

APPENDIX NO. 1A

to procedure no. GG-V- 2025-377-225291- 2000000166

REQUEST FOR PROPOSALS**1. NAME AND ADDRESS OF THE ORDERING PARTY**

Polpharma Biologics Spółka Akcyjna
ul. Trzy Lipy 3
80-172 Gdańsk

2. MODE OF CONTRACT AWARD AND TYPE OF CONTRACT

The procurement will be conducted by means of a request for proposals in accordance with the principle of competitiveness set forth in the Guidelines for the Eligibility of Expenditures for 2021-2027 in the version dated March 14, 2025. The Act of September 11, 2019 shall not apply to this Request for proposals. Public Procurement Law (Dz. U. of 2019, item 2019, as amended).

3. PLACE AND METHOD OF SUBMITTING PROPOSALS

- 3.1. The proposal must be submitted electronically through the Competitive Database service, in accordance with the requirements of the "Bidder's Instructions in BK2021" [https://archiwum-bazakonkurencyjnosci.funduszeuropejskie.gov.pl/info/web_instruction] in the form of documents signed by the Bidder or scans thereof.
- 3.2. The deadline is determined by the date and time of submission of the Proposal to the Competitive Database service.
- 3.3. Proposals submitted after the deadline will not be considered.
- 3.4. A bidder may submit only one Proposal. Submission of two or more Proposals will result in rejection of all Proposals submitted by that Bidder
- 3.5. The Ordering Party does not provide for the public opening of Proposals.

4. METHOD OF COMMUNICATION BETWEEN THE ORDERING PARTY AND CONTRACTORS, CONTACT PERSONS

- 4.1. No information, explanations or answers to inquiries addressed to the Ordering Party by telephone or e-mail shall be provided.
- 4.2. Questions regarding the Request for Proposals and requests for clarifications regarding the content of the Request for Proposals should be sent only through the Competitiveness Database via the "Questions" tab on the Request for Proposals page [<https://bazakonkurencyjnosci.funduszeurope.gov.pl/>], no later than by the end of the day

on which half of the deadline for submission of Proposals expires. After the expiry of such deadline, the Ordering Party may leave the question unanswered. Extension of the deadline for submission of Proposals does not affect the deadline for submission of the aforementioned application.

- 4.3. Responses to Bidders' questions and clarifications to the content of the Request for Proposals will be provided to Bidders only in such a way that the Ordering Party publishes the content of the questions/requests for clarifications, along with the answers/clarifications provided, on the Request for Proposals site in the Competitiveness Database website [<https://bazakonkurencyjnosci.funduszeuropejskie.gov.pl/>].

5. DESCRIPTION OF THE SUBJECT OF THE CONTRACT

5.1. Announcement category: Services / Other Services

5.2. Brief description of the subject of the contract:

	Skrócony opis przedmiotu zamówienia/ Short description of the subject of the contract
	<p><i>Analiza wiązania przeciwciała monoklonalnego do FcRn metodą SPR. Analiza powinna dostarczyć wyników dotyczących względnego wiązania i powinowactwa dla każdej testowanej próbki. Zastosowana metoda analityczna powinna mieć potwierdzone parametry działania (co najmniej specyficzność i precyzję) dla badanego przeciwciała. Szacunkowa liczba próbek do analizy w 2025 roku wynosi do 45. Szczegóły zostaną udostępnione, jeśli będzie to wymagane, po uprzednim podpisaniu umowy o zachowaniu poufności (CDA) między stronami.//</i></p> <p><i>Analysis of monoclonal antibody binding to FcRn by SPR. The analysis should provide relative binding and affinity results for each tested sample. The analytical method applied should have confirmed performance characteristics (at minimum, specificity and precision) for the antibody of interest. The estimate for 2025 includes the analysis of up to 45 samples. Further details will be provided, if required, after the prior signing of a confidentiality agreement (CDA) between the parties.</i></p>

5.3. Place of contract execution: Voivodeship: pomorskie Powiat: gdansk City: GDAŃSK

5.4. Purpose of order:

Continuation of research under project “Development of an innovative drug form containing monoclonal antibody for therapy of non-specific enteritis - phase II” under The European Funds for a Modern Economy 2021-2027 Programme, action SMART Path.

