



**Request for Applications to Participate in a
Dynamic Purchasing System
for the provision of
Third Country Qualification Recognition (TCQR) Examination
Services**

**Open Procedure
Tender Deadline: April 2025**

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Part 1: Introduction

The Pharmaceutical Society of Ireland (PSI), (the “Contracting Authority”) is issuing this Request for Applications to Participate (“RFATP”) in a Dynamic Purchasing System (“DPS”) as a central purchasing body (“CPB”).

The Contracting Authority invites requests to participate (“Applications”) from economic operators (“Applicants”) for appointment to a Dynamic Purchasing System (“DPS”) for the provision of the services described in Part 3 to this RFATP (the “Services”).

In summary, The PSI requires a service provider to fully undertake overseeing the process of conducting examinations and assessing those qualifying Pharmacists/Professionals that fall under the eligibility of Path B of the Third Country Qualification Recognition (TCQR) route.

The TCQR route is the regulatory process operated by the PSI for pharmacists who obtained their qualification as a pharmacist in a country outside the European Union (EU) or the European Economic Area (EEA) who are seeking to have their qualification recognised so that they can then apply to register in Ireland.

This will include the complete end-to-end management of the two assessments outlined in the requirements of this tender document;

- 1) An Objective Structured Clinical Examination (OSCE)
- 2) A Comprehensive Multiple-Choice Questionnaire

This public procurement competition will follow the open procedure under the European Union Regulations 2016 (Statutory Instrument 284 of 2016) (S.I. 284 of 2016) (the “Regulations”).

The Contracting Authority estimates the expenditure on the services covered by the proposed contract to be approximately €6,500,000 (excluding VAT) over the Term and potential extensions. It's crucial for tenderers to understand that this figure is an estimate based on current and anticipated future usage.

Please see Part 3 of this RFATP for further information on the Services.

1.1. Overview of Admittance to the DPS and Award of Contracts

Admittance to the DPS and the subsequent award of any contract(s) thereunder, as set out at Appendix 5 of this RFATP (“Contract(s)”), shall be conducted as follows:

Stage 1 – Admittance to the DPS:

The Contracting Authority invites Applications from Applicants in response to the Compliance and Selection Criteria at paragraphs 4.1 and 4.2 of Part 4 of this RFATP. While Applicants are required to submit a response to and fulfil the Compliance and Selection Criteria, Applicants are **not** required to submit either a tender proposal or a pricing submission at this Stage 1 of the Competition. Tender responses and pricing submissions will instead be required in response to future (Stage 2) mini-competitions conducted under the DPS. All Applicants that meet the Compliance and Selection Criteria will be admitted to the DPS after completion (execution) of the DPS Agreement as set out at Appendix 4 to this RFATP (“DPS Agreement”) along with the Contracting Authority.

Ongoing application process to become a DPS Member

Economic operators may apply for admission to the DPS or re-apply in the case of Applicants who failed to satisfy the Compliance or Selection Criteria, at any point throughout the Term (as defined in paragraph 1.4 below) of the DPS. Regardless of when they submit their application, in order to be admitted to the DPS, Applicants must fulfil all Compliance and Selection Criteria set out in this RFATP.

Stage 2 – Award of Contracts:

All Applicants that enter into a DPS Agreement with the Contracting Authority at Stage 1 (each a “DPS Member”) will be invited to future Stage 2 competition(s) (“Mini-Competitions”) to submit a tender response based on the requirements set out in the relevant Stage 2 Request For Tenders (“RFT”). Mini-Competition(s) will be conducted in accordance with the procedures set out at clauses 5 and 6 of the DPS Agreement. After the assessment of the tenders received in response to an RFT, the DPS Client(s) may decide to award a Contract to the DPS Member that has submitted the most economically advantageous tender based on the award criteria set out in the RFT.

1.2. Overview of Application Process

The DPS will be hosted on the eTenders web platform www.etenders.gov.ie (the “Electronic Platform”). All communications arising out of or in connection with the DPS will be by electronic means. No hard copy documents will be issued or accepted and all communications with the Contracting Authority must be via the Electronic Platform.

The following is an overview of the electronic process that Applicants must follow when submitting an Application for admittance to the DPS.

1. Applicants must register with E-tenders and/or login to the Electronic Platform.
2. Applicants must review in full and comply with all requirements for this Competition set out in the RFATP and any published DPS documents for this Competition.

3. Applicants must complete and upload the electronic European Single Procurement Document (“eESPD”) to the Electronic Platform.
4. Applicants must complete and submit the DPS Applicant Response Document (“ARD”) for each Category applied for. The ARD is available to download from the Electronic Platform. Applicants must respond to the Selection Criteria as detailed at section 4.2 of Part 4 of this RFATP, and upload their response to the Electronic Platform by the Application Deadline. Applicants are **not** required to submit a tender proposal or pricing schedule in response to the Part 3 requirements at this Stage 1. The tender proposal and pricing schedule will instead be required to be submitted in response to future Stage 2 Mini Competitions that may be conducted under the DPS.
5. Following the Application Deadline (as specified at Section 6.6 of this RFATP) and the evaluation of the Applications, the Contracting Authority will inform the Applicants who fulfil the Compliance and Selection Criteria in this RFATP that they are the initial applicants identified for admission.
6. The initial applicants identified for admission (that fulfil the Compliance and Selection Criteria in this RFATP) will receive such notification via the eTenders web platform and they will be required to sign the DPS Agreement at Appendix 4 to this RFATP prior to being admitted to the DPS.
7. The Contracting Authority will then proceed to execute (sign) a DPS Agreement(s) with those initial applicants identified for admission. The DPS will be deemed to be established upon the date on which the last DPS Agreement has been executed by both the Contracting Authority and an initial applicant identified for admission (‘the Establishment Date’). The Establishment Date will more specifically be set out in the contract award notice for this Competition published on OJEU and eTenders which shall also include the Establishment Date.
8. Applicants that do not meet the Compliance and Selection Criteria in this RFATP will not be admitted to the DPS and will be notified accordingly via the eTenders web platform.
9. Unsuccessful Applicants may re-apply for admission onto the DPS at any stage throughout the Term (as defined in paragraph 1.4 below) of the DPS, following the Establishment Date of the DPS.
10. Economic Operators that did not submit an Application in response to this RFATP by the application deadline specified in paragraph 6.6 of this RFATP may apply for admittance onto the DPS at any stage throughout the Term (as defined in paragraph 1.8 below) of the DPS, following the Establishment Date of the DPS.
11. It is envisaged that all successful Applicants will be invited to future Mini-Competitions conducted under the DPS in respect of those categories in which they may have been successfully admitted to the DPS.
12. All future Mini-Competitions will be conducted in accordance with the terms of the DPS Agreement at Appendix 5 and contracts will be awarded in accordance with clauses 5 and 6 of the DPS Agreement.

1.3. DPS Clients

Only the PSI can use this DPS or issue mini-competitions relating to this framework.

1.4. Term

Any DPS that may result from this Competition will, subject to paragraph 1.5 below, have a period of validity of **[5 years]** from the Establishment Date of the DPS (the “Term”). Further, any DPS Agreement that may be completed (executed) under the DPS will, subject to paragraph 1.5 below terminate on the fifth anniversary of the Establishment Date of the DPS.

1.5. Termination of DPS

The Contracting Authority would refer all Applicants to clause 17 of the DPS Agreement at Appendix 4. The Contracting Authority reserves the right to terminate the DPS Agreement at any stage throughout its Term in accordance with the termination provisions set out at clause 17 of the DPS Agreement.

1.6. Estimated Value of Contracts to be Awarded

The Contracting Authority estimates that the aggregate expenditure on the Services to be covered by the proposed DPS Agreement may amount to some €6,500,000 in total (excl. VAT) over the Term. Applicants must understand that the figure is an estimate only based on current and future expected usage.

1.7. SME Participation

Contracting Authority policy seeks to encourage participation on a fair and equal basis by Small and Medium Enterprises (“SME”s) in this Application to Participate in the DPS and, if successful, in future Mini-Competitions. SMEs that believe the scope of this Application is beyond their technical or business capacity are encouraged, subject to paragraph 6.5, to explore the possibilities of forming relationships with other SMEs or with larger enterprises. Through such relationships they can participate and contribute to the successful implementation of any Contracts that may result from this Application and therefore increase their social and economic benefits.

Larger enterprises are also encouraged, subject to paragraph 6.5, to consider the practical ways that SMEs can be included in their proposals to maximise the social and economic benefits of any Contracts that may result from this Application.

Part 2: Overview of the Contracting Authority

2.1 Background

About the PSI – The Pharmacy Regulator

The Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, is a public body established under the Pharmacy Act 2007 to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland. There are currently 7733 pharmacists, and 175 pharmaceutical assistants registered with the PSI. In addition, there are 1,982 retail pharmacies on our register, which includes 76 operating under the governance of hospital pharmacy departments.¹

What we do as the regulator

As the regulator of the profession of pharmacy, the PSI regulates all registered pharmacists, irrespective of where they work, be that in community pharmacies, or hospitals, in other areas of healthcare, or industry, education or regulation. We regulate the profession in accordance with the requirements set out in legislation and in the *Code of Conduct – Professional Principles, Standards and Ethics for Pharmacists*.² We do this in the public interest, which means that we work to assure the public that pharmacists are always working to high standards of practice and that the public can trust in the professionalism of pharmacists wherever they encounter the profession. In achieving this objective, the PSI works across the full extent of each pharmacist's professional career – from setting the standards for the education courses which lead to registration as a pharmacist to supporting continuing professional development (CPD).

The PSI is also charged with the responsibility to regulate retail pharmacies in Ireland. This is an important aspect of our public protection remit. Pharmacies are a critical part of our healthcare system, and it is essential that, as with all healthcare settings, the public can be assured that they provide a safe and reliable healthcare service. In this role, we are required to ensure that all pharmacies are properly registered, and that each pharmacy is operating in accordance with pharmacy and medicines law.

As a public interest regulator, the PSI does not advocate for or represent pharmacists or pharmacies. While we have a high degree of respect for the healthcare practitioners, and all who work in the healthcare settings we regulate, we must, as a public interest regulator, also maintain our objectivity and independence. In keeping with this principle, the PSI must be careful not to become involved in the individual concerns of pharmacists, whether as employees or as business owners. Equally, the PSI must maintain an appropriate distance from the commercial interests of pharmacy owners and pharmacy businesses and their contractual relationships with the State and other parties.

