

Warsaw, 30 November 2023 r.  
*place and date*

**PRICE INQUIRY NO. RIA/3/2023/API**  
**being conducted as a market assessment study**

In connection with the implementation of the project titled „Design and development of an innovative solution - a complex, three-component medicinal product targeting the treatment of hypertension”, financed from the state budget funds from the Medical Research Agency, Zakłady Farmaceutyczne „Polpharma” S.A., requests that you submit bids concerning **the purchase and supply an active substance pharmacologically similar to the pyridine group with blocking action on free calcium channels (calcium channel antagonist), Amlodipine in the form of amlodipine besilate.**

### **I. NAME AND ADDRESS OF THE CUSTOMER**

**Zakłady Farmaceutyczne Polpharma S.A.**  
Pelplińska 19 street  
83-200 Starogard Gdański

### **II. CONTRACT AWARD PROCEDURE**

**2.1** This contract is not subject to the provisions of the Public Procurement Law of 11 September 2019 (consolidated text: Journal of Laws of 2019, item 2019).

**2.2.** The procedure is being conducted as an intentional and cost-efficient market assessment study while respecting the following rules:

- 1) achieving the best possible outcomes using the available measures;
- 2) to choose the best possible means and methods to meet the pre-defined objectives;
- 3) to ensure transparency, fair competition and equal treatment of contractors.

### **III. OPIS PRZEDMIOTU ZAPYTANIA CENOWEGO**

**3.1.** The subject matter of the Request for Quotation is the purchase and supply an active substance for pharmaceutical use, meeting the requirements of the monograph detailed Ph. Eur. nr 1491 Amlodipine, manufactured under GMP conditions., 170 kilos.

**3.2.** The minimum technical requirements (order specification) are attached as Appendix No. 2 to this request for proposal. Bids that do not meet the minimum technical parameters will not be considered.

**3.3.** CPV CODE: 24950000-8 Specialized chemical products.

**3.4.** Scope of the price inquiry:

- 3.4.1. delivery of 170 kg of active substance for pharmaceutical use, meeting the requirements of the monograph detailed Ph. Eur. nr 1491 Amlodipine, manufactured under GMP conditions.

3.4.2. The material should be delivered in quantity and according to the schedule, as in the table below:

	Amount [kg/series]	Number of series	Delivery date – not later than:
	85 kg	1	No later than 30 working days from the date of order
	85 kg	1	No later than 30 working days from the date of order
<b>Total</b>	<b>170 kg</b>	<b>2 different batches</b>	<b>No later than 30 working days from the date of order</b>

3.4.3. The offered price must include all costs related to the execution of the contract, including the cost of transportation, insurance, etc. **INCOTERMS – CIP WARSAW**

3.4.4. Expiration date of the contract item above 24 months from the declared expiration date. At the time of delivery, the expiration date should be at least 80% of the date confirmed by stability tests.

#### IV. PRICE INQUIRY DELIVERY SITE AND DATE

- 4.1. Delivery address: **MWS Starogard Gdański: Pelplińska 19 street, 83-200 Starogard Gdański**
- 4.2. Delivery time of the subject of the price inquiry: up to 30 working days from the date of order.
- 4.3. Since the delivery time of the subject of the price inquiry is a criterion for evaluation of bids, the implementation will be carried out in accordance with the submitted bid, but no later than 30 working days from the date of order.

#### V. REQUIREMENTS FOR CONTRACTORS

- 5.1. Contractors who meet the following conditions may apply for the award of the contract:
  - a) they have knowledge and experience in manufacturing active substances in a GMP-compliant quality system.

Method of verification of grounds/lack of grounds for exclusion::

*Verification will be made on the basis of the Bidder's statement (Appendix No. 3)*

- 5.2. The ordering party does not allow the supply of equivalent products.
- 5.3. The ordering party does not allow partial or variant bids..
- 5.4. The Purchaser does not allow other sizes of substances than those specified.
- 5.5. **The Seller shall provide the following documentation with the bid :**
  - a) CoA,
  - b) DMF open part or ASMF,
  - c) CEP,
  - d) MSDS
  - e) particle size measurement results for the objects of the request.

- 5.6. The purchaser does not allow other than the indicated time of delivery of raw material.



- 5.7. The purchaser does not allow other than the specified particle size distribution of PSD: D(0.9)µm, D(0.5) nmt 100 µm, D(0.1) nmt 40 µm obtained by chemical synthesis with total impurities not exceeding 0.8% m/m and water content up to 0.5% m/m.
- 5.8. Entities for which the following circumstances occur are excluded from the procedure:
- as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;
  - as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

Method of verification of grounds/lack of grounds for exclusion:

*The verification shall take place on the basis of the Bidder's declaration.*

## VI. PRICE CALCULATION

- 6.1. Method of calculating the bid price: the price shall be calculated net and gross.
- 6.2. Bids submitted in a currency other than PLN shall be converted into PLN at the average exchange rate of the National Bank of Poland (<https://www.nbp.pl/>) on the closing date for submission of bids.
- 6.3. The price shall include all costs associated with the preparation and execution of the subject matter of the request.
- 6.4. The price submitted in the bid cannot be changed during the execution of the contract.

## VII. PLACE AND DEADLINE FOR SUBMISSION OF BIDS

- 7.1. Bids must be submitted by the deadline of **13 December 2023**.
- in electronic form (in the form of a scanned signed document or document electronically signed) to: [barbara.wendolowska@polpharma.com](mailto:barbara.wendolowska@polpharma.com)
- 7.2. The submission of a bid shall be considered effective if a complete bid is received in the email box of the above address by the deadline specified in this section.
- 7.3. Bids submitted after the deadline will not be considered.