5.5. Subject of the Contract

Szczegółowy opis przedmiotu zamówienia/ Detailed description of order		
Lp.	Przedmiot zamówienia/order subject	Ilość/quantity
1.	Analiza wiązania przeciwciała monoklonalnego do FcRn metodą SPR - Q2 2025// Analysis of monoclonal antibody binding to FcRn by SPR - Q2 2025	do 15 prób/ up to 15 samples
2.	Analiza wiązania przeciwciała monoklonalnego do FcRn metodą SPR - Q3 2025// Analysis of monoclonal antibody binding to FcRn by SPR - Q3 2025	do 15 prób/ up to 15 samples
3.	Analiza wiązania przeciwciała monoklonalnego do FcRn metodą SPR - Q4 2025// Analysis of monoclonal antibody binding to FcRn by SPR - Q4 2025	do 15 prób/ up to 15 samples

Warunki/ Conditions	
Harmonogram realizacji usługi/ Timelines for execution of the service	<p>Q2 2025 - Analiza do 15 prób// Q2 2025 - Analysis up to 15 samples Q3 2025 - Analiza do 15 prób//Q3 2025 - Analysis up to 15 samples Q4 2025 - Analiza do 15 prób//Q4 2025 - Analysis up to 15 samples</p> <p>Uwaga: Liczba próbek może ulec zmianie. Łącznie planowana jest analiza do 45 próbek. Liczba ta może również zostać zmniejszona w zależności od potrzeb programu.//</p> <p>Note: The number of samples might change. In total, it is planned to analyze up to 45 samples. This number might also be reduced based on the program's needs.</p>

Warunki formalne/ Formal conditions	<p>Podpisanie umowy o zachowaniu poufności – chyba że została podpisana wcześniej przy realizacji innych zamówień lub obowiązuje inny dokument, który reguluje poufność między stronami i pokrywa zakres ujawnianych informacji.</p> <p>Wzór Załącznika nr 3 zostanie udostępniony na wezwanie Oferenta.</p> <p>// Signing a confidentiality agreement - unless one has already been signed for previous orders or another document regulating confidentiality between the parties is in place and covers the scope of the disclosed information.</p> <p>The template for Appendix No. 3A will be provided upon the request of the Bidder.</p> <p>Wyrażenie zgody na audyt kwalifikacyjny dostawcy, jeśli nie został jeszcze zweryfikowany przez Polpharma Biologics S.A.// Consent to a supplier qualification audit, if not yet verified by Polpharma Biologics S.A.</p> <p>Gotowość do podpisania Umowy Jakościowej z Polpharma Biologics, jeśli taka jeszcze nie została podpisana pomiędzy Zamawiającym a Oferentem lub zakres dotychczasowej nie obejmuje aktywności wskazanych w niniejszym zapytaniu ofertowym.// Willingness to sign a Quality Agreement with Polpharma Biologics, if one has not yet been signed between the Ordering Party and the Bidder, or if the scope of the existing agreement does not cover the activities specified in this request for proposal.</p>
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Warunki dopuszczające / Enabling conditions	<p>Dostawca usług musi mieć doświadczenie w technologii opartej na SPR oraz w pełni opracowaną metodę oceny wiązania przeciwciała docelowego z FcRn, z potwierdzoną specyficznością i precyzją pośrednią. Metoda musi być specyficzna dla badanego przeciwciała i odporna na związki matrycowe. Powinna dostarczać wyniki dotyczące względnego wiązania i powinowactwa badanego przeciwciała podczas interakcji z receptorem FcRn. Analizy muszą</p>
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	<p>być przeprowadzane zgodnie z uznanymi praktykami naukowymi i uzupełnione w pełni możliwą do przesłania dokumentacją.//</p> <p>The service provider must have experience in SPR-based technology and a fully developed method for assessing the binding of the antibody of interest to FcRn, with confirmed specificity and intermediate precision. The method must be specific to the tested antibody and robust against matrix compounds. It should provide results for the relative binding and affinity of the tested antibody when interacting with the FcRn receptor. The analyses must be conducted in accordance with sound scientific practices and accompanied by fully traceable documentation.</p>
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<p>Wymagane dokumenty do złożenia oferty/ Documents required for offer submission</p>	<ol style="list-style-type: none"> 1. Podpisana umowa o zachowaniu poufności. Jeśli poufność jest już regulowana umową ramową o świadczenie usług lub innym odpowiednim dokumentem obowiązującym między stronami, a jego zakres obejmuje ujawniane informacje, podpisanie odrębnej umowy o poufności nie jest wymagane. Wzór Załącznika nr 3 zostanie udostępniony na wezwanie Oferenta 2. Oferta zawierająca wszystkie koszty usługi. Oferta powinna być przedstawiona w języku polskim lub angielskim oraz w PLN. 3. Oświadczenie o braku powiązań kapitałowych i osobowych z Zamawiającym (Załącznik nr 2 do niniejszego zapytania). 4. Oświadczenie o spełnieniu warunków oferty (Załącznik nr 4 do niniejszego zapytania).// <p>1. Signed confidentiality. If confidentiality is already governed by a master service agreement or any other relevant document between the parties, and its scope includes the disclosed information, a separate</p>
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	<p>confidentiality agreement is not required</p> <p>Signed confidentiality agreement.</p> <p>The template for Appendix No. 3A will be provided upon the request of the Bidder.</p> <p>2. Offer including all service costs. The offer should be presented in Polish or English and in PLN.</p> <p>3. Declaration of the lack of capital and personal connections with the Ordering Party (Appendix No. 2A to this inquiry).</p> <p>4. Declaration of fulfillment of the offer conditions (Appendix No. 4A to this inquiry).</p>
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5.6. CPV code: 73100000-3