However, a critical responsibility of every healthcare regulator is to take timely and effective action where there is a risk to the public. For the PSI, this means acting in circumstances where quality is not being maintained, where there is a clear risk to public safety, or where the behaviour of a pharmacist or pharmacy creates a serious risk to the public. When this happens, we will not hesitate to act in the

¹ While PSI has a remit to regulate the “retail” supply of medicines through hospital pharmacy departments, we do not regulate the many other activities of pharmacy departments. Regulating these other activities is a matter to be considered as part of work ongoing in the Department of Health to develop an appropriate licensing system for hospitals in Ireland.

² Please see our website at https://www.thepsi.ie/gns/Pharmacy_Practice/code-of-conduct.aspx for more details on the Code.

public interest. In acting, we will, of course, always act in ways that are fair to all involved, and we will use our statutory powers, both reasonably and proportionately.

Our ongoing responsibilities to the public

Our principal purpose as a regulator is to ensure patient safety and public protection. We are committed to carrying out our work independently, ethically, and transparently. The Pharmacy Act 2007, as amended, establishes the statutory role of the PSI as the pharmacy regulator. Under this legislation and all other applicable legal and public policy frameworks, the PSI must ensure that, on an ongoing basis, we:

- operate fair, transparent, and efficient registration procedures for all registrants (pharmacists, pharmaceutical assistants, and retail pharmacies), and maintain the statutory registers
- evaluate, for accreditation purposes, programmes of education leading to qualifications appropriate for practice as a pharmacist in Ireland
- oversee the effective implementation of the mandatory system of CPD for pharmacists,
- promote and support professional practice by pharmacists and share information for the benefit of patients and the wider health system
- communicate and engage with the public, the pharmacy profession, and our many other stakeholders to ensure our work is understood and informed by these stakeholders
- assure the public of the quality and safety of community pharmacy services through ongoing programmes of quality assessment and oversight of compliance with essential safety requirements
- undertake investigations into matters of serious concern regarding the actions of pharmacists and/or pharmacies and initiate enforcement actions, including prosecutions, where appropriate
- manage the professional complaints process in accordance with the law, natural justice, and fair procedure
- contribute to the ongoing review of new and existing pharmacy and medicines legislation, and contribute to public policy developments relating to our regulatory remit
- comply with our own external compliance obligations and with the Code of Practice for the Governance for State Bodies, which provides assurance that the PSI acts in accordance with best practice in the management and governance of public bodies, and operate prudent financial management practices and continue to steward all PSI funds so as to maximise the pool of financial resources available to deliver on our statutory functions.

2.2. Governance of the PSI

The PSI is a public body, which, by law, is independent in the exercise of its statutory functions³. While independent, the PSI is also subject to public accountability requirements and, for these purposes, the PSI operates under the aegis of the Department of Health. In keeping with this principle, the PSI is required to report to the Minister for Health on various matters and to seek the consent of the Minister for Health in relation to, for example, the making of statutory Rules under the Pharmacy Act. A 21-member Council governs the PSI, and the Minister for Health appoints each member in accordance with the provisions of the Pharmacy Act 2007. The Council is responsible for overseeing

³ The PSI is self-funded through statutory fees levied on pharmacists and pharmacies.

the delivery of the PSI functions in the public interest. This includes agreeing on the strategy for the PSI and ensuring that the strategic objectives are met.

The PSI Registrar (Chief Officer) is appointed under the Pharmacy Act and is responsible for leading the day-to-day work and operation of the organisation and seeing that the Council's strategy and decisions are implemented efficiently and effectively. The Registrar reports to the Council at each of its meetings on the organisation's activities and performance. All PSI staff are public servants and are recruited in accordance with public service recruitment principles. Staff numbers and grading are subject to oversight by the Department of Health, and staff are managed according to the policies set by the Department of Public Expenditure and Reform.

2.3 Our Vision, Mission, and Values

Our vision, mission and values that underpin our work in the PSI are set out in the diagram below. Additional information about our role and the work that we do is available on our website at www.psi.ie.

Our Mission, Vision and Values



Our Mission

We assure patient safety and public trust in pharmacy through effective regulation



Our Vision

Safe and effective pharmacy care supporting the health of our communities



Part 3: Requirements and Specifications

SECTION 1 – Overview of Dynamic Purchasing System and Process for Award of Contracts at Mini Competition Stage 2.

3.1. Background to the Dynamic Purchasing System

The Contracting Authority is seeking to establish a Dynamic Purchasing System (DPS) for the Provision of Examination Services for pharmacists applying for qualification recognition under the Third Country Qualification Recognition (TCQR) Route.

The successful DPS members will be required to provide the Examination component of the TCQR route. They will be required to completely oversee this aspect of the assessment; including format, associated procedures and documentation, examination dates etc., must be agreed with the PSI.

3.2. Aims and Objectives

The Dynamic Purchasing System (DPS) is designed to facilitate ease of access for conducting the examination services without the need to submit a full commercial proposal. Admission to the DPS will be made on the basis of the Applicant's capacity, as evidenced by a combination of turnover (financial and economic standing) and previous experience (technical and professional ability).

The DPS lends itself to the dynamic nature of the Procurement Consultancy Services industry, allowing Economic Operators to apply, or re-apply, for admission to the DPS at any stage during its Term.

3.3. Overview of how the Tender Process will operate.

The PSI invites qualified educational organisations who wish to participate in the DPS to respond to this RFATP to submit an Application Response Document

The **PSI** will evaluate the Applications in response to this RFATP. Those successful Applicants included in the DPS will be invited to participate in Mini-Competitions co-ordinated and managed by the Contracting Authority over the lifetime of the DPS. Further details of how the DPS will operate is set out at paragraph 3.5 of Part 1 of the RFATP.

This Part 3 provides a general overview of potential requirements under the DPS. Full specifications and requirements for DPS Clients will be set out in future Mini-Competitions conducted under the DPS at Stage 2. Applicants are reminded that while they are required to submit a response to and fulfil the Compliance and Selection Criteria in Part 4 of the RFATP, Applicants are **not** required to submit a tender proposal or pricing schedule in response to the RFATP at this Stage 1 of the Competition, which will instead be required in response to future Mini-Competitions, (Stage 2) conducted under the DPS.

3.4. Overview of how the Mini-Competitions will operate

On each occasion that the Contracting Authority proposes to award a Contract by way of a Mini-Competition, it shall issue a Request for Tender ("RFT") in accordance with the procedure set out at clauses 5 and 6 of the DPS Agreement at Appendix 4. The RFT issued at Mini-Competition stage shall provide further particulars of the Services required by the DPS Clients and the methodology for evaluating bids.

Decisions in respect of which Category is best suited to meet their requirements remains at the discretion of DPS Clients when undertaking mini-competitions.

3.5. Contracts awarded under the DPS

A successful DPS Member that enters into a Contract is referred to as the "Contractor" in this Part 3.

SECTION 2 – REQUIREMENTS AND SPECIFICATIONS

3.6. Introduction

The Pharmaceutical Society of Ireland (PSI) is seeking qualified educational organisations to oversee the Examination assessment component of the TCQR route.

3.6.1. Examination provision

The TCQR route is the regulatory process operated by the Pharmaceutical Society of Ireland (PSI) for pharmacists who obtained their qualification as a pharmacist in a country outside the European Union (EU) or the European Economic Area (EEA) who are seeking to have their qualification recognised so that they can then apply to register in Ireland.

In order to be eligible to register as a pharmacist in Ireland, a person holding a Third Country qualification (i.e. one obtained in a country outside the European Union – EU, or the European Economic Area – EEA) must initially apply to have that qualification recognised as a qualification appropriate for practice in Ireland. The following stages form part of this process:

- **Stage 1 – Internal review for validity and eligibility:**

Once an application is received, the PSI will conduct an internal review to check that the application is valid. This stage sits outside this tender. The PSI will:

- a. verify the eligibility of the applicant
- b. ensure the application is complete.

Each application must fulfil the following eligibility criteria:

1. The applicant must provide evidence of their professional pharmacy qualifications obtained from a non-EU/EEA country, including any postgraduate qualifications, lifelong learning and professional experience.
2. Applicants must provide a Statement of Comparability from NARIC Ireland confirming that their qualification(s) is sufficient to be eligible to apply i.e. that they hold a pharmacist qualification.
3. The applicant must provide evidence they are eligible to practise pharmacy in the country/jurisdiction where they obtained their qualification, and there must be no outstanding registration issues against the applicant. This must be confirmed in writing by the qualifying state's competent authority or equivalent (i.e. a certificate or letter of confirmation of qualification/professional status certificate). The applicant does not have to be currently registered and practising in that state, but they must be eligible to do so.

- **Stage 2 – Holistic Assessment**

To assess whether an applicant possesses a qualification appropriate for practice, an External Assessor (selected from a panel of External Assessors appointed by the PSI) will carry out a holistic assessment of the application and supporting documentation. Holistic assessment aims to take a more

rounded view in assessing an applicant's qualification by considering the following:

1. The applicant's pharmacy qualification(s) and in-service/practical training (Input components);
2. The quality components of the pharmacy regulatory system in place in the country where they qualified, for example, whether the applicant's primary qualification was accredited (Quality components);
3. The applicant's postgraduate qualifications in pharmacy, professional experience and continuing professional development (Output components).

The External Assessor will first examine the Input and Quality components of the application. If, following assessment of both the Input and Quality components, an application is considered equivalent to the Irish standard, the applicant will be exempt from demonstrating equivalence through examination, and they may be eligible to proceed to certification stage (Stage 4).

If the assessor cannot determine at this stage that the qualification is equivalent to the Irish standard, the Output components will be reviewed and evaluated to see if they compensate for and address any deficiencies. If identified deficiencies have not been addressed through a consideration of the totality of an applicant's professional qualifications, including any postgraduate qualifications, lifelong learning and professional experience, these applicants will be required to complete an examination. The holistic assessment sits outside this tender.

- **Stage 3**

If an applicant's qualification is determined through holistic assessment to be not equivalent to the standard required for practice in Ireland, the applicant will need to take an examination to confirm that the deficiencies identified in their holistic assessment report have been addressed. The examination may take the form of:

- a. an Objective Structured Clinical Examination (OSCE);
- b. a multiple-choice question (MCQ) examination or
- c. an OSCE and a MCQ examination.

Whether the applicant must undertake one or both examinations will be determined by the recommendations of the External Assessor in their assessment report.

- **Stage 4 – Certificate of qualification appropriate for practice.**

Applicants who have successfully completed all required steps within Stages 1-3 of the TCQR process will be issued with a certificate by the PSI recognising their qualification as being a 'qualification appropriate for practice'. This certificate will enable the applicant to apply for registration as a pharmacist in Ireland. Appropriate evidence of the applicant's English language competence will be a requirement of registration. This stage sits outside this tender.

3.6.2. History of the approach to recognising qualifications

Under the Pharmacy Act 2007, an individual wishing to register to practise as a pharmacist in Ireland must, amongst other things, hold a 'qualification appropriate for practice'.

