

Warsaw, 25 November 2022

PRICE INQUIRY NO. 18

In connection with the implementation of the project titled “Development of a universal fast-response platform, based on RNA technology, ensuring the national drug and epidemiological safety”, funded from the state budget by the Medical Research Agency, WZA Polfa Warszawa S.A., you are kindly requested to submit a bid **for the purchase and delivery of the reference drug Spinraza**.

I. NAME AND ADDRESS OF THE BUYER

Warszawskie Zakłady Farmaceutyczne Polfa Spółka Akcyjna

ul. Karolkowa 22/24

01-207 Warszawa

II. PRICE INQUIRY PROCEDURE

- 2.1. This Price Inquiry 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) choosing the best possible means and methods to meet the pre-defined objectives;
 - 3) ensuring transparency, fair competition and equal treatment of contractors.

III. DESCRIPTION OF THE SUBJECT OF THE PRICE INQUIRY

- 3.1. The subject of this Price Inquiry is the *purchase and delivery of 4 packages of the medicinal product named Spinraza 12 mg solution for injection*.
- 3.2. Scope of the Price Inquiry:
Purchase of 4 packages from one batch of the reference product named Spinraza (nusinersen) 12 mg solution for injection.
- 3.3. The subject of the Price Inquiry must be new.
- 3.4. The shelf life of each product supplied must be at least 12 months from the date of delivery to the Customer.
- 3.5. Partial bids or variants will not be accepted.

IV. PRICE INQUIRY DELIVERY SITE AND DATE

- 4.1. The subject of the Price Inquiry must be delivered at the Seller’s expense to the Buyer’s offices at: Warszawskie Zakłady Farmaceutyczne Polfa Spółka Akcyjna, ul. Barska 31, 01-207 Warszawa.
- 4.2. The date of delivery of the subject of the Price Inquiry: up to 60 days from the date when the order is placed.
- 4.3. Since the date of delivery of the subject of the Price Inquiry is a criterion for their evaluation, the order will be delivered as per the submitted bid, but not later than within 60 days from the date when the order is placed.

V. GENERAL REQUIREMENTS

- 5.1. The Buyer does not accept equivalent products.
- 5.2. The Buyer accepts other package sizes.
- 5.3. The Seller will supply quality certificates, if possible.
- 5.4. The Buyer does not accept submission of partial bids.

VI. METHOD OF PRICE CALCULATION

- 6.1. Bid price calculation: the price should be calculated as a net and a gross amount.
- 6.2. Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland (<https://www.nbp.pl/>) on the end date of the time limit for the submission of bids.
- 6.3. The price should include all the costs related to the preparation and performance of the subject of the Price Inquiry.
- 6.4. The price given in the bid cannot change during contract performance.

VII. CONTRACT AWARD CRITERIA

- 7.1. The bids will be evaluated based on the following criteria:
 - Price – 80%
 - Date of delivery – 20%
- 7.2. The evaluation criteria apply both to partial bids and bids covering all parts of the subject of the order. The evaluation will be performed and scores will be awarded for each part of the subject of the order separately, regardless of whether the bid covers all or only some parts of the subject of the order.
- 7.3. The scoring of the bid will be calculated according to the following formula:

$$O_P = P_C + P_S$$

where:

- O_P - the bid score
- P_C - score for the criterion 'price'
- P_S - score for the criterion 'time of delivery'

- 7.4. The score (P_C) for the criterion 'price' will be calculated as follows:

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

where:

- P_C - score for the criterion 'price'
- C_N - the lowest total net price based on non-rejected bids
- C_B - total net price of the bid under evaluation

Bids with the price given in a currency other than PLN will be converted to PLN at the average exchange rate of the National Bank of Poland on the end date of the time limit for the submission of bids.

- 7.5. The score (P_S) for the criterion 'time of delivery' will be calculated as follows:



$$P_C = \frac{C_N}{C_B} * 20 \text{ points}$$

where:

- P_C - score for the criterion 'time of delivery'
- C_N - the shortest time of delivery from among non-rejected bids
- C_B - time of delivery of the evaluated bid

The Buyer understands the date of delivery as time calculated in calendar days from the time when the Buyer receives a confirmation of acceptance of the order for delivery by the Seller.

- 7.6. The bid with the highest score out of all the non-rejected bids will be considered the best bid. The maximum score that can be awarded is 100 points. Calculations will be made to two decimal places.

VIII. PLACE AND DATES FOR SUBMITTING AND OPENING BIDS

- 8.1. The final deadline for submitting bids is 06 December 2022 by 11:59 p.m.: in electronic format as scanned documents to the following address: beata.zywicka@polpharma.com
- 8.2. The date and the time when the bid is received by the Buyer determines whether the delivery date has been complied with.
- 8.3. No bids submitted past the submission deadline will be considered.
- 8.4. The Buyer is not planning to hold a public opening of the bids.
- 8.5. Bids may be modified or withdrawn prior to the end of the time limit for the submission of bids.

