

209178-2026 - Kompetizzjoni

Il-Ġermanja – Servizi tas-saħħa – Storage and labelling of GMP Goods

OJ S 60/2026 26/03/2026

Avviż tal-kuntratt jew tal-konċessjoni – reġim standard

Servizzi

1. Xerrej

1.1. Xerrej

Isem uffiċjali: BiconY Therapeutics GmbH

Email: bicony.tenderprocedure@fgvw.de

Tip legali tax-xerrej: Impriża pubblika, ikkontrollata minn awtorità tal-gvern ċentrali

Attività tal-awtorità kontraenti: Affarijiet ekonomiċi

2. Proċedura

2.1. Proċedura

Titlu: Storage and labelling of GMP Goods

Deskrizzjoni: The proper storage of Investigational Medicinal Products (IMPs), GMP-compliant materials, Master Cell Banks (MCBs), and reference standards is a critical requirement to ensure product quality, integrity, and full traceability throughout their lifecycle. All materials must be stored under strictly controlled and continuously monitored conditions in accordance with applicable EU GMP guidelines, ensuring compliance with defined specifications.

Therefore, we are looking for a service provider ensuring robust storage systems, including qualified infrastructure, validated monitoring systems, and comprehensive documentation practices fully compliant with regulatory expectations. Please refer to the tender documents for further details.

Identifikatur tal-proċedura: f98558f0-09c6-4d47-8c6d-f1b86aefed4b

Identifikatur intern: BiconY 01/2026

Tip ta' proċedura: Miftuħa

Il-proċedura hija aċċellerata: iva

Ġustifikazzjoni għall-proċedura aċċellerata: The current service provider has informed the Client (contracting entity, BiconY Therapeutics GmbH, hereinafter also called "BiconY") recently in March 2026 that he will be discontinuing his business operations, with operational activities expected to wind down by end of June. The Client will receive batch releases by end of April from their Contract Manufacturing Organization (CMO) and must ship it to the new, long term service provider. For this reason, there is a case of urgency that could not have been foreseen by the Client.

Elementi prinċipali tal-proċedura: This is an expedited procedure as an open procedure. No negotiations will take place.

2.1.1. Għan

Natura tal-kuntratt: Servizi

Klassifikazzjoni prinċipali (cpv): 85100000 Servizi tas-saħħa

2.1.2. Post tal-prestazzjoni

Ikun fejn ikun fiż-Żona Ekonomika Ewropea

2.1.4. Informazzjoni ġenerali

Baži legali:

Direttiva 2014/24/UE

vgv -

2.1.6. Raġunijiet għall-esklużjoni

Sors tal-motivi għall-eżklussjoni: Avviż, Dokument tal-Akkwist

Ksur tal-obbligi stabbiliti skont raġunijiet ta' esklużjoni purament nazzjonali: In accordance with §§ 123,124 GWB, § 22 LkSG

Parteċipazzjoni f'organizzazzjoni kriminali:

Reati terroristiċi jew reati marbuta ma' attivitajiet terroristiċi:

Hasil tal-flus jew finanzjament tat-terroriżmu:

Frodi:

Il-korruzzjoni:

Thaddim tat-tfal u forom oħra ta' traffikar tal-bnedmin:

Ksur tal-obbligu relatat mal-ħlas tat-taxxi:

Ksur tal-obbligu relatat mal-ħlas tal-kontribuzzjonijiet tas-sigurtà soċjali:

Ksur tal-obbligi fl-oqsma tal-liġi ambjentali:

Ksur tal-obbligi fl-oqsma tal-liġi soċjali:

Ksur tal-obbligi fl-oqsma tal-liġi tax-xogħol:

Insolvenza:

Assijiet amministrati minn likwidatur:

L-attivitajiet kummerċjali huma sospiżi:

Sitwazzjoni analoga bħal falliment skont il-liġi nazzjonali:

Imġiba professjonali serjament ħażina:

Ftehimiet ma' operatori ekonomiċi oħrajn li għandhom l-għan li jikkawżaw distorsjoni tal-kompetizzjoni:

Kunflitt ta' interess minħabba l-parteċipazzjoni tiegħu fil-proċedura ta' akkwist:

Involvement dirett jew indirett fit-tnejn ta' din il-proċedura ta' akkwist:

Terminazzjoni bikrija, danni jew sanzjonijiet komparabbli oħra:

Dikjarazzjoni falza, informazzjoni moħbija, ma setgħux jiġu pprovduti d-dokumenti meħtieġa jew inkisbet informazzjoni kunfidenzjali ta' din il-proċedura:

5. Lott

5.1. Lott: LOT-0001

Titlu: Storage and labelling of GMP Goods

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Therefore, we are looking for a service provider ensuring robust storage systems, including qualified infrastructure, validated monitoring systems, and comprehensive documentation practices fully compliant with regulatory expectations. Please refer to the tender documents for further details.

Identifikatur intern: BiconY 01/2026

5.1.1. Għan

Natura tal-kuntratt: Servizi

5.1.2. Post tal-prestazzjoni

Ikun fejn ikun fiż-Żona Ekonomika Ewropea

5.1.3. Tul ta' żmien stmat

Data tal-bidu: 01/05/2026

Data tat-tmiem tad-durata: 31/12/2028

5.1.6. Informazzjoni ġenerali

Parteċipazzjoni riżervata:

Il-parteċipazzjoni mhijiex riżervata.

Iridu jingħataw l-ismijiet u l-kwalifiki professjonali tal-istaff assenjat biex iwettaq il-kuntratt:

Rekwiżit tal-offerta

Proġett ta' akkwist mhux iffinanzjat mill-Fondi tal-UE

L-akkwist huwa kopert mill-Ftehim dwar l-Akkwisti Pubbliċi (GPA): iva

Dan l-akkwist huwa adattat ukoll għall-intrapriżi żgħira u ta' daqs medju (SMEs): le

5.1.7. Akkwist strateġiku

Għan tal-akkwist strateġiku: Ebda akkwist strateġiku

5.1.9. Kriterji tal-għażla

Sors tal-kriterji ta' għażla: Avviż

Kriterju: Referenzi fuq servizzi speċifiċi

Deskrizzjoni tal-kriterju ta' selezzjoni: Please provide the following references. Please use the form provided for this purpose (03_Self-declaration for the eligibility of tenderers) At least three references from reference provider (RP) for the performance of comparable services (The proper storage of Investigational Medicinal Products (IMPs), GMP-compliant materials, Master Cell Banks (MCBs), and reference standards that is robust storage systems, including qualified infrastructure, vali-dated monitoring systems, and comprehensive documentation practices fully compliant with regulatory expectations) since January 1, 2023, (it is sufficient that the comparable services were also provided in the reference period in the specified reference project, e.g., a reference that began on January 1, 2022, and ended on February 1, 2023, would be sufficient). Only references to Storage of GMP Goods projects are permitted. Each reference must be either completed or ongoing. In the case of an ongoing reference, specifications of the planned/contractual project duration and information on the current status must be included. It is irrelevant whether the reference provider is a public or private company. For verification purposes, the reference details must include the contact details of a responsible person at the respective company, i.e., name, telephone number, and/or email address. Minimum requirements for each reference: 1. Since January 1, 2023 2. Completed and ongoing reference; if ongoing, specifications of the planned/contractual project duration and information on the current status of the reference project must be included 3. The respective reference must include "The proper storage of Investigational Medicinal Products (IMPs), GMP-compliant materials, Master Cell Banks (MCBs), and reference standards that is robust storage systems, including qualified infrastructure, validated monitoring systems, and comprehensive documentation practices fully compliant with regulatory expectations"

Kriterju: Ċertifikati minn entitajiet indipendenti dwar standards ta' assigurazzjoni tal-kwalità
Deskrizzjoni tal-kriterju ta' selezzjoni: Self-declaration for the following requirements: - QP authorized to approve products for the EU - GMP-compliant labelling Please use the form provided for this purpose (03_Self-declaration for the eligibility of tenderers)

Kriterju: Awtorizzazzjoni jew appartenenza għal organizzazzjoni partikolari meħtieġa għal kuntratti tas-servizzi

Deskrizzjoni tal-kriterju ta' selezzjoni: GMP Certified: issued by EMA (European Medicines Agency) or internationally recognized equivalent. If more than one facility is involved, a separate certificate needs to be available for each. Please submit a copy the relevant certificate with your offer.