Pharmacists who qualified in Ireland, or in another EU/EEA state, who hold a professional qualification recognised under the EC (Recognition of Professional Qualifications) Regulations 2017, are automatically considered to hold a qualification appropriate for practice.

A pharmacist whose qualification is from a non-EU or non-EEA country (a 'third country') must first have their qualification recognised as a 'qualification appropriate for practice,' before they can apply to register with the PSI. This process was known as the Third Country Qualification Recognition (TCQR) route.

The TCQR route was implemented in 2009. The process in its current form was found to be resource-intensive and onerous to both applicants and the PSI and since its implementation, application numbers received have been low, with an average of 24 TCQR applications submitted to PSI annually between 2015 and 2019. However, applications have increased significantly in recent years with over 140 applications (excluding UK candidates) received in 2022 alone. However, it must be acknowledged that these numbers are subject to significant variation annually and are likely to be affected by changing global immigration trends. Consequently, there is no guarantee of a consistent or expected number of applicants each year.

This model has been revised to include a single terminal examination to address any deficiencies identified at the holistic assessment stage. The key change is the removal of the adaptation period as a compensation measure to address deficiencies.

3.6.3. The Examination

The Examination is and will be provided by an appropriately qualified partner.

The examination will be delivered in person, and structured as follows:

- A written paper of **Multiple Choice Questions (MCQs)** covering three sections:
 - Section A: Pharmacy Practice and Pharmacology
 - Section B: Pharmaceutical Calculations and
 - Section C: Basic Sciences & Properties of Medicines
- An **Observed Structured Clinical Examination (OCSE)** with 15 stations examining problems relating to professional practice using a mixture of written exercises and simulated patient interactions.

3.7. Scope of this Procurement

The PSI will require all DPS Members to be capable of providing the following specified requirements:

3.7.1. Syllabus defined for the Examination

Required Outputs:

- A syllabus which has regard to the applicable standards for the education and training of pharmacists in Ireland and minimum EU training requirements.
- The syllabus will encompass the following:
 - The content of the examination, including the subjects covered in the course of training of national pharmacists
 - Skills and attitudes based on the current [Core Competency Framework for Pharmacists](#).
 - The scope of the examination.

3.7.2. Quality Assurance procedures

Please note, PSI requires that all quality assurance policies and procedures in respect of the Examination are facilitated under the institution's internal processes, including the following required outputs:

- Robust quality assurance, review and standard setting procedures to ensure that the examination appropriately assesses the standard of training, examinations and qualifications of the candidates and assures the validity and reliability of the examination results.
- Appeals procedure for candidates who wish to appeal their examination results.
- Policies and procedures for suspected Academic Misconduct cases.
- Complaints process.
- Reasonable accommodation policy for those students who require accessibility assistance.

3.7.3. Format and content of Examination defined

Required Outputs:

- It is expected that the Examination will be delivered in an in person format.
- A DPS member must be able to accommodate a minimum of 80 candidates. If multiple sittings are required to deliver this number, this must be highlighted in your approach to this in your Applicant Response Document (ARD). If there is a maximum that can be accommodated at each sitting this should also be detailed.
- Examination in English comprising a multiple-choice questionnaire (MCQ) and an Observed Structured Clinical Examination (OSCE) based on the prescribed syllabus. It is expected that the OSCE will comprise of both written and interactive stations.

3.7.4. Appropriate information available for candidates

Required Outputs:

- Guidance on how to prepare for the examination, examination format, standards, etc.
- Syllabus.
- Reading lists aligned with the syllabus and other online resources as relevant.
- Relevant logistical information for candidates, such as venue and exam times, etc.
- Sample papers to enable candidates who have applied to sit the Examinations to become familiar with the format and standard of the examination, include the style of MCQ questions and OSCE scenarios.

PSI and DPS Members will agree what elements of this information will be publicly available on the PSI website and what elements will be confined to candidates who have been accepted to sit the Examination.

3.7.5. PSI approval of relevant elements

Required Outputs:

- PSI must approve the following elements obtained prior to delivery of the first Examination:
 - i. Syllabus
 - ii. Format and content of examination
 - iii. Quality assurance procedures, including standard setting and appeals process
 - iv. Examination fee
 - v. Information to be provided to prospective candidates
- Proposed minimum and maximum number of candidates per examination sitting.
- PSI will approve sittings in pursuant to mini competitions.

3.7.6. Examination delivered

Required Outputs:

- Volume of exams, frequency and the numbers sitting will be managed at the mini-competition stage. For the purposes of information, it may be multiple exams per year with between 50 and 80 applicants based on current numbers.
- Reports and feedback on examination performance provided to the PSI and candidates within 4 weeks of the examination taking place.
- If the result is appealed by the candidate, the results of any appeals to be provided within 3 weeks of the deadline for submission of appeals.
- The PSI will provide the Institution with the candidate list and contact details in advance of the examination.
- The Institution will invoice the PSI directly, following the completion of each examination.

3.7.7. Roles and Responsibilities

A. The Pharmaceutical Society of Ireland

- Oversee candidates through the Path B process and provide guidance
- Filter Bad/non-viable candidates and liaise with DPS Member regularly about the suitability/viability of candidates to undertake assessments.
- Final approval of the content within syllabus, exams and any messaging to candidates.
- Contract Management oversight of DPS Member
- Pay the DPS Member for their services

B. DPS Member

- Prepare and design syllabus, exam content and supported reading materials
- Run the examination component of the TCQR Path B route
- Provide logistical and operational support to candidates

- Manage Appeals

C. Candidate/Examination Applicant

- Register for correct Pathway and prepare all required documentation
- Attend the exam
- Pay a One-Time Fee
- Access to supporting materials and syllabus
- Must be in a position to take the assessment.

3.7.8. Other

Required Outputs:

- Reports and such other information on the Examination as may be required by the PSI from time to time.

Part 4: Selection Criteria

4.1. Compliant Applications

Only those Applicants who have:-

- a) Submitted compliant Applications pursuant to part 6.2 below, and
- b) Declared by way of eESPD that either:
 - (i) no grounds for exclusion of the Applicant pursuant to Regulation 57 of the Regulations (the “Exclusion Grounds”) apply to them, or
 - (ii) where any such Exclusion Grounds apply, and where the Applicant is not precluded from doing so under Regulation 57(17) of the Regulations, it can provide evidence to the effect that measures taken by the Applicant are sufficient to demonstrate its reliability despite the existence of any relevant Exclusion Ground, and
- c) Declared by way of eESPD that they satisfy the selection criteria for this Competition as set out in part 3.2 below (the “Selection Criteria”), will be admitted to the DPS.

Applicants should note that where an Applicant (Prime Contractor) is relying on the capacity of other entities (Subcontractors) for the purposes of fulfilling any of the Selection Criteria in part 3.2 below it must:

- (i) complete and submit a separate eESPD in respect of each such Subcontractor and
- (ii) submit proof, to the satisfaction of the Contracting Authority, that each such Subcontractor will place the necessary resources at the disposal of the Prime Contractor.

Where an Applicant (Prime Contractor) intends to subcontract any share of any Contract to a Subcontractor, but is not relying on the capacity of such Subcontractor for the purposes of fulfilling any of the Selection Criteria in part 4.2 below, it must ensure that each such Subcontractor submits a separate eESPD in respect of such Subcontractor completing those sections of the eESPD which are specified in section [2.D] of the eESPD for this Competition.

In order to ensure the proper conduct of the procedure, Applicants are required to submit **with their Application** any or all of the following for the purposes of verification of the status of the Applicant (including the Prime Contractor and any Subcontractor):

- (I) a Declaration in the form attached at Appendix 5;
- (II) evidence to the effect that measures taken by the entity concerned are sufficient to demonstrate its reliability despite the existence of a relevant Exclusion Ground;
- (III) all or any of the supporting documents specified at paragraph 4.2 below.

If an Applicant does not provide evidence which is considered by the Contracting Authority as sufficient to demonstrate (i) its fulfilment of the Selection Criteria (or any one of them) in accordance with this RFATP and (ii) the absence of Exclusion Grounds, or its reliability despite the existence of a relevant Exclusion Ground, it shall not be admitted to the DPS.

If an Applicant does not provide evidence which is considered by the Contracting Authority as sufficient to demonstrate (i) the fulfilment by any Subcontractor on whose capacity the Prime Contractor relies of the Selection Criteria (or any one of them) in accordance with this RFATP and (ii) the absence of Exclusion Grounds in respect of any Subcontractor, or the reliability of any Subcontractor despite the existence of a relevant Exclusion Ground, it shall be excluded from participation in this Competition unless it replaces the Subcontractor with one which meets all relevant requirements of this RFATP.

Subcontractors nominated and relied upon by the DPS Member in their Application for admission to the DPS may not be changed throughout the Term of the DPS without the prior consent in writing of the Contracting Authority. The DPS Member must set out the rationale for the proposed change in Subcontractor. The responsibility will be on the DPS Member to demonstrate to the satisfaction of the Contracting Authority, including by way of submitting updated documentary evidence as set out in clause 3.2 of the DPS Agreement, that by changing Subcontractor the DPS Member continues to fulfil the Compliance and Selection requirements specified at part 3 of the RFATP.

Where an Applicant is not relying on the capacity of a Subcontractor to fulfil the Selection Criteria in paragraph 4.2 of this part 4 of the RFATP, but intends relying on Subcontractors to deliver a share of any Services Contract that it may be awarded, the Applicant must in so far as known, identify such Subcontractor(s) in their eESPD which accompanies their Application for admittance to the DPS. Only where such Subcontractors are unknown at the time of submission of their Application and will instead be known or determined at a later stage such as at Mini Competition stage, the DPS Member must instead identify such Subcontractors when they become known, for example, upon submission of a tender response at Mini Competition stage.

The Contractor and Subcontractors shall have the use of sufficient appropriate resources to satisfy the delivery of Services to meet the requirements of all DPS Clients for the duration of any Services Contract awarded under the DPS.

4.2. Selection Criteria for Admittance to DPS

Applicants will be assessed according to the weighted score or Pass/Fail system outlined below in each of the Selection Criteria in this part 4.2.

The Economical and Financial Selection criteria will be assessed as either Pass or Fail so it should be noted that An Applicant who fails any one of the following Selection Criteria will be eliminated from this Competition if the Selection Criteria are not met and shall not be admitted to the DPS, subject to the Applicant's right to re-apply. As stated in Paragraph 1.2 of this RFATP:

- Applicants that fulfil the Compliance and Selection Criteria in this RFATP will be sent confirmation via the eTenders web platform of their identification for admission to the DPS and will be required to sign the DPS Agreement at Appendix 5 to this RFATP.
- Applicants that do not meet the Compliance and Selection Criteria in this RFATP will not be admitted to the DPS and will be notified accordingly via the eTenders web platform.
- Unsuccessful Applicants may re-apply for admission onto the DPS at any stage throughout the Term (as defined in paragraph 1.8) of the DPS, once the DPS has been established.

