

Warsaw, 23.09.2024.  
*place and date*

**PRICE INQUIRY No. RIA/8/2024/Capsules  
conducted by means of market discernment**

In connection with the implementation of the project entitled "Design and development of an innovative solution - a complex, three-component medicinal product targeting the therapy of arterial hypertension", co-financed from the state budget under competitions held by the Medical Research Agency, Pharmaceutical Plant "Polpharma" S.A., is requesting bids for the purchase and delivery of **gelatin capsules**.

**I. NAME AND ADDRESS OF THE CONTRACTING AUTHORITY**

**Zakłady Farmaceutyczne Polpharma S.A.**

19 Pelplińska Street  
83-200 Starogard Gdanski

**II. MODE OF AWARDING THE CONTRACT**

1. This order is not subject to the provisions of the Act of September 11, 2019. Public Procurement Law (i.e. Journal of Laws of 2019, item 2019).
2. Proceedings conducted by market discernment, in an expedient and economical manner in compliance with the rules:
  - (a) getting the best results from given inputs;
  - b) the optimal selection of methods and means to achieve the objectives;
  - (c) openness, fair competition and equal treatment of contractors.

**III. DESCRIPTION OF THE SUBJECT OF THE PRICE INQUIRY**

- 3.1.** The subject of this Price Request is the purchase and delivery of gelatin capsules, divided into parts:
- 3.1.1. **Part 1 Hard gelatin capsules quantity of 4,000,000 pcs. (two batches of 2,000,000 units each) with the required specification:**
    - size 1
    - green body, yellow cap
    - Imprint on the bottom rectified-radial "5+5+2.5", yellow color without titanium dioxide
    - imprint size: height 2.2 - 2.5 mm optimally 2.3 mm, width 12.4 - 12.8 mm optimally 12.6 mm
    - beef gelatine only
    - without titanium oxide and talc in the formulation
    - without azo dyes
  - 3.1.2. **Part 2 Hard gelatin capsules quantity of 4,000,000 units (two batches of 2,000,000 units each) with the required specifications:**
    - size 1
    - green body, orange cap
    - Imprint on the bottom rectified-radial "5+10+2.5", yellow color without titanium dioxide
    - imprint size: height 2.2 - 2.5 mm optimally 2.3 mm, width 14.2 - 14.6 mm optimally 14.4 mm
    - beef gelatine only
    - without titanium oxide and talc in the formulation

- without azo dyes

**3.1.3. Part 3 Hard gelatin capsules quantity of 4,000,000 units (two batches of 2,000,000 units each) with the required specifications:**

- size 1

- green body, red cap

- Imprint on the bottom rectified-radial "10+5+2.5", yellow color without titanium dioxide

- imprint size: height 2.2 - 2.5 mm optimally 2.3 mm, width 14.2 - 14.6 mm optimally 14.4 mm

- beef gelatine only

- without titanium oxide and talc in the formulation

- without azo dyes

**3.1.4. Part 4 Hard gelatin capsules quantity of 4,000,000 units (two batches of 2,000,000 units each) with the required specifications:**

3.1.5.

- size 1

- green body, brown cap

- Imprint on the bottom rectified-radial "10+10+2.5", yellow color without titanium dioxide

- imprint size: height 2.2 - 2.5 mm optimally 2.3 mm, width 14.5 - 14.9 mm optimally 14.8 mm

- beef gelatine only

- without titanium oxide and talc in the formulation

- without azo dyes

**3.2. Minimum technical requirements:**

The capsules must have:

- ISO 9001:2015 certification

- EXCiPACT™ Certification Standard for Pharmaceutical Excipients.

- Capsule quality document Technical Reference File (TRF) describing every aspect of the process and analysis with test methods and quality specifications.

**3.3. CPV CODE: 33600000-6 Pharmaceutical products.**

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

3.4.1. Delivery of gelatin capsules in one delivery of 16,000,000 units by 31.01.2025

3.4.2. the offered price must include all costs related to the execution of the contract, including the cost of transportation, insurance, etc.