Kriterju: Miżuri biex jiżguraw il-kwalità

Deskrizzjoni tal-kriterju ta' selezzjoni: Self-declaration for the following requirement: Handling of antibodies that are not subject to a specific BSL Please use the form provided for this purpose (03_Self-declaration for the eligibility of tenderers)

5.1.11. Dokumenti tal-akkwist

Lingwi li bihom id-dokumenti tal-akkwist huma disponibbli uffiċjalment: Ingliż

Skadenza biex tintalab informazzjoni addizzjonali: 02/04/2026 23:59:59 (UTC+02:00) Hinn tal-Ewropa tal-Lvant, Hinn tas-sajf tal-Ewropa Ċentrali

Indirizz tad-dokumenti tal-akkwist: <https://www.dtv.de/Satellite/notice/CXP4D9LM921/documents>

Mezz ta' komunikazzjoni ad hoc:

Isem: All communication takes place in English via communication tool in the project area of the procurement portal DTVP.

URL: <https://www.dtv.de/Satellite/notice/CXP4D9LM921>

5.1.12. Termini tal-akkwist

Termini tas-sottomissjoni:

Sottomissjoni elettronika: Meħtieġa

Indirizz għas-sottomissjoni: <https://www.dtv.de/Satellite/notice/CXP4D9LM921>

Lingwi li bihom jistgħu jiġu sottomessi offerti jew talbiet għall-partecipazzjoni: Ingliż

Katalogu elettroniku: Mhux permessa

Varjanti: Mhux permessa

L-offerenti jistgħu jifgħu aktar minn offerta waħda: Mhux permessa

Skadenza biex jintlaqgħu l-offerti: 09/04/2026 11:00:00 (UTC+02:00) Hinn tal-Ewropa tal-Lvant, Hinn tas-sajf tal-Ewropa Ċentrali

Perjodu waqt li l-offerta għandha tibqa' valida: 6 Ġimagħtejn

Informazzjoni li tista' tiġi ssupplimentata wara l-iskadenza għas-sottomissjoni:

Fid-diskrezzjoni tax-xerrej, id-dokumenti kollha neqsin relatati mal-offerent jistgħu jiġu pprezentati aktar tard.

Informazzjoni addizzjonali: Bicony asks - within its discretion - the bidder to submit, complete or correct documents, within the framework laid down by law.

Informazzjoni dwar il-ftuħ pubbliku:

Data tal-ftuħ: 09/04/2026 11:01:00 (UTC+02:00) Hinn tal-Ewropa tal-Lvant, Hinn tas-sajf tal-Ewropa Ċentrali

Termini tal-kuntratt:

L-eżekuzzjoni tal-kuntratt għandha titwettagħ fil-qafas ta' programmi ta' impjiegi protetti: Le Kundizzjonijiet relatati mat-twettiq tal-kuntratt: Capacity available from late April / early May onwards Place of performance: Company is based in the EU.

Fatturazzjoni elettronika: Meħtieġa

Se tintuża l-ordni elettronika: iva

Se jintuża l-pagament elettroniku: iva

5.1.15. Tekniki

Ftehim qafas:

Ebda ftehim ta' qafas

Informazzjoni dwar is-sistema dinamika tax-xiri:

Ebda sistema dinamika ta' xiri

5.1.16. Aktar informazzjoni, medjazzjoni u riežami

Organizzazzjoni tar-riežami: Vergabekammer des Budnes

Informazzjoni dwar l-iskadenzi tar-riežami: According to Article 160, Section 3 of the German Act Against Restraint of Competition (GWB), application for review is not permissible insofar as 1. the applicant has identified the claimed infringement of the procurement rules before submitting the application for review and has not submitted a complaint to the contracting authority within a period of 10 calendar days; the expiry of the period pursuant to Article 134, Section 2 remains unaffected, 2. complaints of infringements of procurement rules that are evident in the tender notice are not submitted to the contracting authority at the latest by the expiry of the deadline for the application or by the deadline for the submission of bids, specified in the tender notice. 3. complaints of infringements of procurement rules that first become evident in the tender documents are not submitted to the contracting authority at the latest by the expiry of the deadline for application or by the deadline for the submission of bids, 4. more than 15 calendar days have expired since receipt of notification from the contracting authority that it is unwilling to redress the complaint. Sentence 1 does not apply in the case of an application to determine the invalidity of the contract in accordance with Article 135, Section 1 (2). Article 134, Section 1, Sentence 2 remains unaffected.

Organizzazzjoni li tipprovdi informazzjoni addizzjonali dwar il-proċedura tal-akkwist: BiconY Therapeutics GmbH

Organizzazzjoni li tirċievi t-talbiet għall-parteeċipazzjoni: BiconY Therapeutics GmbH

8. Organizzazzjonijiet**8.1. ORG-0001**

Isem uffiċjali: BiconY Therapeutics GmbH

Numru tar-reġistrazzjoni: HRB 41594

Indirizz postali: Lagerhofstraße 4

Belt: Leipzig

Kodiċi postali: 04103

Sottodivizjoni tal-pajjiż (NUTS): Leipzig, Kreisfreie Stadt (DED51)

Pajjiż: Il-Ġermanja

Email: bicony.tenderprocedure@fgvw.de

Telefown: +49 69 7191890-12

Rwoli ta' din l-organizzazzjoni:

Xerrej

Organizzazzjoni li tipprovdi informazzjoni addizzjonali dwar il-proċedura tal-akkwist

Organizzazzjoni li tirċievi t-talbiet għall-parteeċipazzjoni

8.1. ORG-0002

Isem uffiċjali: Vergabekammer des Budnes

Numru tar-reġistrazzjoni: 022894990

Indirizz postali: Kaiser-Friedrich-Straße 16

Belt: Bonn

Kodiċi postali: 53113

Sottodivizjoni tal-pajjiż (NUTS): Bonn, Kreisfreie Stadt (DEA22)

Pajjiż: Il-Ġermanja
Punt ta' kuntatt: Vergabekammer des Bundes beim Bundeskartellamt
Email: vk@bundeskartellamt.bund.de
Fax: +492289499163
Rwoli ta' din l-organizzazzjoni:
Organizzazzjoni tar-rieżami

8.1. **ORG-0003**

Isem uffiċjali: Datenservice Öffentlicher Einkauf (in Verantwortung des Beschaffungsamts des BMI)
Numru tar-reġistrazzjoni: 0204:994-DOEVD-83
Belt: Bonn
Kodiċi postali: 53119
Sottodivizjoni tal-pajjiż (NUTS): Bonn, Kreisfreie Stadt (DEA22)
Pajjiż: Il-Ġermanja
Email: noreply.esender_hub@bescha.bund.de
Telefown: +49228996100
Rwoli ta' din l-organizzazzjoni:
TED eSender

Informazzjoni dwar l-avviż

Identifikatur/verżjoni tal-avviż: d2d5fa95-a74d-4fb8-a39f-3c6ba62247a1 - 01
Tip ta' formola: Kompetizzjoni
Tip ta' avviż: Avviż tal-kuntratt jew tal-konċessjoni – reġim standard
Sottotip tal-avviż: 16
Data ta' meta ntbagħat l-avviż: 24/03/2026 17:17:07 (UTC+01:00) Hin tal-Ewropa Ċentrali, Hin tas-sajf tal-Ewropa tal-Punent
Lingwi li bihom dan l-avviż huwa disponibbli uffiċjalment: Ingliz
Numru tal-pubblikazzjoni tal-avviż: 209178-2026
Numru tal-ħarġa tal-ĠU S: 60/2026
Data tal-pubblikazzjoni: 26/03/2026