Applicants must declare by way of eESPD that they satisfy the Financial and Economic standing and Technical and Professional ability requirement(s) set out below for each Category applied for.

In addition to the eESPD, Applicants must complete and submit the relevant sections of the **DPS Applicant Response Document ("ARD")**, for each Category for which an application is being made: **the ARD is** available to download from the Electronic Platform, in line with instructions provided in that document, and upload it to the Electronic Platform by the Application Deadline.

Applicants are reminded that they may (1) rely on the capacities of other entities in order to meet any of the Selection Criteria, and (2) re-apply for admittance onto the DPS at any stage throughout the Term of the DPS, once the DPS has been established.

In order to ensure the proper conduct of the procedure, the Contracting Authority requires Applicants to submit all supporting documentation (as set out section 4.2 below) with their Application.

4.2.1 Economic and Financial Requirements

Evaluation – Pass / Fail

Applicants must confirm and declare by way of eESPD and ARD that their turnover when averaged over the three most recent years of financial accounts equals or exceeds the minimum annual turnover level in the table below in respect of EACH Category applied for.

1. Tenderers have a current Tax Clearance Certificate and will provide evidence to this effect on contract award.
2. Tenderers will be compliant with their social security and revenue obligations for the duration of any contract awarded.
3. Tenderers shall provide evidence about the insurance policies specified in section 6.21.
4. Tenderers meet the minimum turnover requirement of **€500,000** over each of the last three financial years and will provide evidence from their auditors to this effect.

Tenderers must provide the supporting documentation specified above in the form of ARD which must satisfy the requirements of the Contracting Authority, in order to be appointed to the DPS.

In the case of the Applicant being a consortium, this financial criterion may be fulfilled by the consortium members as a whole.

NOTE to Applicants: For the avoidance of doubt if an Applicant is submitting a response for multiple Categories they must submit an eESPD, ARD and Documentary Evidence of Financial and Economic Standing for all Categories applied for.

However, where the Applicant is unable, for a valid reason, to provide the documentation specified, the Applicant must inform the Contracting Authority of the reason why the documentation cannot be supplied and, if the Contracting Authority considers the reason given to be valid, provide such other suitable alternative documentation to prove, to the satisfaction of the Contracting Authority, their economic and financial capacity.

4.2.2 Technical and Professional Ability

Evaluation –Weighted Score out of 100%

Applicants will be assessed based on the total score received from each individual assessment of the Selection Criteria. Any Applicant who scores a total score less than **[60%]** will be immediately disqualified from the competition.

Applicants must declare by way of eESPD and in the ARD that they satisfy the technical and professional requirement(s) set out and must provide the information (and, where indicated, documents) below to demonstrate that they satisfy the technical and professional requirement(s) as set out.

Applicants must demonstrate in a clear and comprehensive manner that they have the level of experience and capacity necessary to deliver the services required for this DPS, for which they intend to submit an Application.

To demonstrate experience, Applicants must complete the **Applicant Response Document (ARD) specific to the application is being submitted**. Applicants must provide details of three (3) reference contracts relating to the provision of examination services delivered within the last four (4) years prior

to the DPS application date applied for. Each of the three reference contracts must be of a similar nature, scope and complexity to the Services sought as set out in this RFATP.

Applicants shall also set out in their Applicant Response Document (ARD) the duration of the reference contracts including when each commenced and when each is either due to expire / has expired, and the relevant reference contract referee's contact details including name, position, email address and telephone number of the referees. The Contracting Authority may contact the referees provided for verification purposes without any prior notice being given to the Applicant.

SELECTION CRITERIA	PASS REQUIREMENT	Weighted Percentage of Total Score
Previous Experience	Applicants must demonstrate the successful delivery of at least TWO comparable contracts (in scale, nature, quality and complexity) delivered during the three previous years. Describe in detail the extent and scope of which the Tenderer managed communications effectively to deliver goods and outline contingencies in place to ensure the quality of goods delivered.	50%
Organisation Profile & Background	i) Organisation: - Applicants must provide a detailed description on their organisations profile and background relevant to this DPS. - Provide an organisation chart clearly defining roles and responsibilities (identify employees and sub-contractors). ii) Quality Assurance: - Applicants must provide information which demonstrates a commitment to quality assurance and provide details of any quality assurance policies and systems and any accreditation attained. iii) Proposed Approach to Service Delivery Please ensure that your application highlights: - Your Understanding of this assessment as one for registered professionals. - Accessibility/ Accommodation Policy - Support Services for non-students/students - Your existing infrastructure to support non-students (access to reading libraries, campus facilities, digital tools etc.)	25%
Contract Management	The Applicant must provide: - The proposed approach to contract management - The CVs of the Account Manager(s)/ Lead Contact	25%

In order to facilitate evaluation of responses, **Applicants must submit the above within the Applicant Response Document (ARD)**, completed in line with instructions provided in that document.

4.3. Presentation Proposals

Not used

4.4. Notification and Admittance to DPS

- 4.4.1 The Contracting Authority will notify Applicants of its decision in relation to the establishment of the DPS and/or of the outcome of their Application to participate in the DPS.
- 4.4.2 Admittance to the DPS will be conditional upon the successful Applicant(s) (including the Prime Contractor and any Subcontractors) having submitted the following to the Contracting Authority along with their Application:
- (i) a Declaration in the form attached at Appendix 3;
 - (ii) if applicable, evidence to the effect that measures taken by the entity concerned are sufficient to demonstrate its reliability despite the existence of a relevant Exclusion Ground;
 - (iii) all or any of the evidence and supporting documents specified at paragraphs 4.1 and 4.2 above.

4.5. DPS Agreement

4.5.1 The successful Applicant(s) must sign and return the DPS Agreement(s) to the Contracting Authority no later than seven (7) calendar days from the date of request by the Contracting Authority. A signed DPS Agreement returned by the successful Applicant(s) is not binding on the Contracting Authority until the Contracting Authority has signed the DPS Agreement in accordance with paragraph 4.1.2 above.

Part 5: Award Criteria for Future Mini Competition

DPS Clients shall specify their own requirements, award criteria (including sub-criteria) and Grade structure in any future Mini-Competitions conducted under the DPS. The following are examples of requirements and award criteria/sub-criteria that may be applied by DPS Clients (and which DPS Members may be required to demonstrate that they fulfil) in future Mini-Competitions and are included in this Appendix 1 to provide Applicants with an overview of potential requirements and criteria in future Mini-Competitions. Applicants are reminded that while they are required to submit a response to, and fulfil the Compliance And Selection Criteria in Part 4 of the RFATP, Applicants are **not** required to submit a tender proposal in response to the requirements and award criteria below, nor is a pricing proposal required at this Stage 1 of the Competition. Qualitative and Cost Award Criteria will instead be required in response to any future Mini Competitions conducted under the DPS.

Mini Competition Tenders will be evaluated on the basis of a Qualitative/Cost assessment to determine the Most Economically Advantageous Tender ("MEAT").

The Award Criteria for these mini competitions shall include all, or some, of the following criteria:

No.	Award Criterion	Details	Maximum Marks	Minimum Marks
A.	Understanding of the requirements	- Understanding of the requirements of the contracting authority - Key risks to the delivery of the requirements	600	100
B.	Approach to delivering the tender	- Comprehensiveness of approach to delivering [describe goods] - Quality of plan and ability to meet deadlines for tender	600	100
C.	Proposed management team	The successful proposal will be expected to demonstrate the ability to: - Proposals in response to this brief should include the name, role description, skills and experience of each team member who will be undertaking the project and the specific areas for which they will be responsible. - Tenderers are asked to provide CV's for the proposed person(s) that will deliver on the services required.	400	100
D.	Contract management	- Contract governance - Approach to risk and issue management - Approach to communications and progress reporting	200	50
E.	Price		300	0
Total				

The Contracting Authority is seeking to promote Environmental, Sustainability and Social considerations through this DPS arrangement.

Part 6: Instruction to Applicants

6.1 Important Notices

6.1.1 While every effort has been made to provide comprehensive and accurate information in all notices and documents prepared for the purposes of this Competition, the Contracting Authority does not accept any liability or provide any express or implied warranty in respect of any such information. Applicants must form their own conclusions about the solution needed to meet the requirements set out in this RFATP and may wish to consult their legal advisers.

6.1.2 The Contracting Authority does not bind itself to accept any Application.

This RFATP does not constitute an offer or commitment to establish a DPS and/or to enter into a DPS Agreement or a Contract.

Admittance of an Applicant to the DPS will not take place unless and until a DPS Agreement has been signed by the Applicant and the Contracting Authority.

Admittance of an Applicant to the DPS does not guarantee the award of any Contract.

No contractual rights in relation to any DPS Client will exist unless and until a formal Contract has been executed by or on behalf of the DPS Client. Any notification of preferred bidder status by the Contracting Authority / a DPS Client at Mini Competition shall not give rise to any enforceable rights by the Applicant.

The Contracting Authority reserves the right to cancel this Competition at any time prior to executing a formal DPS Agreement or to terminate a DPS Agreement at any time during the Term in accordance with the termination provisions set out at clause 17 of the DPS Agreement.

Admission to the DPS or award of a Contract under a Mini-Competition does not confer exclusivity on the successful Applicant(s).

Applicants should note that the Contracting Authority or DPS Clients shall be under no obligation to purchase any minimum value of Services under the DPS Agreement or any Contract.

6.1.3 This RFATP supersedes and replaces any and all previous documentation, communications and correspondence between the Contracting Authority and Applicants, and Applicants should place no reliance on such previous documentation and correspondence.

6.1.4 In this clause 6.1.4, "Data Protection Laws" means all applicable national and EU data protection laws, regulations and guidelines including but not limited to Regulation (EU) 2016/679 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 (the "General Data Protection Regulation"), and any guidelines and codes of practice issued by the Office of the

Data Protection Commission or other supervisory authority for data protection in Ireland from time to time.

The Contracting Authority will be a Data Controller (where Data Controller has the meaning given under the Data Protection Laws) in respect of any Personal Data (where Personal Data has the meaning given under the Data Protection Laws) required to be provided by the Applicant in response to this RFATP.

