Warsaw, 06 May 2024

PRICE INQUIRY NO. SEMA/33/A/PR52982-56041/2024

In connection with the implementation of the project titled "Design and development of an innovative solution – a drug belonging to the class of GLP-1 receptor agonists in the treatment of type 2 diabetes", funded from the state budget by the Medical Research Agency, Zakłady Farmaceutyczne Polpharma S.A. kindly request you to submit bids for the **purchase of a service related to the development and delivery of reusable injector pens.**

I. NAME AND ADDRESS OF THE CUSTOMER

Zakłady Farmaceutyczne Polpharma Spółka Akcyjna

ul. Pelpińska 19, 83-200 Starogard Gdański

II. PRICE INQUIRY PROCEDURE

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. 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

III.1. The subject of this Price Inquiry is **the purchase of a service related to the development and delivery of reusable injector pens. The service consists of three stages.**

III.2. Stages and scope of service:

3.2.1. Development of reusable injector pens and performance of formative usability testing according to ISO 11608-1:2022.

3.2.2. Delivery of the developed reusable injector pens at the stage of medicinal product development.

3.2.3. Delivery of the developed reusable injector pens at the stage of medicinal product manufacturing validation.

III.3. The subject of contract is as follows:

3.3.1. For Section 3.2.1. provision of the following documents in English:

3.3.1.1. Technical documentation of the device containing;

3.3.1.1.1. Product specification

3.3.1.1.2. List of components of the injector pen

3.3.1.1.3. 3D CAD models and technical drawings of the injector pen, dosing mechanism, cartridge holder and cap (including critical dimensions and tolerances)

3.3.1.1.4. Report on measurements of accuracy of the administered dose

3.3.1.2. Process documentation of the device including:

3.3.1.2.1. Project validation protocol and report (with standard cartridges filled with water or saline)

3.3.1.2.2. Process validation protocol and report

3.3.1.2.3. Usability testing protocol

3.3.2. For sections 3.2.2 and 3.2.3. providing the appropriate number of reusable injector pens, in accordance with the Detailed Price Inquiry Specification.

III.4. A detailed description of the scope of the service (**Appendix 3)** for each of the stages described in 3.2.1-3.2.3 will be made available to Contractors after signing the Confidential Disclosure Agreement **(Appendix 4).**

To sign the Confidential Disclosure Agreement, please contact via email at: barbara.wendolowska@polpharma.com. The Contractor should send the completed Confidential Disclosure Agreement in editable version via email to barbara.wendolowska@polpharma.com. After the receipt of the Confidential Disclosure Agreement, signatures by authorised person(s), in accordance with the rules of representation of the respective Contractor, will be collected via the DocuSign platform. The Customer will make *Appendix 3* hereto available via digital channels no later than within two business days of signing the Confidential Disclosure Agreement.

III.5. The Customer does not accept partial or variant bids, since the development and delivery of reusable injector pens and performance of formative usability testing must be carried out by a single Bidder for reasons of compatibility.

III.6. CPV code: 33100000-1 Medical devices.

IV. PRICE INQUIRY DELIVERY SITE AND DATE

IV.1. Time limit for delivery of the subject of contract:

4.1.1. The subject of contract described in section 3.2.1 will be delivered within 24 months counting from the date of signing the contract.

4.1.2. The delivery date of the subjects of contract described in sections 3.2.2 and 3.2.3 will be agreed with the Customer, with the Bidder undertaking to deliver the order no later than 60 days from the order date.

IV.2. The subject of contract described in sections 3.2.2 and 3.2.3. must be delivered to the Customer's offices at: **Zakłady Farmaceutyczne Polpharma Spółka Akcyjna, Dział Badań i Rozwoju [Research and Development Department], ul. Barska 31, 02-315 Warszawa.**

V. CONDITIONS FOR PARTICIPATING IN THE PROCEDURE

V.1 The tender procedure is open to any Contractors who meet all of the following requirements:

1. The Contractor has at least five years of experience in the development of devices for the administration of drugs for subcutaneous and intramuscular injection (Contractor will provide a reference list of implemented/certified injector pens (at least one) together with a list of markets for which they were introduced)

   Assessment procedure:

   The Customer will accept that this requirement has been met by the Contractor if the Contractor submits

   declaration on fulfilment of the conditions for participating in the procedure (Appendix 2 to the Request for Quotations) and provides the above list.

2. The Contractor holds valid ISO 13485:2016 certificate to be submitted along with the bid.
   Assessment procedure:
   The Customer will accept that this requirement has been met by the Contractor if the Contractor submits declaration on fulfilment of the conditions for participating in the procedure (Appendix 2 to the Request for Quotations) and provides the above certificate.

V.2 Confirmation of the sanctions statement.