#### **IV. PLACE AND DATE OF EXECUTION OF THE PRICE INQUIRY**

**4.1. Delivery address: MWS Starogard Gdański: 19 Pelplińska Street, 83-200 Starogard Gdański.**

**4.2. Delivery time of the subject of the price inquiry: one delivery until 31.01.2025.**

#### **V. REQUIREMENTS FROM CONTRACTORS**

**5.1. The contracting authority allows the submission of partial bids.**

**5.2. The purchaser does not allow other quantities than those specified.**

**5.3. The vendor will provide the following documentation along with the bid:**

**a) certification: ISO 9001:2015**

**b) Certificate: EXCiPACT**

**c) Capsule quality document Technical Reference File (TRF) describing every aspect of the process and analysis with test methods and quality specifications.**

- 5.4. The purchaser does not allow other than the indicated delivery time.
- 5.5. Excluded from participation in the proceedings are entities in relation to which there are circumstances:
- described in Article 7 (1) of the Law of April 13, 2022, on special solutions to prevent support for aggression against Ukraine and to protect national security;
  - described in Article 5k of Council Regulation (EU) No. 833/2014 of July 31, 2014, concerning restrictive measures in connection with Russia's destabilizing actions in Ukraine.

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

Verification will be made on the basis of the Bidder's statement in accordance with **Attachment 1**.

## VI. DESCRIPTION OF PRICE CALCULATION METHOD

- How to calculate the bid price: the price should be calculated net and gross.
- Bids submitted in a currency other than PLN will 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.
- The price should include all costs associated with the preparation and execution of the subject of the request.
- 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 30/09/2024.**
- in electronic form (in the form of a scanned signed document or an electronically signed document) to: [barbara.wendolowska@polpharma.com](mailto:barbara.wendolowska@polpharma.com)
- 7.2. Submission of a bid will be considered successful if a complete bid is received at the e-mail box with the above address by the deadline specified in this section.
- 7.3. Bids submitted after the deadline will not be considered.

## 8. DESCRIPTION OF THE CRITERIA THAT THE CONTRACTING AUTHORITY WILL BE GUIDED BY WHEN SELECTING A BID

- 8.1. When evaluating bids, the Buyer will be guided by the given criteria:
- Price- 100%,
- 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 scoring of the bid will be done according to the formula:
- 8.4. The number of points ( $P_C$ ) in the criterion "Price" 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 criterion "Price"               |
| $C_N$ | - | of the non-rejected bids, the lowest total net bid price |
| $C_B$ | - | total net price of the tested offer                      |

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 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 decimal places.

## 9. DESCRIPTION OF BID PREPARATION

- 9.1. The bidder should prepare one price quotation in accordance with the model form attached as Annex 1 to the request.
- 9.2. The bidder may amend or withdraw its bid before the deadline for submission of bids.
- 9.3. Bidders are required to carefully review the information contained in the Price Request.
- 9.4. For matters related to this inquiry, please contact the Contracting Authority, e-mail: [barbara.wendolowska@polpharma.com](mailto:barbara.wendolowska@polpharma.com)

## 10. CHANGE THE CONTENT OF THE AGREEMENT

- 10.1 The Contracting Authority 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:
- 10.1.1. changes in the provisions of law, in the scope affecting the execution of the Agreement (in particular, changes in VAT rates);
- 10.1.2. improvement of the technical parameters of the subject of the Agreement, resulting from the update of solutions due to technological progress, without affecting the gross lump sum price.
- 10.1.3. extension of the deadline for execution of the Contract as a result of the necessity to perform additional work, the performance of which is necessary for proper execution of the Contract, and the performance of which the Ordering Party, acting with due diligence, could not have foreseen earlier, subject to section 10.1.6 below;
- 10.1.4. Extension of the deadline for execution of the Agreement as a result of force majeure, together with all consequences occurring in connection with such extension;
- 10.1.5. changes in the parameters of the subject matter of the Agreement, not leading to changes in the nature of the Agreement - technological changes, in particular: the need to implement the Agreement using other technical/technological, material solutions than those indicated in the Request for Proposal, in a situation where the use of the provided solutions would threaten non-performance or faulty performance of the Agreement, subject to item 10.1.7. below;
- 10.1.6. changes relate to the implementation of additional supplies or services of the Contractor, not covered by the Contract, if they have become necessary and all the following conditions have been met:
- the change of the Contractor cannot be made for economic or technical reasons, in particular concerning interchangeability or interoperability of equipment, services or installations, ordered under the basic subject of the Contract,
  - the change of the Contractor would cause significant inconvenience or a 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 net subject of the Agreement;