The Applicant, as Data Controller in respect of any Personal Data provided by it in its Application, is required to confirm in the statement required under paragraph 6.4 below that all Data Subjects (where Data Subject has the meaning given under the Data Protection Laws) whose Personal Data is provided by the Applicant have consented to the processing of such Personal Data by the Applicant, the Contracting Authority, the Evaluation Team and the supplier of the etenders.gov.ie website, for the purposes of the participation of the Applicant in this Competition or that the Applicant otherwise has a legal basis for providing such Personal Data to the Contracting Authority for the purposes of its participation in this Competition .

6.2 Compliant applications

6.2.1 If an Applicant fails to comply in any respect with the requirements of this paragraph

6.2.2 The Contracting Authority reserves the right to reject the Applicant's Application as non-compliant or, without prejudice to this right and subject to its obligations at law, to take any other action it considers appropriate including but not limited to:

- seeking written (electronic) clarification from the Applicant;
- seeking further information from the Applicant;
- waiving a requirement, which in the Contracting Authority's view, is nonmaterial or procedural.

Applicants are required:

- (a) To complete and submit with their Application the electronic version of the European Single Procurement Document ("eESPD") which is available to download separately from www.etenders.gov.ie. Alternatively, Applicants may submit an eESPD which has already been used in a previous procurement procedure PROVIDED THAT they confirm that:
 - i. the information contained in it continues to be correct; and
 - ii. that they satisfy the Selection Criteria for this DPS as set out at part 3.2 below;
- (b) To submit all documentation which this RFATP requires to be submitted;
- (c) To follow the format of this RFATP and respond to each element in the order as set out in this RFATP;
- (d) To conform to and comply with all instructions and requirements set out in this RFATP;

- (e) To submit the Applicant's Statement (Appendix 1) required under paragraph 6.4, below;
- (f) Not to alter or edit this RFATP in any way; and
- (g) To complete and submit with their Application, the individual Category specific DPS Applicant Response Document ("ARD"). The individual ARDs must be completed in line with the instructions provided in each Category specific ARD document. The Category Specific ARD documents are available to download from www.etenders.gov.ie.

6.2.3 Without prejudice to the generality of paragraph 6.2.1, failure to comply with paragraph 6.6 below will render the Application non-compliant and it will be rejected.

6.3 DPS Agreement and Contract

6.3.1 Applicants should note the terms and conditions of the DPS Agreement and the Contract set out at Appendix 4 and Appendix 5 to this RFATP respectively.

6.3.2 Applicants are required to confirm their acceptance of the DPS Agreement and the Contract in the Applicant's Statement at Appendix 1. Applicants may not amend the DPS Agreement or the Contract.

6.4 Acceptance of RFATP Requirements

Each Applicant is required to accept the provisions of this RFATP. ALL APPLICANTS MUST RETURN, with their Application, a scanned signed copy of the Applicant's Statement, as set out in Appendix 1, printed on the Applicant's letterhead. The Contracting Authority must be able to read the scanned signature of the Applicant. If possible, please sign documents using blue ink. If the Contracting Authority cannot read the scanned signature, Applicants may be requested to resubmit. Applicants may not amend the Applicant's Statement.

6.5 Consortia and Prime/ Subcontractors

Where a group of undertakings (in whatever form and regardless of the legal relationship between them) come together to submit an application in response to this RFATP the Contracting Authority will deal with all matters relating to this Competition through a single nominated entity authorised to represent all members of the group of undertakings and who will carry overall responsibility for the DPS Agreement and performance of any Contract (the "Prime Contractor"), irrespective of whether or not tasks are to be performed by a subcontractor or other consortium member (the "Subcontractor").

The Applicant must provide details of all members of the group of undertakings and their role in the Application and clearly and comprehensively set out the name, title, telephone number, postal address, and email address of the nominated contact personnel of the Prime Contractor authorised to represent the Applicant and to whom all communications shall be directed and accepted until this Competition has been completed or terminated. Correspondence from any other person (including from any Subcontractor) will NOT be accepted, acknowledged or responded to.

6.6 Application and Submission Requirements

- 6.6.1.** Applications must be submitted via the electronic post-box available on www.etenders.gov.ie (the “Electronic Platform”). Only Applications submitted to the electronic post-box will be accepted. Applications submitted by any other means (including but not limited to by email, fax, post or hand delivery) will NOT be accepted.

Applicants must ensure that they give themselves sufficient time to upload and submit all required Application documentation before the initial Application Deadline (as defined in paragraph 6.6.2) has passed. Applicants should take into account the fact that upload speeds vary. There is a maximum of 4GB for the total (combined) documents sent to the electronic post-box. In order to submit a document to the electronic post-box, please note that you must click “Submit Response”. After submitting you can still modify and re-send your response up until response deadline. Applicants should be aware that the “Submit Response” button will be disabled automatically upon the expiration of the response deadline.

6.6.2. Application Deadline

Subject to paragraph 6.8.1 of this RFATP, Applications must be received not later than **[Insert date and time]** (the “Application Deadline”). Please note that this deadline is an administrative date to establish the DPS. Applicants are reminded that applications will continue to be accepted in line with Clause 1.2, once the DPS has been established.

- 6.6.3.** Applications must be submitted in English

- 6.6.4.** Each Applicant is limited to submitting one Application per Category in its own capacity and one Application per Category as part of a consortium/group of undertakings under this RFATP for admittance to the DPS.

- 6.6.5.** All parts of the Applications must be submitted in soft copy to the Electronic Platform and must be compiled such that they can be read immediately using a PDF Reader. The Contracting Authority is not responsible for corruption in electronic documents. Applicants must ensure electronic documents are not corrupt.

6.7 Queries and Clarifications

- 6.7.1** All queries relating to any aspect of this Competition or of this RFATP must be directed to the messaging facility on the Electronic Platform www.etenders.gov.ie. Subject to paragraph 6.8.1 of this RFATP, queries must be submitted by no later than **[Insert date and time]**. For the avoidance of doubt, Applicants may not contact potential DPS Clients regarding any aspect of this Competition.

- 6.7.2** All responses to queries will be issued by the Contracting Authority via the messaging facility on the Electronic Platform www.etenders.gov.ie Where appropriate, queries may be

amalgamated. Applicants should note that the Contracting Authority will not respond to individual Applicants privately.

- 6.7.3** The Contracting Authority reserves the right to issue or seek written clarifications via the Electronic Platform.
- 6.7.4** The Contracting Authority reserves the right, at any time before the Application Deadline, to update or amend the information contained in this document and/or to extend the Application Deadline. Participating Applicants will be informed of any such amendment or extension through the Electronic Platform.
- 6.7.5** Applicants should ensure that they register their interest in this Competition, by clicking on the “Accept” button on the Electronic Platform, in order to receive all responses to queries and other updates in relation to this Competition.

6.8 Applications for Admittance to DPS and Applicant Cost

- 6.8.1** Notwithstanding the Application Deadline in paragraph 6.6.2 and the deadline for submission of clarification queries in paragraph 6.7.1, both unsuccessful Applicants that submit an Application but fail to fulfil the Compliance and Selection criteria in this RFATP, and economic operators that did not submit an Application in response to this RFATP by the Application Deadline may raise clarification queries relating to any aspect of this Competition or of this RFATP and apply / re-apply and submit an Application in response to this RFATP at any stage throughout the Term of the DPS, once established. The Contracting Authority shall evaluate any such Application(s) against the Compliance and Selection Criteria set out in this RFATP and shall duly notify the Applicant of the outcome of that Application in accordance with paragraph 4.4.1 of this RFATP.
- 6.8.2** All costs and expenses incurred by Applicants relating to their participation in this Competition shall be borne by and are a matter for discharge by the Applicants exclusively.

6.9 Confidentiality

- 6.9.1** All documentation, drawings, data, statistics, information, patterns, samples or material disclosed or furnished by the Contracting Authority to Applicants during the course of this Competition:
 - (a) are furnished for the sole purpose of replying to this RFATP only;
 - (b) may not be used, communicated, reproduced or published for any other purpose without the prior written permission of the Contracting Authority;
 - (c) shall be treated as confidential by the Applicant and by any third parties (including subcontractors) engaged or consulted by the Applicant; and
 - (d) must be returned immediately to the Contracting Authority upon cancellation or completion of this Competition if so requested by the Contracting Authority.

6.10 Pricing

- 6.10.1** Applicants are reminded that they are **not** required to submit a Pricing Schedule in response to this RFATP. Successful Applicants appointed to the DPS will however be required to submit pricing in response to future Mini-Competitions conducted under the DPS.
- 6.10.2** All prices quoted in any subsequent Mini-Competitions must be all-inclusive (i.e. including but not being limited to shipping, packaging, delivery, ancillary costs and all other costs/expenses), be expressed in Euro only and exclusive of VAT. The VAT rate(s) where applicable should be indicated separately.
- 6.10.3** *Not Used*
- 6.10.4** Any currency variations occurring over the term of any Contract shall be borne by the Applicant.
- 6.10.5** Payments for Services provided pursuant to this RFATP shall be made subject to and in accordance with the Contract at Appendix 5 to this RFATP and the terms of any subsequent RFT.
- 6.10.6** *Not Used*

6.11 Environmental, Social and Labour Law

- 6.11.1** In the performance of any Contract awarded, the successful Applicant(s) and their Subcontractors (if any), shall be required to comply with all applicable obligations in the field of environmental, social and labour law that apply at the place where the goods or related services are provided, that have been established by EU law, national law, collective agreements or by international, environmental, social and labour law listed in Schedule 7 of the Regulations.
- 6.11.2** Applicants shall be required to include an undertaking to comply fully with the provisions of Council Directive 2001/23/EC of 12 March 2001 on the approximation of the laws of the Member States relating to the safeguarding of employees' rights in the event of transfers of undertakings, business or parts of undertakings or business and as implemented in Irish law by Statutory Instrument S.I. No. 131 of 2003, the European Communities (Protection of Employees on Transfer of Undertakings) Regulations 2003 and to indemnify the Contracting Authority for any claim arising or loss or costs incurred as a result of its failure or incapacity to fulfil its obligations under the said Directive and Statutory Instrument.
- 6.11.3** The Protection of Employees (Temporary Agency Work) Act 2012 (the "2012 Act") provides that an Agency Worker (as defined in the 2012 Act) is entitled to the same basic working and employment conditions as those which apply to employees recruited directly by the Hirer (as defined in the 2012 Act) to do the same or a similar job. Where the provision of the Services

will involve the provision to the Contracting Authority of Agency Workers (within the meaning of the 2012 Act), Applicants should ensure that they consider their obligations under the 2012 Act when pricing their Application. The Contracting Authority shall have no liability for any increase in salaries that may be payable as a result of the application of the 2012 Act to the provision of the Services.

6.12 Publicity

No publicity regarding this DPS or any DPS Admission, Agreement, Mini-Competition, or Contract pursuant to this DPS is permitted unless and until the Contracting Authority has given its prior written consent to the relevant communication.