Entities for which the following circumstances occur are excluded from the tender:

- 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: *Verification will take place on the basis of the Bidder's declaration provided in Appendix 1. The Customer reserves the right to verify the fulfilment of the conditions at the Bidder's site or to call for relevant documentation to be submitted.*

V.3 The Contractor will sign the Confidential Disclosure Agreement prior to the commencement of work.

V.4 Bids submitted by Contractors who demonstrate that they meet the specified requirements will be taken forward to the bid examination and evaluation stage. Compliance with the above conditions will be assessed based on a 'meet/does not meet' basis. Bids submitted by Contractors who fail to meet any of the above requirements will be rejected.

VI. METHOD OF PRICE CALCULATION

VI.1. Bid price calculation: the price should be calculated as a net amount.
VI.2. For the purpose of the evaluation, the 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/) as at the final date for the submission of bids.
VI.3. The price should include all the costs related to the preparation and performance of the subject of the Price Inquiry.
VI.4. The price given in the bid cannot change during contract performance.

VII. CONTRACT AWARD CRITERIA

VII.1. The following criteria will be used by the Customer for the assessment of bids:
- Price – 70%,

- Warranty period for developed pens – 20%,
- Spring mechanism for dose delivery – 10%

VII.2. The scoring of the bid will be calculated according to the following formula:

$$\boldsymbol{O_P = P_C + P_G + P_S}$$

where:

O_P	-	the bid score
P_C	-	score for the criterion 'Price'
P_G	-	score for the criterion "Developed pen warranty period"
P_S	-	score for the criterion "Spring mechanism for dose delivery"

VII.3. The score (P_c) for the criterion 'Price' will be calculated as follows:

$$P_C = \frac{C_N}{C_B} * 70 \text{ points}$$

where:

P_C - score for the criterion 'Price'
C_N - the lowest net price proposed in the bids which were not rejected
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 as at the final date for the submission of bids.

VII.4. The score (P_G) for the criterion "Developed pen warranty period" will be calculated according to the formula**:**

$$P_G = \frac{G_N}{G_B} * 20 \text{ points}$$

where:

P_G - score for the criterion "Developed pen warranty period"
G_N - pen warranty period in the bid under evaluation

G_B - the longest warranty period for developed pens proposed in the bids which were not rejected

the Customer understands that the warranty period for developed pens is the maximum period of use of the pens by patients at 2°C–25°C, calculated in calendar months.

The bid will be rejected if the warranty period for developed pens is shorter than 24 months at 2°C-25°C.

VII.5. Score (P_s) for the criterion "Spring mechanism for dose delivery" will be calculated as follows:

$P_s = 0$ points – out of all the non-rejected bids, the developed pen does not have a spring mechanism for dose delivery

$P_s = 10$ points – out of all the non-rejected bids, the developed pen has a spring mechanism for dose delivery

VII.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

VIII.1. The final deadline for submitting bids is **13 May 2024**.
- in electronic form to the address: barbara.wendolowska@polpharma.com in the form of scans of documents or electronically signed documents.

VIII.2. The date and the time when the bid is received by the Customer determines whether the submission deadline has been complied with.

VIII.3. No bids submitted past the submission deadline will be taken into consideration.

VIII.4. The Customer is not planning to hold a public opening of the bids.

VIII.5. Bids may be modified or withdrawn prior to the end of the time limit for the submission of bids.

IX. PREPARATION OF BIDS

IX.1. The Seller must draw up a single price bid using the form attached as Appendix 1 hereto. Submitting more than one bid will result in all bids submitted by the Seller being rejected.

IX.2. The Buyer does not accept equivalent products.

IX.3. The Buyer does not accept quantities other than those specified.

IX.4. The Buyer does not accept submission of partial bids.

IX.5. The bid must be prepared in Polish or English language version.

IX.6. Bidders are required to carefully read the information contained in the Price Inquiry.

IX.7. Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Bidders.

IX.8. 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.

IX.9. The Bidder submitting the bid remains bound by it for 90 calendar days from the end date of the time limit for the submission of bids.

IX.10. The minimum payment term for an invoice is 30 days from the date of its issue.

IX.11. If the supplier's income earned in association with project execution is subject to withholding tax in Poland, ZF Polpharma S.A. is obliged by law to deduct the withholding tax from the supplier's remuneration and remit it to the Polish tax authorities (remuneration includes withholding tax).

IX.12. Transfer to the Principal (within the agreed remuneration) of all exclusive rights and any and all transferable other rights to intangible property that arise in connection with the delivery of the subject of order (hereinafter referred to as "Intellectual Property Rights"). Accordingly, all

Intellectual Property Rights arising in connection with the delivery of the order will become the sole property of the Principal. The scope of Intellectual Property Rights includes the "work", the "inventive design" and the "know-how", which will be specified in detail in the order.

