submitted in electronic form require, at the request of each party, immediate confirmation of their receipt.
- IX.3.** If the Seller does not confirm receipt of the correspondence, the Buyer will assume that the correspondence sent by the Buyer to the e-mail address provided by the Seller has been delivered to him in a way that allows him to read its content.
- IX.4.** Correspondence related to this inquiry should be sent to the following e-mail address: domonika.radzanowska@polpharma.com
- IX.5.** In correspondence related to this inquiry, the Seller should use the procedure number SEMA/40/2024/API.
- IX.6.** The person authorized to communicate with the Seller is Ms. Dominika Radzanowska.

- IX.7.** No oral or telephone information, explanations or answers are provided to inquiries addressed to the Buyer.
- IX.8.** Any questions regarding this inquiry should be submitted by e-mail to the address indicated above no later than 3 days before the deadline for submitting offers.
- IX.9.** Answers to questions and details Inquiries resulting from questions from potential Sellers will be sent to the entity that sent the question.

X. PROCEDURE FOR EVALUATING OFFERS AND ANNOUNCEMENT OF RESULTS

- X.1.** In the course of examining and evaluating offers, the Buyer may request from the Seller supplements (if this does not affect competitiveness) and explanations regarding the content of the submitted offers. It may also request the correction of obvious errors and calculation errors.
- X.2.** During the evaluation of the offer, the Buyer reserves the right to check the credibility of the documents, statements, lists, data and information presented by the Sellers.
- X.3.** If two or more Sellers obtain the same number of points, the offer with the most advantageous impact on the environment and climate will be selected. For this purpose, the Buyer has the right to call on the Bidders whose offers received the highest final number of points to supplement their offer by providing information indicated by the Buyer regarding the impact of the subject of the offer on the environment.
- X.4.** **The Ordering Party reserves the right to cancel the procedure without giving a reason.** If the procurement procedure is canceled, suppliers are not entitled to a claim for reimbursement of the costs of participation in the procedure.
- X.5.** **The Ordering Party reserves the right to negotiate with bidders,** who meet the requirements of the specification, in particular if the offered price exceeds the budget allocated by the Ordering Party for the execution of the order.

XI. OTHER INFORMATION

- XI.1.** The bidder bears all costs related to the preparation and submission of the offer.
- XI.2.** Until the deadline for submitting offers, the Ordering Party reserves the right to change or supplement the content of this price inquiry.

XII. CHANGE OF THE CONTENT OF THE AGREEMENT

- XII.1.** The Ordering Party reserves the right to make significant changes to the provisions of the Agreement for the offered services in relation to the content of the offer on the basis of which the Contractor was selected, in the following scope and situations:
- XII.1.1.** changes in legal provisions to the extent affecting the implementation of the Agreement (in particular changes in VAT rates);
- XII.1.2.** improving technical parameters subject of the Agreement, resulting from updating solutions due to technological progress, without affecting the gross lump sum price
- XII.1.3.** extending the deadline for the implementation of the Agreement due to the need to perform additional works that are necessary for the proper performance of the Agreement, and the execution of which the Ordering Party, acting with due diligence, could not have predicted in advance, subject to point. XII.1.6 below;

XII.1.4. extension of the deadline for the implementation of the Agreement as a result of force majeure, along with all the consequences arising in connection with the extension of this deadline;

XII.1.5. changes in the parameters of the subject of the Agreement, not leading to a change in the nature of the Agreement - technological changes, in particular: the need to implement the Agreement using other technical/technological and material solutions than those indicated in the Request for Quotation, in a situation where the use of the provided solutions would pose a risk of non-performance or defective performance of the Agreement, subject to point XII.1.7. below;

XII.1.6. the changes concern the provision of additional deliveries or services of the Contractor not covered by the Agreement, provided that they have become necessary and the following conditions have been met:

- the change of the Contractor cannot be made for economic or technical reasons, in particular regarding the interchangeability or interoperability of equipment, services or installations ordered under the basic subject of the Agreement,
- a change of the Contractor would result insignificant inconvenience or significant increase in costs for the Ordering Party,
- the value of each subsequent change does not exceed 50% of the net value of the original subject of the Agreement;

XII.1.7. the change does not lead to a change in the nature of the Agreement and the following conditions have been met:

- the need to change the Agreement is caused by circumstances which the Ordering Party, acting with due diligence, could not have predicted,
- the value of the change does not exceed 50% of the net value of the original subject of the Agreement;

XII.1.8. The contractor is to be replaced by a new contractor:

- as a result of a merger, division, transformation, bankruptcy, restructuring or acquisition of the Contractor or his enterprise, provided that the new contractor meets the conditions for participation in the proceedings, there are no grounds for exclusion against him and it does not result in other significant changes to the Agreement,
- as a result of the Ordering Party taking over the Contractor's obligations towards its subcontractors.
- changing the contract does not lead to changes in its nature.