6.13 Registrable Interest

Any Registrable Interest involving any Applicant or Subcontractor and the Contracting Authority, any DPS Client, members of the Government, members of the Oireachtas, or employees and officers of the Contracting Authority or the DPS Clients and their relatives must be fully disclosed in the Application or, in the event of this information only coming to the notice of the Applicant or Subcontractor after the submission of an Application, must be communicated to the Contracting Authority immediately upon such information becoming known to the Applicant/Subcontractor. The terms “Registrable Interest” and “Relative” shall be interpreted as per Section 2 of the Ethics in Public Office Acts 1995 and 2001, copies of which are available at www.irishstatutebook.ie. The Contracting Authority will, in its absolute discretion, decide on the appropriate course of action, which may in appropriate circumstances include eliminating this Applicant from this Competition or a Mini-Competition or terminating any DPS Agreement and / or Contract entered into by such Applicant.

6.14 Anti-Competitive Conduct

Applicants’ attention is drawn to the Competition Act 2002 (as amended, the “2002 Act”). The 2002 Act makes it a criminal offence for Applicants to collude on prices or terms in a public procurement competition.

6.15 Industry Terms Used in RFATP

Where reference is made to a particular item, source, process, trademark, or type in this RFATP then all such references are to be given the meaning generally understood in the relevant industry and operational environment.

6.16 Freeform of Information

6.16.1 Applicants should be aware that, under the Freedom of Information Act 2014, information provided by them during this Competition may be liable to be disclosed.

6.16.2 Applicants are asked to consider if any of the information supplied by them in their Application should not be disclosed because of its confidentiality or commercial sensitivity. If Applicants consider that certain information is not to be disclosed because of its confidentiality or

commercial sensitivity, Applicants must, when providing such information, clearly identify such information and specify the reasons for its confidentiality or commercial sensitivity. If Applicants do not identify information as confidential or commercially sensitive, it is liable to be released in response to a Freedom of Information request without further notice to or consultation with the Applicant. The Contracting Authority will, where possible, consult with Applicants about confidential or commercially sensitive information so identified before making a decision on a request received under the Freedom of Information Act. The Contracting Authority accepts no liability whatsoever in respect of any information provided which is subsequently released (irrespective of notification) or in respect of any consequential damage suffered as a result of such obligations.

6.17 Tax Clearance

It will be a condition of admission to the DPS and any Contract resulting from a MiniCompetition that the successful Applicant(s) shall, for the term of such Contract(s), comply with all EU and domestic tax laws. Applicants are referred to www.revenue.ie for further information. Prior to the award of any DPS Agreement or Contract arising out of a MiniCompetition, the successful Applicant shall be required to supply its Tax Clearance Access

Number and Tax Reference Number to facilitate online verification of their tax status by the Contracting Authority. By supplying these numbers the successful Applicant acknowledges and agrees that the Contracting Authority has the permission of the successful Applicant to verify its tax cleared position online.

6.18 Conflict of Interest

Any conflict of interest or potential conflict of interest on the part of an Applicant, Subcontractor or individual employee(s) or agent(s) of the Applicant or Subcontractor(s) must be fully disclosed to the Contracting Authority as soon as the conflict or potential conflict is or becomes apparent. In the event of any actual or potential conflict of interest, the Contracting Authority may invite Applicants to propose means by which the conflict of interest might be removed. The Contracting Authority will, at its absolute discretion, decide on the appropriate course of action, which may in appropriate circumstances include eliminating an Applicant from this Competition or any Mini-Competition or terminating any DPS Agreement or Contract entered into by an Applicant.

6.19 Withdrawal from Participation in this DPS

Applicants are required to notify the Contracting Authority immediately, via the Electronic Platform, if at any stage they decide to withdraw from participation in this Competition.

6.20 Site Visit

Not Used

6.21 Insurance

6.21.1 The successful Applicant(s) shall be required to hold, for the term of any Contract awarded pursuant to a Mini-Competition, insurances of the type and to the level specified in each Mini-Competition. Applicants should note that they are not obliged to have insurances in place in order to enter into a DPS Agreement with the Contracting Authority. The types of and levels of insurance required are not likely to exceed the following insurances:

Type of Insurance	Indemnity Limit
Employer's Liability	€12.7m
Public Liability	€6.5m
Product Liability	€6.5m
Professional Indemnity	€1,500,000

6.21.2 By signing the Applicant's Statement at Appendix 1, Applicants confirm, that if awarded a Contract arising from a Mini-Competition pursuant to the DPS Agreement,

- a) they will, from the Effective Date of the Contract (as defined in the Contract), obtain and hold the types and levels of insurance as specified in the relevant RFT
- b) (ii) confirm that the territorial limits and jurisdiction of the insurance policies will include Ireland and
- c) confirm that they are not aware of any exclusions, restrictions, conditions or warranties or, in the case of policies with an aggregate limit of indemnity, any outstanding claims, which could have a material adverse impact on the level of coverage specified above. A formal confirmation from the Applicant's insurance company or broker to this effect will be requested from the successful DPS Member(s) prior to the award of (and shall be a condition of) any Contract.

6.21.3 The successful Applicant will, during the term of any Contract, be required to:

- a. immediately advise the Contracting Authority and the DPS Client of any material change to its insured status;
- b. produce proof of current premiums paid upon request;
- c. produce valid certificates of insurance upon request.

Appendix 1: Applicant's Statement

TO: The Pharmaceutical Society of Ireland (PSI) (the "Contracting Authority").

RE: Request to Participate in the DPS for the provision of Third Country Recognition (TCQR) Examination services

Having examined the Request for Application to Participate in the DPS (the "RFATP") including the Instructions to Applicants, the Selection Criteria, the Requirements and Specifications, and the terms and conditions of the DPS Agreement and the Contract we hereby agree and declare the following:

1. We understand the nature and extent of the Services required to be delivered as described in the Requirements and Specifications at Part 3 to the RFATP.
2. We accept all of the Terms and Conditions of the RFATP, and the DPS Agreement, Contract and Confidentiality Agreement appended to the RFATP, and agree if awarded any contract pursuant to the DPS Agreement to execute the Contract and Confidentiality Agreement appended to the RFATP.
3. We confirm that we have complied with all requirements as set out at Part 6 of the RFATP.
4. We accept all the Selection Criteria as set out in Part 4 of the RFATP.
5. We agree to provide the Services in accordance with the RFATP, our Application, the RFT and our response to the RFT if awarded any Contract pursuant to the DPS Agreement.
6. We agree that, if admitted to the DPS, we will be bound by the DPS Agreement at Appendix 4 and that, if awarded any Contract pursuant to a Mini-Competition, we shall comply with the terms and conditions of the Contract at Appendix 5.
7. We shall, if awarded any Contract pursuant to the DPS, have in place on the Effective Date of the Contract all insurances (if any) as required by paragraph 6.21.1 of the RFATP or as required by the RFT issued at Mini-Competition stage.
8. We agree that, if awarded any Contract, we shall, in the performance of such contract, comply with all applicable obligations in the field of environmental, social and labour law.
9. We confirm that all Data Subjects whose Personal Data is provided in our Application have consented to the processing of such Personal Data by us, the Contracting Authority, the Evaluation Team and the supplier of the etenders.gov.ie website, for the purposes of our participation in this Competition or that we otherwise have a legal basis for providing such Personal Data to the Contracting Authority for the purposes of our participation in this Competition and that we will provide evidence of such consent and / or legal basis to the Contracting Authority upon request.

Signed: (Authorised Signatory)	
Print Name in Block Capitals:	Click here and insert name
Position:	Click here and insert details
Company:	Click here and insert details
Registered Office Address:	Click here and insert address
	Click here and insert address
Date:	Click here and insert date

Appendix 2: Electronic European Single Procurement Document (eESPD)

The Electronic European Single Procurement Document is available to download separately from www.etenders.gov.ie and must (in accordance with paragraph 4.1 of the RFATP) be submitted with the Applicant's Application in response to this RFATP.

Appendix 3: Declaration as to Personal Circumstances of Applicant

Re: Request to Participate in a Dynamic Purchasing System for Third Country Recognition (TCQR) Examination services.

NAME: *[Click here and insert name]*

ADDRESS: *[Click here and insert name]*

I, *[click here and insert name of Declarant]* having been duly authorised by *[click here and insert name of entity]*, sincerely declare that *[click here and insert name of entity]* itself or any person who has is a member of the administrative, management or supervisory body of *[click here and insert name of entity]* or has powers of representation, decision or control in *[click here and insert name of entity]* :

- (a) Has never been the subject of a conviction for participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA.
- (b) Has never been the subject of a conviction for corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union and Article 2(1) of Council Framework Decision 2003/568/JHA as well as corruption as defined in the national law of the Contracting Authority or The Pharmaceutical Society of Ireland (PSI)
- (c) Has never been the subject of a conviction for fraud within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests.
- (d) Has never been the subject of a conviction for terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA respectively, or for inciting or aiding or abetting or attempting to commit an offence, as referred to in Article 4 of that Framework Decision.
- (e) Has never been the subject of a conviction for money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council.
- (f) Has never been the subject of a conviction for child labour and other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council.
- (g) Is not in breach of its obligations relating to the payment of taxes or social security contributions.

- (h) Has, in the performance of all public contracts, complied with applicable obligations in the field of environmental, social and labour law that apply at the place where the works are carried out or the Services provided, that have been established by EU law, national law, collective agreements or by international, environmental, social and labour law listed in Schedule 7 of the European Union (Award of Public Authority Contracts) Regulations 2016 (SI 284 of 2016).
- (i) Is not bankrupt or the subject of insolvency or winding-up proceedings, its assets are not being administered by a liquidator or by the court, it is not in an arrangement with creditors, its business activities are not suspended nor is it in any analogous situation arising from a similar procedure under national laws and regulations.
- (j) Is not guilty of grave professional misconduct.
- (k) Has not entered into agreements with other economic operators aimed at distorting the DPS.
- (l) Is not aware of any conflict of interest due to its participation in the DPS;
- (m) Has not had any prior involvement in the preparation of the DPS;
- (n) Is not guilty of significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity, or a prior concession contract, which led to early termination of that prior contract, damages or other comparable sanctions.
- (o) Is not guilty of serious misrepresentation in supplying the information required for the verification of the absence of grounds for exclusion or the fulfilment of the Selection Criteria for this DPS and did not withhold such information and did not fail to submit supporting documents in respect of this DPS as required under Regulation 59 of the European Union (Award of Public Authority Contracts) Regulations 2016 (SI 284 of 2016).
- (p) Has not undertaken to unduly influence the decision-making process of the Contracting Authority in respect of the DPS, or obtain confidential information that may confer upon it undue advantages in respect of the DPS; or negligently provided misleading information that may have a material influence on decisions concerning exclusion, selection or award.