5.7. **Schedule of contract execution: Service completion date: 31.12.2025**

5.8. **List of documents/declarations required from the Contractor:**

5.8.1. Required Documents:

- **Declaration of no capital or personal relationships, no grounds for exclusion from the procurement process with confirmation of the terms and conditions of the Proposal (in accordance with the annex attached to the Request for Proposals) with the Proposal,**
- **a signed CDA document unless the Bidder is bound by the current CDA agreement with the Ordering Party,**
- **Statement containing answers to all requirements specified in Application deliver together with the offer (in accordance with the annex attached to the Request for Proposals).**

6. GROUNDS FOR EXCLUSION FROM PARTICIPATION IN THE PROCUREMENT PROCESS

6.1. Entities with personal or capital relationships to the Ordering Party are excluded from participation in the procurement process. A capital or personal relationship means a mutual relationship between the Ordering Party or persons authorized to incur liabilities on its behalf, or persons performing activities on its behalf related to the preparation and conduct of the contractor selection procedure on the one hand, and the contractor on the other, consisting in particular of:

- 6.1.1. participation in the company as a partner in a civil law partnership or commercial partnership,

- 6.1.2. owning at least 10% of shares, unless a lower threshold is required by law, serving as a member of the supervisory or management board, proxy or attorney,
- 6.1.3. being married, related by blood or marriage in the direct line, related by blood or marriage in the collateral line up to the second degree, or related through adoption, guardianship, or custody, or being in cohabitation with the Bidder, its legal representative, or members of the management or supervisory bodies of the Bidder applying for the contract,
- 6.1.4. being in such a legal or factual relationship with the Bidder that raises reasonable doubt as to impartiality or independence in connection with the procurement procedure;

Method of determining the absence of grounds for exclusion:

Verification will be based on the Contractor's declaration according to Annex No. 2 to the Request for Proposals.

- 6.2. Also excluded from participation in the procurement are entities with respect to which the following circumstances hold true:
 - 6.2.1 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,
 - 6.2.2 circumstances described in Article 5k of Council Regulation (EU) No. 833/2014 of July 31, 2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (OJ. of Laws EU No. L 229, 31.07.2014, p. 1), as amended by Council Regulation (EU) No. 2022/576 amending Regulation (EU) No. 833/2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine (OJ. of Laws EU No. L 111, 8.04.2022, p. 1, as amended).

Method of determining the absence of grounds for exclusion:

Verification will be based on the Contractor's declaration according to Annex No. 2 to the Request for Proposals.