IX. PREPARATION OF BIDS

- 9.1. The Seller must draw up a single price bid using the form attached as Appendix 1 hereto. Submitting more than one bid for a particular part will result in all bids submitted by the Seller being rejected.
- 9.2. Bid must be prepared in the Polish or English language version.
- 9.3. Bidders are required to carefully read the information contained in the Price Inquiry.
- 9.4. Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Bidders.
- 9.5. Until the end of the time limit for the submission of bids, the Customer reserves the right to amend or add new information to this Price Inquiry.
- 9.6. The submitted bids will remain valid and binding for 30 days from the end date of the time limit for the submission of bids.

X. COMMUNICATIONS BETWEEN THE BUYER AND SELLERS, PERSONS AUTHORIZED FOR CONTACT

- 10.1. During the tender procedure the Buyer and the Seller submit all statements, requests, notices and information in Polish or in English.
- 10.2. The receipt of any notices, statements, requests and information submitted electronically must be immediately confirmed at the request of either Party.

- 10.3. If the Seller has not confirmed the 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 in a way that enables the Seller to read it.
- 10.4. Any correspondence about this Price Inquiry should be sent to e-mail: beata.zywicka@polpharma.com
- 10.5. In any correspondence related to this Price Inquiry, the Seller should use the procedure number: Price Inquiry No. 18.
- 10.6. Ms. Beata Żywicka is the person authorized to communicate with the Seller.
- 10.7. No information, clarifications or replies to any queries submitted to the Buyer will be provided orally or by phone.
- 10.8. Any questions about this Price Inquiry should be sent by e-mail to the address provided above, not later than 3 days before the end of the time limit for the submission of bids.
- 10.9. Replies to the answers and adding more detailed information to the Price Inquiry following from questions from prospective Sellers will be sent to the entity requesting that information.

XI. BID EVALUATION PROCEDURE AND PUBLICATION OF RESULTS

- 11.1. During the examination and evaluation of the submitted bids, the Buyer may request the Sellers to provide additional information (if it does not infringe competition) and clarifications related to the submitted bids. The Buyer may also ask the Sellers to correct evident mistakes and calculation errors.
- 11.2. The Buyer reserves the right to verify, during the procedure, the documents, statements, lists, data and information provided by the Sellers.
- 11.3. If two or more Sellers have the same score, the bid which is best in terms of the environmental and climate impact will be selected. For the purpose, the Buyer has a right to request the Sellers with the highest final score to supplement the bid with more information requested by the Buyer with respect to the environmental impact of the subject of the bid.

XII. AMENDMENTS TO THE CONTRACT

- 12.1. The Buyer reserves the right to make material amendments to the concluded contract in relation to the bid on the basis of which the Seller was selected to the following extent and in the following situations:
 - 12.1.1. changes to the European Union or national law that affect the performance of the Contract (in particular changes of the VAT rate);
 - 12.1.2. improving technical standards of the subject of the order resulting from new solutions brought about by technological progress, without any impact on the gross flat rate;
 - 12.1.3. extending the deadline for the performance of the Contract due to additional work which must be completed for the proper performance of the Contract and which the Buyer, acting with due diligence, could not have foreseen earlier, subject to subsection 12.1.6 below;
 - 12.1.4. extending the deadline for the performance of the Contract due to force majeure, with all the consequences of such extension;
 - 12.1.5. changing the parameters of the subject of the Contract which does not lead to a change in the nature of the Contract – technological changes, in particular: the need to perform the Contract using technical/technological or material-related solutions other than as specified in the Price Inquiry if the application of the planned solutions could lead to a failure to perform or to improper performance of the Contract, subject to subsection 12.1.7 below;
 - 12.1.6. changes relate to additional supplies or services from the Seller which are not covered by the Contract, as long as they are necessary and all of the following conditions are met: – the Seller cannot be changed due to economic or technical reasons, in particular relating to the



- interchangeability or interoperability of the equipment, services or installation ordered in connection with the original subject of the Contract, – the change of the Seller would cause significant inconvenience or a considerable increase of costs for the Buyer,
- the value of each subsequent change does not exceed 50% of the value of the original subject of the Contract (net amount);
- 12.1.7. the change does not lead to a change in the nature of the Contract and all of the following conditions are met: – the Contract must be changed due to the circumstances which the Buyer, acting with due diligence, could not have foreseen,
- the value of the change does not exceed 50% of the value of the original subject of the Contract (net amount);
- 12.1.8. The Seller may be replaced with a new contractor:
- as a result of merger, division, transformation, bankruptcy, restructuring or purchase of the Seller or its enterprise as long as the new contractor meets the conditions for participating in the tender procedure, there are no grounds for exclusion and the change does not entail other material changes to the Contract,
 - as a result of the Buyer taking over the Seller's obligations towards his subcontractors.
- 12.1.9. No amendment of the Contract will result in changes to its nature.
- 12.2. The Buyer also allows for making non-material amendments to the concluded Contract in relation to the bid on the basis of which the Seller was selected.
- 12.3. Amendments to the Contract will be made in the form of an annex signed by both parties and they are subject to the Buyer's approval.

