



EUROPEAN MEDICINES AGENCY
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Frequently asked questions relating to the assignment and maintenance of SME Status by the EMA

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Introduction

This questions and answers document addresses frequent questions received by the SME Office relating to the assignment and maintenance of SME Status by EMA. It complements information included in the European Commission User guide on the SME definition ([Link](#)).

The document provides informal general guidance and is not legally binding. Applicant SMEs are advised to direct specific queries relating to their SME application to the SME Office, which will consult with the relevant Agency's and European Commission's services, if applicable.

Frequently asked questions relating to the assignment and maintenance of SME Status by the EMA

Procedural aspects

Question		Answer
1	How and when should I submit my SME declaration and supporting documentation?	Applicants should submit an electronic copy of the SME declaration form via email to the SME Office, with one original signed hard copy of the declaration form by post. All supporting documentation can be submitted via email only. The e-documents can be sent through Eudralink, a secure web-based email system (contact eudralink@ema.europa.eu to open an account if applicable). SME declarations can be submitted at any time.
2	Which languages can be used to submit SME declarations to the EMA?	SME declarations should be submitted in English. Supporting documentation e.g. the proof of establishment of the company in the EEA, the annual report or annual accounts can be submitted in their original languages. There is no need to translate supporting documents; however the figures (headcount, annual turnover, and balance sheet total) declared should be highlighted in the annual accounts or annual reports to facilitate processing.
3	Why should SME renewal applications be submitted?	The SME status granted by the EMA is valid for 2 years as from the date of closure of the annual accounts (audited, if possible) submitted in support of a SME declaration. In order to maintain the SME status, companies are advised to submit annual accounts (audited, if possible) to the Agency, on a yearly basis, as soon as available or at the latest three months prior to the expiry date. This would permit SME status to be extended by one additional year.
4	What evidence can be provided to support establishment of the company in the European Economic Area (EEA)?	In order to fulfil this requirement the applicant must have a permanent legal structure which is formed in accordance with the law of an EU or an EEA Member State. Proof of establishment should be submitted with the SME

Question	Answer
	declaration: a copy of the certificate of inclusion of the company into a commercial register e.g. for UK-based entities a Certificate of Incorporation issued by the Companies House, for French entities the 'Extrait du registre du commerce et des sociétés, K-Bis'. The document can be submitted in any EU language and translation into English is not required.

SME criteria

Question	Answer
1 What should be considered in the turnover figure for R&D companies with no product sales?	The definition of turnover is provided in article 28 of the Fourth Council Directive 78/660/EEC of 25 July 1978 based on Article 54 (3) (g) of the Treaty on the annual accounts of certain types of companies (Link). Revenues from collaborations and licensing deals have to be considered as revenues coming from "provision of services falling within the company's ordinary activities" and thus included as annual turnover of the company as applicable. According to the definition given above, this figure can not therefore be negative. If the profit and loss statement shows no operating income but operating expenses, an annual turnover of "0" should be declared.
2 Which figure should be considered under 'balance sheet total'?	The definition of 'balance sheet total' is provided in article 12(3) of the Fourth Council Directive 78/660/EEC of 25 July 1978 based on Article 54 (3) (g) of the Treaty on the annual accounts of certain types of companies (Link). The balance sheet total corresponds to the subscribed capital unpaid, the formation expenses, the fixed assets, the current assets and the prepayments and accrued income.
3 How should company directors be considered in the headcount?	Directors should be counted in the staff headcount. If the same directors are involved in a series of linked companies, they should be counted as fractions of one unit per linked company (even if dormant) to which they belong.

Question	Answer
4 Which figures should I declare if my company is a newly established company and has no accounts yet?	If your enterprise is newly established and annual accounts are not yet available, a realistic <i>bona fide</i> estimate of the relevant data for the financial year should be provided in the declaration. The first accounts should be submitted to the Agency once finalised together with an updated SME declaration. A provisional expiry date will be determined considering the expected date of submission of the first annual accounts.
5 Can a company which has exceeded the SME thresholds lose its SME status?	If a company has exceeded the headcount and financial ceilings, this will not result in the loss of its SME status unless these ceilings are exceeded for two consecutive accounting periods, on the basis of the two latest approved annual accounts. SMEs which grow beyond the headcount and financial ceilings through a merger or acquisition will cease to be considered as SMEs as of the date of the merger or acquisition.
Which exchange rate should be used for declarations based on accounts which are not drawn in €?	The exchange rate at the end of the reference period declared should be specified in the SME declaration.

Ownership structure

Question	Answer
1 Why is information on the ownership structure critical in each SME declaration?	Significant (>25%) participations of shareholders in the applicant enterprise and those of the applicant SME in other companies directly impact on the declaration as the figures of these related entities may need to be added partially or fully to the headcount and financial figures of the applicant company. For complex company structures, it is strongly recommended to detail, for the applicant company and any related enterprise, the upstream ('shareholders') and downstream ('participations in other entities') ownership structures in terms of capital/voting rights (see 14). This can be outlined in the cover letter of the SME declaration application or in an ownership chart submitted as an appendix.
2 Do I have to provide the ownership structure for a SME renewal declaration?	As the ownership structure of the company may have changed since the last assignment, the applicant is recommended to specify whether there have

Question		Answer
		been changes to the upstream and downstream ownership structures for the applicant company and any related enterprise since the last SME declaration. If this is the case the changes should be detailed and their impact on the SME declaration outlined as applicable.
3	How should a 'holding company' be addressed in the declaration?	A holding company should be treated as a normal enterprise and included in the SME declaration as applicable. As a holding company generally does not have any staff, only the financial figures (turnover and balance sheet) have to be declared. The accounts should be submitted if applicable.
4	How should 'Venture Capital companies' (VCC) be addressed in the declaration?	VCC can invest in companies up to 50% without the need to being included in a SME provided they do not have links to the applicant SME in accordance with article 3.3 of the Annex of Commission Recommendation 2003/361/EC of 6 May 2003. Once this threshold is exceeded, VCC should be treated as normal investors and thus included in the SME declaration of the applicant company. Furthermore the data of other companies where the VCC invests would also need to be considered in a SME declaration. However in this latter case acting as a VCC in other enterprises, the VCC would be able to participate in other companies up to 50% without having to add the data of the participated companies.
5	How much can 'business angels' invest in SMEs without the need for the amounts invested to be declared?	The threshold for business angel investment is 1250000€. If there is more than one business angel investing in an enterprise the threshold applies per business angel investing and not to the total of all combined business angels investments.
6	How should 'dormant' enterprises be handled in a SME declaration form?	Dormant companies have to be included in the declaration form. In this case, the figures declared for each criterion will be "0".