- 6.3. The Ordering Party has the right to reject a proposal if the proposal is incomplete or inconsistent with the Request for Proposals.

7. DESCRIPTION OF PROPOSAL PREPARATION

- 7.1. How to prepare a proposal:
 - Each Supplier may submit only one proposal,
 - The proposal should be prepared in Polish or English,

- **the proposal must include:**
 - **The net price or net value calculated for the Request for Proposals, including transportation and other additional costs. The absence of a provision for additional costs in the proposal is considered to be the value calculated into the price of the products.**
 - **The term of execution of the subject of the contract (expressed in days / weeks),**
 - **declaration of no capital relationships, no grounds for exclusion from the procurement process with confirmation of the conditions of the proposal (according to the annex attached to the request). The declaration must be signed by persons authorized to represent the Contractor in accordance with the representation resulting from the relevant register or on the basis of the power of attorney granted. If the person(s) signing the statement (representing the Contractor) acts on the basis of a Power of Attorney, the Power of Attorney must be attached to the proposal (acceptable form: scan or electronic signature).**
 - **A proposal validity period must be not less than 60 days. The time limit runs from the day the proposal is submitted. The Supplier will remain bound by its final proposal to the Ordering Party for the entire term of the contract execution.**
- If the prices on the proposal are expressed in a currency other than the Polish zloty, they will be converted using the average sales exchange rate announced by the National Bank of Poland (NBP), in effect on the day of termination of the Request for Proposals in the European Funds Competitiveness Database.
- The absence of any of the above-mentioned elements will result in rejection of the proposal (offering a one-time opportunity to supplement the submitted documents).

7.2. The proposal may additionally include:

- Supplier's name and address,
- Request for Proposals number,
- The name and catalogue number of the product,
- Net list price,
- Payment terms and deadlines (expressed in days).
- Information about the reservation of the proposal, which constitutes a business secret.

7.3. The Ordering Party does not allow for partial Proposals,

7.4. The supplier shall bear all costs associated with the preparation and submission of the proposal. The Ordering Party does not offer to reimburse for participation in the procurement process.

7.5. The Supplier shall pay contractual penalties to the Ordering Party for delay in the delivery date of the subject matter of the order, for each commenced day of delay, unless the delay

is due to the fault of the Ordering Party. The Supplier agrees to have the amount of liquidated damages deducted directly upon payment of the VAT invoice for delivery.

7.6. Proposals submitted after the deadline will not be considered.

8. DESCRIPTION OF THE CRITERIA THAT THE ORDERING PARTY WILL BE GUIDED BY WHEN SELECTING A PROPOSAL

8.1. In evaluating Proposals, the Ordering Party will be guided by the criteria given below:

- Price - 70%,
- Delivery time - 30%,

8.2. The scoring of the proposal will be done according to the formula:

$$L = C + D$$

Where:

- L - proposal score
- C - score obtained in the criterion "Price"
- D - score obtained in the criterion "Delivery time"

8.3. The score (C) in the criterion "Price" will be calculated according to the formula:

$$C = \frac{C_N}{C_B} * 70 \text{ pkt}$$

Where:

- C - score for the criterion "Price"
- C_N - the lowest total net proposal price out of the non-rejected proposals
- C_B - total net price of the evaluated proposal

The Price means the net value of the order or, if partial Proposals are allowed, the net item value. Proposals submitted in a currency other than PLN will be converted into PLN using the average selling rate announced by the National Bank of Poland (NBP), in effect on the day of closing the Request for Proposals in the European Funds Competitiveness Database

8.4. The score (D) in the criterion "Delivery time" will be awarded as follows:

$$D = \frac{D_N}{D_B} * 30 \text{ pkt}$$

Where:

- D - Score for the criterion "Delivery time"
- D_N - Shortest delivery time proposed
- D_B - Delivery time proposed

Delivery time - means the delivery period expressed in business or calendar days counted from the date of order (depending on the use of the term, a week will be converted to 7 calendar days while a business week indicates 5 business days). The Supplier's indication of a delivery time within a time range (e.g., 5 - 10 days) will result in taking the maximum delivery date for the proposal evaluation purposes. Using only the wording "days" or specifying only an integer will be understood as calendar days for the purposes of proposal evaluation. Delivery time will be converted to calendar days, as follows:

- 1-5 business days = 1-5 calendar days,
- 6-10 working days = 8-12 calendar days (i.e., number of working days +2 days),
- 11-15 working days = 15-19 calendar days (i.e., number of working days +4 days),

and accordingly for other periods expressed in working days.