I understand and acknowledge that the provision of inaccurate or misleading information in this declaration may lead to my business/firm/company/partnership being excluded from participation in this or future Applications to participate in this DPS, and I make this solemn declaration conscientiously

believing the same to be true and by virtue of the Statutory Declarations Act, 1938. This declaration is made for the benefit of the Contracting Authority.

Signature of Declarant

Name of Declarant in print or block capitals

Declared before me by _____ who is personally known to me (or who is identified to me by _____ who is personally known to me) at _____ this _____ day of _____ 20__

_____(signed)

Practising Solicitor/Commissioner for Oaths

Appendix 3A: Foreign Subsidies Regulation

Tenderers are referred to the provisions of Regulation (EU) 2022/2560 of the European Parliament and of the Council on Foreign Subsidies distorting the Internal Market, in addition to Commission Implementing Regulation (EU) 2023/1441, and their obligation to comply therewith. In particular, tenders and candidates should note the requirements under Articles 28 and 29 of Regulation (EU) 2022/2560 relating to the prior notification or declaration of a foreign financial contribution, where the estimated value of the public procurement procedure is equal to or greater than the applicable financial thresholds set out therein.

Where the estimated value of the public procurement procedure is equal to or greater than the financial threshold set out at Article 28 of Regulation (EU) 2022/2560, economic operators are required to comply in full with their obligations under both that Regulation and Implementing Regulation (EU) 2023/1441. In that regard, economic operators are required to complete the relevant form of declaration or notification that apply to their particular circumstances.

Appendix 3A: Schedule A-Declaration of No Foreign Financial Contributions

[Tenderers shall complete and return the following form]

[To be completed by notifying parties where the value of the procurement procedure is equal to or greater than the financial thresholds in Article 28 of Regulation (EU) 2022/2560 and where the notifying party has not been in receipt of any foreign financial contributions]

TO: The Pharmaceutical Society of Ireland (PSI) (the “Contracting Authority”)

RE: DPS Tender for the provision of examinations services

We hereby declare that none of the notifying parties has been in receipt of any foreign financial contributions within the meaning of Regulation (EU) 2022/2560

Signed

Notifying Party

Authorised Signatory
(Print Name)

Registered Address:

Date

Appendix 3A: Schedule B-Declaration that any Foreign Financial Contributions are non-notifiable having regard to the de minimis threshold

[To be completed by notifying parties where the value of the procurement procedure is equal to or greater than the financial thresholds in Article 28 of Regulation (EU) 2022/2560 and where the notifying party has been in receipt of foreign financial contributions that do not exceed de minimis aid as defined in Article 3(2) of Regulation (EU) 1407/2013 (i.e. €200,000) per third country over any consecutive three period.]

Form FS-PP relating to the notification of financial contributions in the context of public procurement procedures pursuant to Regulation (EU) 2022/2560

1. Description of the public procurement (Section 1 of Form FS-PP)

2. Information about notifying parties (Section 2 of Form FS-PP)

3. Declaration (Section 7 of Form FS-PP)

None of the notifying parties have received foreign financial contributions notifiable under Chapter 4 of Regulation (EU) 2022/2560

4. Attestation (Section 8 of Form FS-PP)

The notifying party(ies) confirm(s) that, to the best of their knowledge and belief, the information given in this declaration is true, correct, and complete, that true and complete copies of documents required by this Form FS-PP have been supplied, that all estimates are identified as such and are their best estimates of the underlying facts, and that all the opinions expressed are sincere. The notifying party(ies) confirm that they are aware of the provisions of Article 33 of Regulation (EU) 2022/2560 concerning fines and periodic penalty payments.

Date:

[Signatory 1]

Name:

Organisation:

Position:

Address:

Phone Number:

Email:

Signed:

[Signatory 2]

Name:

Organisation:

Position:

Address:

Phone Number:

Email:

Signed:

Appendix 3A: Schedule C-Declaration of non-notifiable foreign financial contributions (valued between €200,000 and €999,000 in the last three years preceding the declaration)

[To be completed by notifying parties where the value of the procurement procedure is equal to or greater than the financial thresholds in Article 28 of Regulation (EU) 2022/2560 and where the notifying party has been in receipt of foreign financial contributions which are valued between €200,000 and €999,000 in the last three (3) years preceding the declaration. Notifying parties are required to complete Table 2 below and they may aggregate the foreign financial contributions without indicating their values.]

Form FS-PP relating to the notification of financial contributions in the context of public procurement procedures pursuant to Regulation (EU) 2022/2560

- 1. Description of the public procurement (Section 1 of Form FS-PP)**
- 2. Information about notifying parties (Section 2 of Form FS-PP)**
- 3. Declaration (Section 7 of Form FS-PP)**

None of the notifying parties have received foreign financial contributions notifiable under Chapter 4 of Regulation (EU) 2022/2560

4. Attestation (Section 8 of Form FS-PP)

The notifying party(ies) confirm(s) that, to the best of their knowledge and belief, the information given in this declaration is true, correct, and complete, that true and complete copies of documents required by this Form FS-PP have been supplied, that all estimates are identified as such and are their best estimates of the underlying facts, and that all the opinions expressed are sincere. The notifying party(ies) confirm that they are aware of the provisions of Article 33 of Regulation (EU) 2022/2560 concerning fines and periodic penalty payments.

Date:

[Signatory 1]

[Signatory 2]

Name:

Name:

Organisation:

Organisation:

Address:

Address:

Phone Number:

Phone Number:

Email:

Email:

Signed:

Signed:

Table

For reporting of foreign financial contributions which are of a value between €200,000 and €999,000 in the last three (3) years preceding the declaration:

Third Country	Brief Description of the Financial Contributions
Country A	
Country B	
Country C	
Country D	

Appendix 3A: Schedule D- Declaration of non-notifiable foreign financial contributions (valued between €1,000,000 and €3,999,000 in the last three years preceding the declaration)

[To be completed by notifying parties where the value of the procurement procedure is equal to or greater than the financial thresholds in Article 28 of Regulation (EU) 2022/2560 and where the notifying party has been in receipt of foreign financial contributions which are valued between €1,000,000 and €3,999,000 in the last three (3) years preceding the declaration. Notifying parties are required to complete the table below. They must list all foreign financial contributions received, to include all non-notifiable foreign contributions received in the last three (3) years preceding the declaration.]

Form FS-PP relating to the notification of financial contributions in the context of public procurement procedures pursuant to Regulation (EU) 2022/2560

- 1. Description of the public procurement (Section 1 of Form FS-PP)**
- 2. Information about notifying parties (Section 2 of Form FS-PP)**
- 3. Declaration (Section 7 of Form FS-PP)**

None of the notifying parties have received foreign financial contributions notifiable under Chapter 4 of Regulation (EU) 2022/2560

4. Attestation (Section 8 of Form FS-PP)

The notifying party(ies) confirm(s) that, to the best of their knowledge and belief, the information given in this declaration is true, correct, and complete, that true and complete copies of documents required by this Form FS-PP have been supplied, that all estimates are identified as such and are their best estimates of the underlying facts, and that all the opinions expressed are sincere.

The notifying party(ies) confirm that they are aware of the provisions of Article 33 of Regulation (EU) 2022/2560 concerning fines and periodic penalty payments.

Date:

[Signatory 1]

[Signatory 2]

Name:

Name:

Organisation:

Organisation:

Position:

Position:

Address:

Address:

Phone Number:

Phone Number:

Email:

Email:

Signed:

Signed:

Table

For reporting of foreign financial contributions which are of a value between €1,000,000 and €3,999,000 in the last three (3) years preceding the declaration, to include all non-notifiable foreign contributions.

Third Country	Type of Financial Contribution (FC)	Brief Description of the Financial Contributions (FC)	Estimated Value of the Financial Contribution (FC)
Country A			
Country B			
Country C			
Country D			

Appendix 3A: Schedule E- Notification of Foreign Financial Contributions

[To be completed by notifying parties where the value of the procurement procedure is equal to or greater than the financial thresholds in Article 28 of Regulation (EU) 2022/2560 and where the notifying party has been in receipt of aggregated foreign financial contributions in the three (3) years prior to notification, valued equal to or greater than €4M per third country].

Form FS-PP relating to the notification of financial contributions in the context of public procurement procedures pursuant to Regulation (EU) 2022/2560

1. Description of the public procurement (Section 1 of Form FS-PP)

2. Information about notifying parties (Section 2 of Form FS-PP)

3. Foreign Financial Contributions (Section 3 of Form FS-PP)

3.1. For the purposes of this section 3.1, the notifying party(ies) should report foreign financial contributions falling into the scope of Article 5(1), points (a), (b), (c) and (e) of Regulation (EU) 2022/2560, which are amongst the most likely to distort the internal market.

3.1.1. In order to allow the Commission to determine whether a foreign financial contribution has been granted to an undertaking that was ailing within the meaning of Article 5(1)(a) of Regulation (EU) 2022/2560, notifying parties should indicate whether any of the following conditions were met at any point of time in the three years prior to the notification.

3.1.1.1. Is the notifying party a limited liability company, where more than half of its subscribed share capital has disappeared as a result of accumulated losses?

☐ yes ☐ no

3.1.1.2. Is the notifying party a company where at least some members have unlimited liability for the debt of the company, and where more than half of its capital as shown in the company accounts has disappeared as a result of accumulated losses?

☐ yes ☐ no

3.1.1.3. Is the notifying party subject to collective insolvency proceedings or does it fulfil the criteria under its domestic law for being placed in collective insolvency proceedings at the request of its creditors?

☐ yes ☐ no

3.1.1.4. In the case the notifying party in question is not an SME:

3.1.1.4.1. has the notifying party's book debt to equity ratio been greater than 7,5 for the past two years

and

3.1.1.4.2. has the notifying party's EBITDA interest coverage ratio been below 1,0 for the past two years?

☐ yes ☐ no

3.1.1.5. If the reply to any of the questions in sections 3.1.1.1 to 3.1.1.4 was 'yes' in relation to any of the notifying parties, please indicate whether during the period in which the undertaking in question was ailing, it received any foreign financial contributions that may have contributed to restore its long-term viability (including any temporary liquidity assistance designed to support that restoration of viability) or to keep that party afloat for the short time needed to work out a restructuring or liquidation plan.

Notifying Party (ies) ☐ yes ☐ no

3.1.1.6. If the reply to any of the questions in sections 3.1.1.1 to 3.1.1.4 was 'yes' in relation to any of the notifying parties, indicate if there is a restructuring plan capable of leading to the long-term viability of that party and if this restructuring plan includes a significant own contribution by the notifying party and provide details of that plan.