**10.1.7.** the change does not lead to a change in the nature of the Contract and the following conditions have been met jointly: - the need to amend the Contract is caused by circumstances that the Contracting Authority, acting with due diligence, could not foresee,

- the value of the change does not exceed 50% of the value of the original net subject of the Agreement;

**10.1.8.** The contractor is to be replaced by a new contractor:

- as a result of a merger, demerger, transformation, bankruptcy, restructuring or acquisition of the Contractor or its enterprise, provided that the new contractor meets the conditions for participation in the proceedings, there are no grounds for exclusion against it and it does not involve other material changes to the Contract,
- as a result of the Ordering Party's assumption of the Contractor's obligations to its subcontractors.

**10.2.** The Contracting Authority also provides for **the possibility of making non-substantive changes to the provisions of** the Contract in relation to the content of the offer on the basis of which the Contractor was selected.

**10.3.** Amendments to the Contract shall be made in the form of annexes signed by both Parties, and the possibility of their introduction shall be subject to acceptance by the Ordering Party.

## 11. OTHER INFORMATION

**11.1.** The bidder shall bear all costs associated with the preparation and submission of the bid.

**11.2.** Until the deadline for submission of bids, the Procuring Entity reserves the right to amend or supplement the contents of this price inquiry.

**11.3. The Procuring Entity reserves the right to negotiate bids with all bidders**, especially if the prices offered exceed the budget the Procuring Entity has allocated for the contract.

## 12. LIST OF ANNEXES

The following documents are attached to this Price Request:

Annex Designation	Name of the Annex
Appendix 1	Sample price form

## PRICING FORM

### **Bidder:**

<b>Full name (company) or first and last name</b>	
<b>Registered office/place of residence/address of main place of business</b>	
<b>The e-mail address to which the Employer should send correspondence related to the price inquiry</b>	
<b>NIP</b>	
<b>REGON</b>	
<b>Phone</b>	
<b>Contact person for the Purchaser</b>	

We offer to perform the subject of the contract for the *purchase and delivery of gelatin capsules.*, in accordance with the requirements of the **price** inquiry, for the **price of**

Part of	Subject of the price inquiry	i.m. pcs/package	Quantity	Net price PLN/EUR/USD per IU.	Total net value PLN/EUR/USD	Total gross value PLN/EUR/USD	Delivery time [please enter date in dd.mm.yyyy format].
1							
2							
3							
4							

**At the same time, we declare that:**

- a. we have familiarized ourselves with the Request for Quotation and its attachments and do not raise any objections, and we have acquired the necessary information to prepare our offer,
- b. by submitting this offer we are bound by it for a period of 60 days counting from the closing date for submission of offers,
- c. The price includes a lump-sum remuneration for all obligations of the future Contractor necessary to complete the subject of the Request for Quotation,
- d. By submitting this offer, we declare that we meet the conditions of participation specified in point. V of the price inquiry.
- e. By submitting this offer, we declare that there are no circumstances with respect to us:
  - described in Article 7 (1) of the Law of April 13, 2022, on special solutions to prevent support for aggression against Ukraine and to protect national security;

- described in Article 5k of Council Regulation (EU) No. 833/2014 of July 31, 2014 concerning restrictive measures in connection with Russia's destabilizing actions in Ukraine.

.....  
(place and date)

.....  
(signature)

**Bid attachments:**

- 1. ISO 9001:2015 certification**
- 2. EXCiPACT Certification**
- 3. Capsule quality document Technical Reference File (TRF)**