X. COMMUNICATIONS BETWEEN THE CUSTOMER AND SELLER, PERSONS AUTHORISED FOR CONTACT

X.1. During the tender procedure, the Customer and the Seller will submit all statements, requests, notices and information in Polish or in English.

X.2. The receipt of any notices, statements, requests and information submitted electronically must be immediately confirmed at the request of either Party.

X.3. If the Seller has not confirmed the receipt of the correspondence, the Customer will assume that the correspondence sent by the Customer to the email address provided by the Seller has been delivered in a way that enables the Seller to read it.

X.4. Any correspondence about this Price Inquiry should be sent to email: barbara.wendolowska@polpharma.com

X.5. In any correspondence related to this Price Inquiry, the Seller should refer to the tender number: Price Inquiry No. **SEMA/33/A/PR52982-56041/2024.**

X.6. The person authorised to communicate with the Seller is Ms. Barbara Wendołowska.

X.7. No information, clarifications or answers will be provided orally or by phone to queries addressed to the Customer.

X.8. Any questions about this Price Inquiry should be sent by email to the address provided above, not later than 3 days before the end of the time limit for the submission of bids.

X.9. Replies to the questions and more detailed information on the Price Inquiry following from questions asked by prospective Sellers will be sent to the entity requesting that information.

XI. BID EVALUATION PROCEDURE AND PUBLICATION OF RESULTS

XI.1. During the examination and evaluation of the submitted bids, the Customer may request the Seller to provide additional information (if this does not infringe competition) and clarifications related to the submitted bids. The Customer may also ask the Seller to correct evident mistakes and calculation errors.

XI.2. The Customer reserves the right to verify, during the bid evaluation, the documents, statements, lists, data and information provided by the Sellers.

XI.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 this purpose, the Customer has the right to request the Bidders with the highest final score to supplement the bid with more information requested by the Customer with respect to the environmental impact of the subject of the bid.

XI.4. The Customer reserves the right to cancel the tender without stating the reason.

XI.5. If the tender procedure is cancelled, suppliers will not be entitled to claim reimbursement of the costs of participating in the tender.

XI.6. When the Contractor was notified of the selection of its bid, withdrawal by the Customer from concluding the contract may not be the basis for a claim for the costs incurred in participating in the tender.

XI.7. During the evaluation of the submitted bids, the Customer may request that the Contractors provide clarifications on the content of the documents submitted by them.

XI.8. If the bid does not contain all the required elements, the Customer may, in justified cases, request the Contractor to supplement it.

XI.9. **The Customer reserves the right to negotiate bids with all Bidders**, especially if the price offered by the Contractor exceeds the budget intended by the contracting institution for the execution of the contract. Negotiations may have several rounds, with the possibility to invite the bidder to submit an updated bid after each round of negotiations.

XII. CONTRACT TERMS

XII.1. All deliveries of goods, works, services and rights will be based solely on contracts or Orders, an integral part of which is constituted, in each case, by the Customer's General Terms and Conditions of Contracting. Unless otherwise agreed, the General Terms and Conditions of Contracting preclude the application of any of the Contractor's general terms and conditions.

XII.2. The settlement for payment for stage 3.2.1 will be made according to the following schedule:
XII.2.1 30% – upon signing the contract, commencement of work
XII.2.2 30% – upon approval of the specification of injector pens
XII.2.3 40% – at the end of development, upon delivery of all documents described in section 3.3.1.

XII.3. The settlement for payment for stages 3.2.2 and 3.2.3 will take place upon receipt of the delivery of injector pens by the Customer against the issued invoice.

XII.4. The Supplier will be required to pay contractual penalties for:

12.4.1. postponement of the order delivery deadline for each day of delay if the delay is not attributable to the Customer,

12.4.2. improper performance of the contract;

12.4.3. incomplete performance of the contract.

XII.5. The Customer reserves the right to **make material amendments to the Contract** for the services offered as compared to the bid based on which the Contractor was awarded the contract, to the following extent and in the following situations:

12.5.1. to reflect changes in the law to the extent that they affect performance of the Contract (in particular changes in VAT rates);

12.5.2. to improve technical parameters of the subject of the Contract resulting from updated solutions brought about by technological progress, without any impact on the gross flat rate

12.5.3. to extend the deadline for the performance of the Contract due to additional works which need to be carried out to ensure proper performance of the Contract and which the Customer, while exercising due diligence, could not have foreseen beforehand, subject to section 12.5.6 below;

12.5.4. to extend the deadline for the performance of the Contract due to force majeure, with all the consequences of such extension;

12.5.5. to change the parameters of the subject of the Contract without altering the nature of the Contract – technology-related changes, in particular: the need to perform the Contract using other solutions – in terms of technology or materials – than those specified in the Request for Quotation in the event that the use of the original solutions could lead to non-performance or improper performance of the Contract, subject to section 12.5.7 below;