XII.2. The Ordering Party also provides for the possibility of making insignificant 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.

XII.3. Changes to the Agreement will be introduced in the form of annexes signed by both Parties, and the possibility of their introduction depends on the acceptance by the Ordering Party.

XIII. LIST OF ATTACHMENTS

The following attachments are attached to this request for quotation: :

Annex number	Title of the Annex
Appendix 1	Offer form
Appendix 2	Sample declaration on meeting the conditions specified in the request for quotation

OFFER FORM

The Contractor:

Company name	
Registered office/Place of residence/Address of main place of business	
E-mail address to which the Ordering Party may send correspondence related to the inquiry	
NIP (Tax Identification Number)	
REGON (Statistical identification number)	
Phone number	
Contact person for the Ordering Party	

Net price: per 1 gram of active substance per anhydrous material without sodium ions in €, \$, PLN (underline as appropriate)

Net value: per 42 grams of active substance per anhydrous material without sodium ions in €, \$, PLN (underline as appropriate)

VAT rate:(if applicable)%, VAT value: in €, \$, PLN (underline as appropriate), gross value for 42g: in €, \$, PLN (underline as appropriate)

Delivery time:..... (maximum 30/09/2024)
(date, dd.mm.yyyy)

Invoice payment deadline days from delivery of goods (minimum 30 days)

We also declare the following:

- a. We have read the request for quotation and its attachments and have no objections. We have obtained the necessary information to prepare our offer.
- b. The price of our offer includes a lump sum remuneration that covers all the obligations of the future Contractor related to the implementation of this contract.
- c. By submitting this offer, we declare that we meet the conditions for participation specified in Section V of the request for quotation.
- d. We consider ourselves bound by this offer for 60 calendar days from the deadline for submitting offers,
- e. By submitting this offer, we declare that no circumstances apply to us:

- described in Article 7(1) of the Act of April 13, 2022 on special measures aimed at counteracting support for aggression against Ukraine and protecting national security;
- described in Article 5k of Council Regulation (EU) No. 833/2014 of 31 July 2014 on restrictive measures in connection with Russia's actions destabilizing the situation in Ukraine.

.....
place and date)

.....
(signature)

Appendix 2 to the Price Inquiry no. SEMA/40/2024/API

STATEMENT OF MEETING THE CONDITIONS SPECIFIED IN THE REQUEST FOR QUOTE

..... (company/Contractor) declares that it meets the conditions specified in the request for quotation in accordance with the table below: :

Yeah.	Criteria	Yes No	Value
1	having knowledge and experience of at least 3 years in the production of active substances belonging to the class of therapeutic peptides, in accordance with the GMP quality system		Number of years:
2	having at least 3 years of experience in preparing registration documentation for an active substance belonging to the class of therapeutic peptides		Number of years
3	Full documentation available: ASMF		availability date.....
4	Availability of full documentation: DMF		availability date.....
5	delivery after placing the order of an open part of the ASMF/DMF quality documentation or related documents, such as material specification, description of substance control methods used, detailed description of impurities, their source of origin, stress tests, minimum stability period of 6 months under accelerated conditions (minimum 2 batches) and proof of substance compatibility		date availability
6	The active substance meets the quality requirements specified in ICH Q6A, ICH Q11, monograph EP 2034 Substances for pharmaceutical use, monograph USP1503 Quality attributes of synthetic peptide drug substances.		X
7	Confirmation of the assessment of the similarity of the offered substance with respect to the active substance of the reference product in accordance with the current FDA recommendation ANDAs for Certain Highly Purified Synthetic Peptides Drug Products That Refer to Listed Drugs of rDNA Origin		X
8	Semaglutide 42g API comes from certified batches that fully represent the final process material, but may be produced in non-GMP conditions. The certificate will be attached to the offer along with a statement that the material comes from the final production process.		number of series: (preferred number of series 3, allowed quantities 1, 2, 3)

.....
(place and date)

.....
(signature)