## 8. CRITERIA USED BY THE ORDERING PARTY FOR BID SELECTION

- 8.1. When evaluating bids the Ordering Party will use the following criteria:
- Price – 80%,
  - Delivery time – 20%,
- 8.2. The evaluation criteria apply to both partial bids and bids covering all parts of the subject matter of the contract. Evaluation and thus scoring will be carried out individually for each part of the subject matter of the contract, regardless of whether the offer will cover all parts of the subject matter of the contract or will be a partial offer.
- 8.3. The score will be awarded as per the formula:

$$O_P = P_C + P_S$$

where:

- $O_P$  - Score of the bid
- $P_C$  - score for the "Price" criterion
- $P_S$  - score for the „Delivery time ” criterion

**8.4.** The score ( $P_C$ ) for the “Price” criterion will be calculated for the net amount as follows:

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

where:

- $P_C$  - score for the “Price criterion”
- $C_N$  - the lowest net price proposed in the bids which were not rejected
- $C_B$  - total net price of the bid being evaluated

Bids submitted in a currency other than PLN will be converted into PLN at the average exchange rate of the National Bank of Poland on the closing date for submission of bids.

**8.5.** The score ( $P_S$ ) for the “delivery time” criterion will be calculated for the net amount as follows:

$$P_S = \frac{S_N}{S_B} * 20 \text{ points}$$

where:

- $P_S$  - score for the “delivery time”
- $S_N$  - the shortest bid delivery time in the bids were not rejecter
- $S_B$  - total delivery time of the bid being evaluated

By delivery time the Buyer means the time counted in calendar days from the date of the Buyer's order to the Seller's execution.

The bid will be rejected if the delivery time of the subject of the price inquiry is longer than 30 working days.

**8.6.** The most advantageous offer will be considered the offer from among the offers that have not been rejected, which in total will obtain the highest number of points. The maximum the Seller can obtain is 100 points. Calculations will be made to two places after the decimal point.

## 9. DESCRIPTION OF BID PREPARATION

- 9.1.** The bidder shall prepare one price offer in accordance with the sample form attached as Appendix No. 1 to the request.
- 9.2.** The Bidder may, before the deadline for submission of bids, change or withdraw its bid.
- 9.3.** The Bidder shall be obliged to carefully read the information contained in the Price Inquiry.
- 9.4.** In matters related to this inquiry, please contact the Contracting Authority, e-mail: [barbara.wendolowska@polpharma.com](mailto:barbara.wendolowska@polpharma.com)

## 10. OTHER INFORMATION

- 10.1.** The bidder shall bear all costs associated with the preparation and submission of the bid.
- 10.2.** Until the deadline for submission of bids, the Contracting Authority reserves the right to amend or supplement the contents of this price inquiry.



## 11. LIST OF APPENDICES

The following documents are appendices to the Request for Quotation:

<b>Appendix number</b>	<b>Appendix name</b>
Appendix 1	Bid form
Appendix 2	Minimum technical requirements (product specification)
Appendix 3	Model statement of compliance with the conditions set in the price inquiry

**BID FORM FOR THE API**

**Contractor:**

<b>Business name</b>	
<b>Address of the principal place of business</b>	
<b>E-mail address for the Customer to send correspondence related to the Price Inquiry</b>	
<b>NIP (Taxpayer Identification Number)</b>	
<b>REGON (statistical identification number)</b>	
<b>Phone number</b>	
<b>Contact person for the Customer</b>	

We offer to perform the subject of the contract for **the purchase and delivery an active substance pharmacologically similar to the pyridine group with blocking action on free calcium channels (calcium channel antagonist), Amlodipine in the form of amlodipine besilate**, in accordance with the requirements of the price inquiry, for the price:

**Net value:** ..... PLN/EURO/USD per kilo of the substances

VAT rate\*: .....%, VAT value: ..... PLN

Gross value: ..... PLN/EURO/USD

\*if applicable

**Total:**

Net value:: ..... PLN/EURO/USD za **170 kilos of the substances**

VAT rate\*: .....%, VAT value: ..... PLN

Gross value: ..... PLN/EURO/USD

\*if applicable

**Delivery time:**

..... working days from the date of order placement.

**Product expiration date ..... months for batch 1**

**Product expiration date ..... months for batch 2**

**Along with the bid we submit documentation :**

- a) CoA, YES / NO\*
- b) DMF open part YES / NO\*
- c) ASMF YES / NO\*,
- d) CEP YES / NO \*,
- e) MSDS YES / NO\*
- f) particle size measurement results for the subjects of the request YES / NO\*.

**\* DELETE AS APPROPRIATE**

**We also declare as follows:**

- a. We have read the Price Inquiry and its appendices, and we raise no objections. We have obtained all information necessary to prepare our bid.
- b. The price in our bid includes a flat-rate remuneration which covers all obligations of the future Contractor related to the performance of this contract.
- c. By submitting this bid we represent that we meet the conditions for participation set out in section V of the Price Inquiry.
- d. The present bid will remain valid and binding for us for 60 calendar days from the bid submission deadline.
- e. By submitting this bid, we declare that none the following circumstances apply to us:
  - as described in Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract Support for the Aggression against Ukraine and to Protect National Security;
  - as described in Article 5k of the Council Regulation (EU) No 833/2014 of 31 July 2014 concerning restrictive measures in view of Russia's actions destabilising the situation in Ukraine.

.....  
(place and date)

.....  
(signature)

**STATEMENT ON FULFILMENT OF THE CONDITIONS DEFINED IN THE PRICE  
INQUIRY**

... .. (business/Contractor) declares that it meets the conditions specified in the Price Inquiry, in accordance with the table below:

1. having knowledge and experience in the manufacture of active pharmaceutical substance in compliance with the GMP quality system,

.....  
(place and date)

.....  
(signature)