3.1.1.7. If the reply to any of the questions in points 3.1.1.1 to 3.1.1.4 was 'yes', please substantiate the answer, including references in the answer to the supporting evidence or documents that are to be provided in annexes (such documents may include, but are not limited to, the notifying party's latest profit and loss account statements with balance sheets, or court decision opening collective insolvency proceedings on the company or documents providing evidence that the criteria for being placed under insolvency proceedings at the request of creditors under national company law are met, etc.).

3.1.2. Has the notifying party been in receipt of a foreign financial contribution in the form of an unlimited guarantee for the debts or liabilities of the undertaking, namely without any limitation as to the amount or the duration of such guarantee (Article 5(1)(b)) of Regulation (EU) 2022/2560.

☐ yes ☐ no

3.1.3. Has the notifying party been in receipt of an export financing measure that is not in line with the OECD Arrangement on officially supported export credits (Article 5(1)(c)) of Regulation (EU) 2022/2560.

☐ yes ☐ no

3.1.4. Has the notifying party been in receipt of a foreign financial contribution enabling an undertaking to submit an unduly advantageous tender on the basis of which the undertaking could be awarded the relevant contract (Article 5(1)(e)) of Regulation (EU) 2022/2560.

☐ yes ☐ no

3.2. For each foreign financial contribution equal to or in excess of EUR 1 million granted to the notifying parties in the three years prior to the notification that may fall into any of the categories of Article 5(1), points (a) to (c) and (e) of Regulation (EU) 2022/2560, the notifying party must provide the following information and provide supporting documents:

3.2.1. Form of the financial contribution (e.g. loan, tax exemption, capital injection, fiscal incentive, contributions in kind, etc.).

3.2.2. Third country granting the financial contribution. Specify also the granting public authority or entity.

3.2.3. Amount of each financial contribution.

3.2.4. Purpose and economic rationale for granting the financial contribution to the party

3.2.5. Whether there are any conditions attached to the financial contributions as well as its use.

3.2.6. Describe the main elements and characteristics of those financial contributions (e.g. interest rates and duration in the case of a loan).

3.2.7. Explain whether the financial contribution confers a benefit within the meaning of Article 3 of Regulation (EU) 2022/2560 to the undertaking to which the foreign financial contribution has been granted. Please explain why, with reference to the supporting documents provided under Section 6 (below).

3.2.8. Explain whether the financial contribution is limited in law or in fact, within the meaning of Article 3 of Regulation (EU) 2022/2560, to certain undertakings or industries. Please explain why, with reference to the supporting documents provided under Section 6 (below).

3.2.9. Explain if the financial contribution is granted only for operating costs exclusively linked with the public procurement at stake.

3.3 Having regard to foreign financial contributions not falling within the categories set out in Section 3.1 above, notifying parties are required to provide an overview of the foreign financial contributions equal to or in excess of EUR 1 million granted to the notifying parties in the three years prior to the notification that do not fall into any of the categories of Article 5(1), points (a) to (e) of Regulation (EU) 2022/2560. In that regard, notifying parties are required to complete Table 1 below. Notifying parties should follow the instructions provided at Section 8 (Annex II) of Commission Implementing Regulation (EU) 2023/1441.

Table 1

Information to be included in Table 1 below by notifying parties.

- I. Group the different financial contributions per third country and per type, such as direct grant, loan/financing instrument/repayable advances, tax advantage, guarantee, risk capital instrument, equity intervention, debt write-off, contributions provided for the non-economic activities of an undertaking (see recital 16 of Regulation (EU) 2022/2560), or other.
- II. Include only those countries where the estimated aggregate amount of all financial contributions per country granted in the three years prior to the notification (calculated according to point (iv) below) is EUR 4 million or more.
- III. For each type of financial contribution, provide a brief description of the purpose of the financial contributions and the granting entities.
- IV. Quantify the estimated aggregate amount of financial contributions granted by each third country in the three years prior to the notification in the form of ranges, as specified in the notes to the Table below. For the calculation of this amount, the following considerations are relevant:
 - a. Take into account foreign financial contributions falling into the categories of Article 5(1) of Regulation (EU) 2022/2560 and on which information has been provided under Sections 3.1 and 3.2 (above) and;
 - b. do not take into account foreign financial contributions excluded according to points (v) and (vi) below
- V. Notifying Parties do not need to include (in the Table below) a description of the following foreign financial contributions:
 - a. Deferrals of payment of taxes and/or of social security contributions, tax amnesties and tax holidays as well as normal depreciation and loss-carry forward rules that are of general application. If these measures are limited, for example, to certain sectors, regions or (types of) undertakings, they have to be included.
 - b. Application of tax reliefs for avoidance of double taxation in line with the provisions of bilateral or multilateral agreements for avoidance of double taxation as well as unilateral tax reliefs for avoidance of double taxation applied under national tax legislation to the extent they follow the same logic as the provisions of bilateral or multilateral agreements.
 - c. Provision/purchase of goods/services (except financial services) at market terms in the ordinary course of business, for example the provision/purchase of goods or services carried out following a competitive, transparent and non-discriminatory tender procedure.

d. Foreign financial contributions below the individual amount of EUR 1 million

- VI. The foreign financial contributions that may be relevant for the assessment of each public procurement may depend on a number of factors such as the sectors or activities involved, the type of financial contributions or other specificities of the case. In light of these specificities, the Commission may request additional information where it considers such information necessary for its assessment.

Third Country	Type of Financial Contribution (FC)	Brief Description of the Financial Contributions (FC)	Total Estimated Value of the Financial Contribution (FC)
Country A			
Country B			
Country C			
Country D			

Note: please provide a separate table for each of the notifying parties. Third countries and, where possible, types of contributions, should be ordered by total amount of foreign financial contribution, from the highest to the lowest.

* Identify the financial contributions grouping them by type: such as direct grant, loan/financing instrument/repayable advances, tax advantage, guarantee, risk capital instrument, equity intervention, debt write-off, contributions provided for the non-economic activities of an undertaking (see recital 16 of Regulation 2022/2560), or other.

** General description of the purpose of the financial contributions included in each type and of the granting entity(ies). For instance, 'tax exemption for the production of product A and R & D activities', 'several loans with State-owned banks for purpose X', 'several financing measures with State investment agencies to cover operating expenses/for R & D activities', 'public capital injection in Company X'.

*** Use the following ranges: 'EUR 45-100 million', 'EUR > 100-500 million', 'EUR > 500-1 000 million', 'more than EUR 1 000 million'

4. Justification for absence of unduly advantageous tender – (Section 4 of Form FS-PP)

4.1. For any of the foreign financial contributions enabling an undertaking to submit an unduly advantageous tender on the basis of which the undertaking could be awarded the relevant contract (Article 5(1)(e) of Regulation (EU) 2022/2560), are there any elements which can be adduced to demonstrate that the tender is not unduly advantageous directly or indirectly due to the financial contribution(s) received, including the elements referred to in Article 69(2) of Directive 2014/24/EU.

In that regard, notifying parties should detail any elements that in their view may demonstrate that their tender is not unduly advantageous.

4.2. The elements may in particular refer to:

4.2.1. The economics of the manufacturing process, of the services provided or of the construction method;

4.2.2. The technical solutions chosen or any exceptionally favourable conditions available to the tenderer for the supply of the products or services or for the execution of the work;

4.2.3. The originality of the work, supplies or services proposed by the tenderer;

4.2.4. Compliance with applicable obligations in the fields of environmental, social and labour law;

4.2.5. Compliance with obligations regarding subcontracting.

5. Possible Positive Effects - (Section 5 of Form FS-PP)

5.1. If applicable, notifying parties should list and substantiate any possible positive effects on the development of the relevant subsidised economic activity on the internal market. Notifying parties should also list and substantiate any other positive effects of the foreign subsidies, such as broader positive effects in relation to the relevant policy objectives, in particular those of the Union, and specify when and where those effects have or are expected to take place. Notifying parties should provide a description of each of those positive effects.

6. Supporting Documentation – (Section 6 of Form FS-PP)

Notifying parties are required to provide the following for each notifying party:

6.1. Copies of all the supporting official documents relating to the financial contributions that may fall into any of the categories of Article 5(1), points (a) to (c) and (e) of Regulation (EU) 2022/2560 pursuant to Section 3.1.

6.2. Copies of the following documents prepared by or for or received by any member of the board of management, the board of directors or the supervisory board: Analyses, reports, studies surveys, presentations and any comparable documents discussing the purpose, use and economic rationale of the foreign financial contributions that may fall into any of the categories of Article 5(1), points (a) to (c) and (e) of Regulation (EU) 2022/2560.

Provide the same documents prepared by or for or received by the entity granting the foreign financial contribution to the extent that they are in your possession or that they are publicly available.

6.3. An indication of the internet address, if any, at which the most recent annual accounts or reports of the notifying party(ies) are available, or if no such internet address exists, copies of the most recent annual accounts and reports.

6.4. Where the notifying party(ies) provide(s) justifications of the absence of an undue advantage of the tender by filling in Section 4 of this form, they also need to provide documentation for the period covering the three years preceding the notification, substantiating the adduced elements. Such documentation may include, inter alia, as relevant: (a) tax declarations for the period under review, including copies of company tax returns and VAT returns, (b) business plans and market research underlying the decision to participate in the public procurement procedure.

7. Attestation (Section 8 of Form FS-PP)

The notifying party(ies) confirm(s) that, to the best of their knowledge and belief, the information given in this declaration is true, correct, and complete, that true and complete copies of documents required by this Form FS-PP have been supplied, that all estimates are identified as such and are their best estimates of the underlying facts, and that all the opinions expressed are sincere. The notifying party(ies) confirm that they are aware of the provisions of Article 33 of Regulation (EU) 2022/2560 concerning fines and periodic penalty payments.

Date:

[Signatory 1]

Name:

Organisation:

Position:

Address:

Phone Number:

Email:

Signed:

[Signatory 2]

Name:

Organisation:

Position:

Address:

Phone Number:

Email:

Signed:

Appendix 4: Dynamic Purchasing System Agreement

Dynamic Purchasing System Agreement for the provision Third Country Recognition (TCQR) Examination services is attached as a separate Tender Document.

Appendix 5 - Services Contract

The Service Contract for the provision Third Country Recognition (TCQR) Examination services is attached as a separate Tender Document and is included in the Tender Pack.

Appendix 6: Confidentiality Agreement

The Confidentiality Agreement for the provision of [Third Country Recognition (TCQR) Examination services is attached as a separate Tender Document and is included in the Tender Pack.