The use of other forms to specify the delivery time (e.g., by specifying the date of delivery of products), will result in rejection of the proposal in the procurement process.

- 8.5. The Ordering Party will select the most advantageous proposal based on the evaluation criteria specified in this Request for Proposals. The maximum score the Contractor can obtain is 100 points. Calculations will be made to two decimal places. The Ordering Party will post the results of the procurement process in the Competitive Database
- 8.6. The Ordering Party reserves the right to negotiate with the selected Bidder whose proposal scores the highest score and meets the formal criteria.
- 8.7. **After the selection of the most advantageous offer, the Ordering Party will send a contract to the selected Bidder, which must be signed by both sides, within 3 working days from the date of sending the contract by the Ordering Party.**

9. PROCEDURE FOR EVALUATION OF PROPOSALS AND ANNOUNCEMENT OF RESULTS

- 9.1. In the course of evaluating the submitted Proposals, the Ordering Party may request clarifications from Bidders (if this does not violate competitiveness) regarding the content of their Proposals excluding items from the evaluation criterion. The deadline for submission of explanations will be indicated in the message sent to the Supplier (at least 2 working days from receipt of the request for explanations).
- 9.2. In the course of evaluating the submitted Proposals, the Ordering Party may call on Bidders to supplement the documents once (if this does not violate competitiveness). It can also make requests to correct obvious mistakes and calculation errors. The deadline for submission of supplements will be indicated in the message sent to the Supplier (min. 2 working days from receipt of the request).

- 9.3. Failure to submit explanations and/or supplementary documents within the time limit outlined by the Ordering Party and in the required form will be grounds for rejection of the proposal.
- 9.4. In the event that the Bidder who submitted the most advantageous Proposal does not proceed to the conclusion of the Contract, the Ordering Party reserves the right to sign the Contract with the next Bidder who obtained the next highest score without initiating a new procurement process.
- 9.5. If two or more Contractors obtain the same score, the proposal with the most favorable environmental and climate impact will be selected. To this end, the Ordering Party has the right to call on Bidders whose Proposals received the highest final score to supplement their Proposals by providing the information indicated by the Ordering Party regarding the environmental impact of the subject of the proposal.
- 9.6. The Ordering Party does not provide for objections and appeals.

10. TERMS AND CONDITIONS OF CONTRACT AMENDMENT

- 10.1. The Employer reserves the right to make significant changes to the provisions of the contract in relation to the content of the proposal, on the basis of which the Contractor was selected, in the following scope and situations:
 - 10.1.1. changes to the provisions of European Union law or national law to the extent affecting the implementation of the Agreement (in particular, changes in VAT rates);
 - 10.1.2. Upgrading the technical parameters of the subject of the contract, without affecting the net lump sum price,
 - 10.1.3. Extension the term of the contract due to the need to perform additional work, the performance of which is necessary for the proper implementation of the contract, and the necessity of which the Employer, acting with due diligence, could not have foreseen earlier, not included in the basic contract, if they have become necessary and all the following conditions have been met:
 - a) change of contractor cannot be made for economic or technical reasons, in particular concerning interchangeability or interoperability of equipment, services or installations, ordered under the basic contract,
 - b) change of contractor would cause significant inconvenience or a significant increase in costs to the Ordering Party,
 - c) the value of the changes does not exceed 50% of the value of the contract originally specified in the contract;
 - 10.1.4. extension of the deadline for execution of the order due to force majeure, with all the consequences occurring in connection with the extension;
 - 10.1.5. extension of the deadline for completion for other reasons beyond the control of the Contractor;
 - 10.1.6. changes to the parameters of the subject matter of the contract, changes in the material scope of the contract and changes in the manner of performance of the

contract without leading to changes in the nature of the contract - technological changes, in particular: the need to implement the contract using other technical/technological, material solutions than those indicated in the Request for Proposals, in a situation where the use of the provided solutions would threaten non-performance or defective performance of the contract;

