

ANNEX B
to
Tender Specifications

Guidance on the European Single Procurement Document (ESPD)

and documentation for grounds for exclusion
(Version 13.0 of August 2025)

Table of Contents

1. Use of the European Single Procurement Document (ESPD) and ESPD documentation in Amgros' medicine tenders
2. Mandatory grounds for exclusion
3. Documentation for grounds for exclusion
 - 3.1 ESPD documentation for Danish tenderers
 - 3.2 ESPD documentation for non-Danish tenderers
4. Uploading ESPD documentation for exclusion grounds on Amgros' Supplier and Tender Portal
5. Reuse of ESPD documentation for exclusion grounds
6. Timeline for obtaining documentation for exclusion grounds.

1. USE OF THE EUROPEAN SINGLE PROCUREMENT DOCUMENT (ESPD) AND ESPD DOCUMENTATION IN AMGROS' PHARMACEUTICAL TENDERS

According to the Danish Public Procurement Act (Consolidated Act No. 116 of 3 February 2025, including subsequent amendments), contracting authorities must require that all tenderers use the European Single Procurement Document during the procurement process.

In everyday language, the document is referred to as “**ESPD**”, which derives from its English title *European Single Procurement Document*.

The Danish Competition and Consumer Authority (Konkurrence- og Forbrugerstyrelsen) updated on 4 March 2024 the note *Review of the rules on documentation*, describing, among other things, the final documentation that a contracting authority may request from companies in relation to grounds for exclusion. The guidance is available on the Authority's website www.kfst.dk.

In Amgros' pharmaceutical tenders, the ESPD is used as a **self-declaration** from each tenderer. The self-declaration serves as preliminary proof that the tenderer is not subject to the compulsory grounds for exclusion in Sections 135–136 of the Public Procurement Act.

For each tender for pharmaceuticals published by Amgros, the tenderer must complete an ESPD when submitting a tender. Completion of the ESPD takes place electronically in Amgros' tender system and is an integrated part of the tender submission process (eESPD). The tenderer must complete the electronic ESPD each time a tender is submitted.

For guidance on how to complete the electronic ESPD, please refer to *User Guide – Tender Submission* on Amgros' Supplier and Tender Portal.

Before contract award, the tenderer(s) with whom Amgros intends to enter into a contract or framework agreement must make available documentation showing that the information given in the ESPD regarding the compulsory grounds for exclusion is correct.

2. COMPULSORY GROUNDS FOR EXCLUSION

According to Section 135(1) of the Danish Public Procurement Act, a tenderer must, as a rule, be excluded if the tenderer has been convicted or fined by final judgment within the past five years for:

- participation in a criminal organisation;
- bribery;
- fraud;
- terrorist offences or offences linked to terrorist activities;
- money laundering or financing of terrorism; and
- child labour or other forms of human trafficking.

The same applies to persons who are part of the tenderer's board of directors, executive management, supervisory board, or others who can represent, control, or make decisions within these bodies, cf. Section 135(2).

Furthermore, pursuant to Section 135(3) of the Danish Public Procurement Act, the tenderer must be excluded if:

- the tenderer has outstanding overdue debt of DKK 100,000 or more to public authorities relating to taxes, duties, or contributions to social security schemes under Danish law or the law of the country in which the tenderer is established.

Finally, the tenderer must be excluded under Section 136 if Amgros can demonstrate that:

- There is a conflict of interest arising from the tenderer's participation in the tender procedure that cannot be remedied.
- There is distortion of competition resulting from the tenderer's advice or involvement in the preparation of the tender procedure that cannot be remedied.
- The tenderer has provided grossly misleading information, withheld information, or failed to submit supplementary documentation.
- The tenderer has committed serious professional misconduct casting doubt on the tenderer's integrity.

For the full wording of the grounds for exclusion, refer to Sections 135–136 of the Danish Public Procurement Act.

3. DOCUMENTATION FOR GROUNDS FOR EXCLUSION

Prior to the award, the tenderer(s) with whom Amgros intends to enter into a contract or framework agreement must provide documentation demonstrating that the information provided in the ESPD regarding Section 135(1) and (3) is correct, cf. Sections 152–153 of the Danish Public Procurement Act.

The documentation requirement for compulsory grounds for exclusion under Section 135(1) of the Danish Public Procurement Act covers both the tenderer as a company and certain persons associated with the tenderer, cf. Section 135(2) (see Section 2 above).

Amgros cannot exclude a tenderer who is subject to one or more compulsory exclusion grounds if the tenderer can present sufficient documentation showing that they remain reliable, cf. Section 138 on self-cleaning.

Amgros accepts ESPD documentation in the following languages: **Danish, Swedish, Norwegian, and English.**

3.1 ESPD DOCUMENTATION FOR DANISH TENDERERS

A Danish company submitting a tender must document whether it is covered by the compulsory exclusion grounds in Section 135(1) and (3), and whether certain associated persons are covered by the compulsory grounds in Section 135(1).

Associated persons include individuals who are members of the company's board of directors, executive management, supervisory board, or other persons who can represent, control, or make decisions in these bodies.

A Danish company may submit a **service certificate** (serviceattest) issued by the Danish Business Authority (Erhvervsstyrelsen) as documentation that it is not subject to the compulsory grounds for exclusion in Section 135(1) and (3). It should be noted that the issuance of a service certificate involves processing time and cannot be obtained at short notice.