12.5.6. changes relate to additional deliveries or services from the Contractor which are not covered by the Contract, provided that they have become necessary and that all of the following conditions are met:
– Contractor cannot be replaced due to economic or technical reasons, in particular relating to the interchangeability or interoperability of equipment, services or systems contracted

under the original Contract,
– Contractor replacement could cause significant inconvenience or a material increase in costs for the Customer,
– each subsequent change does not exceed 50% net of the original Contract net amount;

12.5.7. the change does not lead to a change in the nature of the Contract and all of the following conditions are met:
– the Contract needs to be changed due to circumstances which could not have been foreseen by the Customer while exercising due diligence,
– the change does not exceed 50% of the original Contract net amount;

12.5.8. Contractor is to be replaced with a new contractor:
– as a result of merger, division, transformation, bankruptcy, restructuring or purchase of Contractor or its enterprise as long as the new contractor meets the conditions for participating in the procedure, there are no grounds for its exclusion and the change does not result in other material amendments to the Contract,
– as a result of the Customer taking over Contractor's obligations towards its subcontractors;
– amendment of the Contract does not result in changes to its nature.

12.5.9. The Customer also **allows for making non-material amendments to the concluded Contract** in relation to the bid on the basis of which the Contractor was selected.

12.5.10. Amendments to the Contract will be made in the form of annexes signed by both Parties and will require approval from the Customer.

XIII. ADDITIONAL INFORMATION

XIII.1. Any costs and expenses incurred in connection with the preparation and submission of bids are to be paid by the respective Bidders.

XIII.2. 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.

XIV. LIST OF APPENDICES

The following appendices are attached to this Price Inquiry:

Appendix number	Appendix title
Appendix 1	Bid Form
Appendix 2	Declaration on Fulfilment of the Conditions of the Request for Quotation
Appendix 3	Detailed Price Inquiry Specification
Appendix 4	Confidential Disclosure Agreement – template

Appendix 1 to the Price Inquiry No. ***SEMA/33/A/PR52982-56041/2024***

BID FORM

Bidder:

Name / Company	
Registered office/place of residence/address of the principal place of business	
Email address for the Customer to send correspondence related to the Price Inquiry	
NIP [Taxpayer ID Number]	
REGON [Statistical ID Number]	
Phone number	
Contact person for the Customer	

We offer the delivery of the subject of contract for **the purchase of a service related to the development and delivery of reusable injector pens,** in accordance with the requirements of the Price Inquiry, for the following **price:**

Contract Stage No.	Subject of the Price Inquiry	Total net value PLN/EUR/USD*	Delivery date:
1	Development of reusable injector pens and performance of formative usability testing according to ISO 11608-1:2022 (in accordance with Detailed Price Inquiry Specification).		**……. months counted from the contract signature date**
2	Delivery of the developed reusable injector pens at the stage of medicinal product development (in accordance with the quantities specified in the Detailed Price Inquiry Specification).		**……. days calculated from the agreed order date**
3	Delivery of the developed reusable injector pens at the stage of medicinal product manufacturing validation (in accordance with the quantities specified in the Detailed Price Inquiry Specification).		**……. days calculated from the agreed order date**

Proposed invoice payment date (minimum 30 days) – ___

We declare that the warranty period for developed pens is **……. months** at 2°C–25°C**.**

We declare that the developed reusable pens **have/do not have*** a spring mechanism for dose delivery.

***DELETE AS APPROPRIATE**

We also declare that:

a. We have read the Price Inquiry and appendices thereto and 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 all the obligations of the Seller** as necessary to deliver the subject of this Price Inquiry,
c. Our bid will remain valid and binding for 90 calendar days from the end date of the time limit for the submission of bids,
d. We represent that the following circumstances do not apply to us:
    a) 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;
    b) 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(s) of person(s) authorised to submit statements of will on behalf of the Bidder)

Appendix 2 to the Request for Quotations No. **SEMA/33/A/PR52982-56041/2024**

DECLARATION ON FULFILMENT OF THE CONDITIONS SET OUT IN THE REQUEST FOR QUOTATION

…… *(name of the Bidder)* declares that it fulfils the conditions set out in the Request for Quotation within the following scope:

1. The Contractor has at least five years of experience in the development of devices for the administration of drugs for subcutaneous and intramuscular injection.
2. The Contractor holds ISO 13485:2016 certificate.

Appendices to the Declaration:

1. Reference list of implemented/certified injector pens along with the list of markets in which they were introduced
2. ISO 13485:2016 certificate

…… (place and date)

…… (signature(s) of person(s) authorised to submit statements of will on behalf of the Bidder)