10.1.7. changes in the amount of the Contractor's remuneration - since the contract will be concluded for a period longer than 12 months, the Contractor's remuneration may change in the event:

- a) of changes in the price of materials or costs related to the execution of the order in excess of 10%: (1) the change in remuneration will be effective no earlier than from the month following the month in which the aforementioned change in the price of materials or costs occurred (2) the method of determining the change in remuneration: (a) using a reference to the rate of change in the price of materials or costs, in particular, the rate announced in the publication by the President of the Central Statistical Office, or (b) by indicating another basis, in particular, a list of types of materials or costs for which the change in price entitles the parties to the contract to demand a change in remuneration, (3) the manner of determining the effect of a change in the price of materials or costs on the cost of performance of the contract and the determination of the periods during which the contractor's remuneration may change, (4) the maximum value of the change in remuneration allowed by the Ordering Party as a result of the application of the provisions on the principles of changing the amount of remuneration will be 25% of the net proposal price,
- b) changes in the amount of the minimum wage or the amount of the minimum hourly rate, determined on the basis of the Act of October 10, 2002 on the minimum wage,
- c) changes to the rules for being subject to social insurance or health insurance, or the rate of social insurance or health insurance premiums, the rules for collecting and the amount of payments to employee capital plans, as referred to in the Act of October 4, 2018 on employee capital plans
- insofar as the changes listed in this paragraph will affect the Contractor's cost of performance;

10.1.8. changes listed in Section 3.2.4(4) of *the 2021-2027 Expenditure Eligibility Guidelines*.

10.2. The Ordering Party also provides for the possibility of making non-material changes to the provisions of the contract in relation to the content of the proposal on the basis of which the Contractor was selected.

10.3. The Ordering Party reserves the right to award to the Contractor, selected in accordance with the principle of competitiveness, a contract for the repetition of a similar service in line with the subject of the initial contract (applies only to Requests for Services).

10.4. Amendments to the contract shall be made in the form of an annex signed by both parties, and the possibility of their introduction is subject to approval by the Ordering Party.

11. OTHER TERMS

11.1. The Ordering Party reserves the right:

11.1.1. to cancel or close the procurement process, at any stage of the procurement process without giving any reason,

11.1.2. not to select any of the Proposals submitted,

11.1.3. to extend the deadline for submitting Proposals.

11.1.4. to amend or supplement the documents included in the Request for Proposals, which will become an integral part of it;

At the same time, the Bidder shall not be entitled to any claim for damages against the Ordering Party on the above grounds.

11.2. Data Protection:

With regard to the personal data contained in the Proposals, the Ordering Party shall, upon submission of the proposal, become the controller of such data within the meaning of Article 4(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and on the free flow of such data and repealing Directive 95/46/EC ("RODO"). The Ordering Party will process the data for the purpose of evaluating Proposals, concluding a contract with the selected contractor, and for the purpose of executing the concluded contract, i.e. on the basis of Article 6(1)(b) GDPR.

The Ordering Party will provide personal data contained in the submitted Proposals, on the basis of the relevant provisions of law, to authorized bodies and institutions entitled to inspect projects co-financed from funds originating from the budget of the European Union. In particular, the data will be transferred to the Intermediate Body - the National Center for Research and Development, while the administrator of the data will be the minister responsible for development under Article 71 (1). Information on the scope of data processing by relevant institutions can be found at: <https://www.funduszeuropejskie.gov.pl/strony/o-funduszach/ogolne-zasady-przetwarzania-danych-osobowych-w-ramach-funduszy-europejskich/>

The Ordering Party will process personal data for the period in which it is required by applicable law to keep all documentation related to the project co-financed from the EU budget.

12. ANNEXES

12.1. The annexes to this Request for Proposals include:

- 1) Declaration of No Capital Links, No Grounds for Exclusion from the Procedure, and Confirmation of the Proposal Requirements (Appendix No. 2A)
- 2) CDA template (Appendix No. 3A)
- 3) Declaration of compliance with the terms of the offer (Appendix No. 4A)