To obtain a service certificate that covers the grounds for exclusion in Section 135(1), the company must submit sworn statements and consent forms to the Danish Business Authority for both the company and all persons in the above-mentioned group. The certificate may include Danish and non-Danish persons.

If a service certificate does not cover all persons in the relevant group, the tenderer must in addition to the service certificate provide separate ESPD documentation to Amgros demonstrating whether those persons are subject to the compulsory grounds for exclusion under Section 135(1).

As a rule, the documentation for these persons must consist of extracts from the relevant criminal register or equivalent documentation demonstrating whether the person concerned is subject to the grounds for exclusion in Section 135(1). Amgros must receive documentation concerning criminal offences issued in the country of which the person is a national.

If the person is not resident in the country of nationality, Amgros may alternatively receive documentation concerning criminal offences issued in the country of residence.

Such documentation may, for example, take the form of a copy of a criminal record certificate.

The EU Commission's database "e-Certis" may be consulted in this regard.

3.2 ESPD DOCUMENTATION FOR NON-DANISH TENDERERS

A foreign company submitting a tender to Amgros must document whether it is subject to the compulsory grounds for exclusion under Section 135(1) and (3), and whether Section 135(1) of the Danish Public Procurement Act covers certain associated persons.

Associated persons have the same definition as under 3.1.

The documentation for the persons associated with the tenderer must consist of an extract from the relevant register or equivalent documentation demonstrating whether the person is subject to the grounds for exclusion set out in Section 135(1).

As a rule, Amgros must receive documentation concerning criminal offences issued in the country of which the person is a national. If the person is not resident in the country of nationality, documentation concerning criminal offences issued in the country of residence may be accepted. The documentation may, for example, be submitted as a copy of a criminal record certificate.

The specific documentation requirement will depend on what is available in the country in which the foreign company is established. The EU Commission's "e-Certis" database may be consulted in this regard.

4. UPLOADING ESPD DOCUMENTATION FOR EXCLUSION GROUNDS ON AMGROS' SUPPLIER AND TENDER PORTAL

An upload function is available on Amgros' Supplier and Tender Portal under *My Company Pages / My Documents (Mine firmasider/Mine dokumenter)*. This function enables all registered users of Amgros' tendering system to upload ESPD documentation, ensuring that documents are always accessible to both the tenderer and can be used immediately in Amgros' pharmaceutical tenders.

Once the ESPD documentation is uploaded, the risk is significantly reduced that Amgros will need to conduct a new evaluation and award the contract to another tenderer because the winning tenderer is unable to provide the required documentation within the deadlines set by Amgros.

It is the tenderer's responsibility to ensure that the ESPD is accurate and correctly completed. It is also the tenderer's responsibility to ensure that the uploaded ESPD documentation is accurate. The tenderer must immediately notify Amgros if the uploaded/submitted ESPD documentation is no longer relevant or accurate and must therefore be deleted by Amgros from the tenderer's 'My Company Pages/My Documents.'

For some suppliers, the ESPD documentation will consist of several documents. Once the supplier has uploaded/submitted complete ESPD documentation, the supplier must inform Amgros by marking under 'My Company Pages/My Documents' in the section 'ESPD Documentation Status' that the ESPD documentation is complete (Fuldstændig). The tenderer must also inform Amgros if the uploaded/submitted ESPD documentation is no longer complete.

A quick guide explaining how to upload documentation is available under *My Company Pages / My Documents*.

Documentation concerning specific persons' criminal records **must not be uploaded** to the portal. Instead, it must be sent to espd@amgros.dk (encrypted). Instructions and Amgros' public encryption certificate are available on the portal.

Apart from the attached documentation concerning criminal offences, the email itself must not contain any personal data other than the name(s) of the person(s) to whom the documentation relates.

Documentation concerning specific persons' criminal offences may also be sent by post or courier to Amgros I/S at the specified addresses. The envelope must be marked on the front with "ESPD documentation – confidential."

5. REUSE OF ESPD DOCUMENTATION FOR GROUNDS FOR EXCLUSION

Valid ESPD documentation uploaded under *My Company Pages* is reused in Amgros' pharmaceutical tenders. If Amgros has already received the documentation, it is not necessary to provide the ESPD documentation to Amgros again.

In pharmaceutical tenders, Amgros will assume that the documentation uploaded remains valid for up to **12 months** from the date of issue unless the tenderer requests its deletion. The same applies where the tenderer has indicated in the ESPD where Amgros can obtain the required documentation free of charge and through direct access to a national database.

6. TIMELINE FOR OBTAINING DOCUMENTATION FOR EXCLUSION GROUNDS

Before awarding a contract or framework agreement (issuing award notification), Amgros will contact the tenderer(s) with whom it intends to conclude a contract or framework agreement if the required ESPD documentation has not already been uploaded.

In such cases, the tenderer will be requested to upload/submit documentation as soon as possible, generally within **18 days**, unless exceptional circumstances justify an extension. If the documentation is not provided within the deadline, Amgros may choose to award the contract/framework agreement to the tenderer that has submitted the second most economically advantageous tender.

If the supplier has already made accurate and complete documentation available, the tenderer will not be contacted by Amgros before the notification letter is issued.