XIII. ADDITIONAL INFORMATION

- 13.1. Submitted bids will remain valid and binding for 30 days from the end date for the submission of bids. Following the procedure the Buyer may conclude a Contract for the performance of the subject of the order with the Seller whose bid is considered to be the best. The selection of the best bid does not mean that the Buyer is obliged to conclude a Contract with the Contractor.
- 13.2. The Buyer reserves the right to place with the Seller additional orders, not covered by the Subject of the original Price Inquiry, up to 50% of the value of the Subject of the original Price Inquiry, necessary for the proper performance of the task and resulting among others from the following circumstances:
- due to technical or organizational reasons, the separation of the additional order from the Subject of the original Price Inquiry would incur excessively large costs,
 - the performance of the Subject of the original Price Inquiry depends on the performance of the additional order.
- 13.3. The Buyer reserves the right to place with the Seller a supplementary order (consistent with the description of the subject of the original order) up to 50% of the value of the original order specified in the contract concluded with the Seller.
- 13.4. The Buyer makes the reservation that it has:
- the right not to choose any of the submitted Bids;
 - the right to cancel the Tender Procedure at any time, without giving a reason or without prior notification of the Bidders;
 - the right to change or supplement the documents making up the Price Inquiry, in which case such documents will become an integral part of the Inquiry;
 - the right to extend the time limit for the submission of bids;
- and the Bidders have no claims against the Buyer with respect to the above rights.



13.5. PERSONAL DATA PROTECTION.

As far as personal data contained in bids are concerned, the Buyer – as soon as the bid is submitted – will become the Data Controller as defined under 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 Buyer will process the data for the purposes of bid assessment, concluding agreement with the awarded contractor and implementing the concluded agreement, i.e. under Article 6(1)(b) of the GDPR.

The Buyer will transfer the personal data contained in the submitted bids, under relevant regulations, to authorized bodies and institutions entitled to audit projects co-financed from the funds of the Medical Research Agency. For more information on the processing of personal data by competent institutions, visit <https://abm.gov.pl/pl/wolnytekst/198,Polityka-dotyczaca-cookies.html>

The Buyer will process the personal data throughout the period during which it is required, under relevant regulations, to store the whole documentation related to projects co-financed from the funds of the Medical Research Agency.

XIV. LIST OF APPENDICES

The following appendices are attached to this Price Inquiry:

Appendix number	Appendix title
Appendix 1	Bid Form
Appendix 2	Model statement on the absence of grounds for exclusion from the tender procedure



Appendix 1 to the Price Inquiry No. 18

BID FORM

Bidder:

Name / Company	
Registered office/home address/address of the principal place of business	
E-mail address for the Buyer to send information related to the Price Inquiry	
NIP [Taxpayer ID Number]	
REGON [Statistical ID Number]	
Phone number	
Contact person for the Buyer	

We offer the delivery of the order for the **purchase and delivery of the reference drug Spinraza.**

.....,
in accordance with the terms of the Price Inquiry **for the following price:**

No. of packages	Subject of the Price Inquiry	Expiry date	Batch number	Country of manufacture	MAH	Total net value PLN / EUR*	Payment terms



We also declare as follows:

- a.** We have read the Price Inquiry and appendices thereto, we raise no objections and we have obtained the information necessary to prepare our bid.
- b.** Our bid price includes a lump sum that covers for all the obligations of the future Seller as necessary to deliver the subject of this Price Inquiry.
- c.** Our bid will remain valid and binding for 30 days from the end date of the time limit for the submission of bids.

.....
(place and date)

.....
(signature(s) of person(s) authorized to submit
statements of will on behalf of the Bidder)



.....
(Seller's stamp)

Buyer:

Warszawskie Zakłady Farmaceutyczne Polfa Spółka Akcyjna

ul. Karolkowa 22/24

01-207 Warszawa

ACKNOWLEDGEMENT FORM

I declare that when submitting a bid for the **purchase and delivery of the reference drug Spinraza** funded from the state budget by the Medical Research Agency, **I have no capital or personal ties with the Customer:** WZF Polfa Spółka Akcyjna.

Capital or personal ties mean mutual ties between the Bidder and the Buyer or persons authorized to contract obligations on behalf of the Buyer, or persons performing on behalf of the Buyer any actions involved in the preparation and performance of the Seller selection procedure, including in particular:

- a) participation in the company in the capacity of a partner in a civil law company or partnership;
- b) holding of at least 10% of stocks or shares;
- c) holding the function of a member of a supervisory or management body, a commercial representative or an attorney;
- d) being married to or having lineal consanguinity or direct affinity, collateral consanguinity or affinity to the second degree to or being adopted by, under the guard or custody of the beneficiary or of such persons.

I also declare that **I am not an entity designated in the Act of 13 April 2022 on Special Measures to Counteract the Support of Aggression Against Ukraine and to Protect National Security.**

.....
(place and date)

.....
(signature(s) of person(s) authorized to submit statements of will on behalf of the Seller)