

Policy document

Two-round assessment policy for national procedures

MEB 43

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1. Introduction

A limit has been imposed on the number of assessment rounds for national procedures. This maximum number of rounds varies per procedure. Limiting the number of assessment rounds ensures that the (legally) stipulated time within which the MEB must take a decision on an application/variation is not exceeded. The two-round assessment policy was implemented to limit the number of assessment rounds. This policy means that serious concerns from the first assessment round must be addressed adequately in the second assessment round. In other words, the serious concerns must be resolved by the applicant's response to the first letter with concerns from the MEB.

2. Purpose and scope

The aim of the two-round assessment policy is to limit the number of assessment rounds for national procedures (primarily applications and type II variations) in order to prevent the total procedure time being exceeded. The two-round assessment policy facilitates the aim to make a decision on an application or variation within the (legally) stipulated procedure time.

3. Procedure

If all the serious concerns have not been resolved at the end of the second assessment round for an application or variation procedure, the applicant is informed by letter that the MEB intends to refuse the application or variation.

On the grounds of the General Administrative Law Act, the applicant then has the right to submit their opinion on the matter before the MEB proceeds to take a decision (Article 4:7 of the General Administrative Law Act). This can take place orally or in writing (article 4:9 of the General Administrative Law Act). An oral explanation will take place in the form of a hearing. The policy document MEB 18 contains more information about the opinion procedure in conjunction with a proposed primary decision.

If the applicant chooses to submit their opinion in a written response, this written response will be expected within a standard period. Following assessment of this opinion, the MEB will take a final decision.

If the applicant opts for a hearing, the MEB will take a final decision after the hearing. The applicant can be given the opportunity to submit additional data at the hearing. Following receipt and assessment of this additional information, the MEB will take a final decision.

If there are no serious concerns at the end of the second assessment assignment, but there are 'other' concerns, a third round of assessments for variations (and for applications a fourth round) can take place to resolve these other concerns. The fact that a national

procedure can consist of more than two rounds therefore does not mean that the two-round assessment policy does not apply.

If the serious concerns have not all been resolved at the end of the second assessment round, the MEB will – as a rule – not assign a third assessment round without announcing the intention of refusal. However, the MEB can only decide not to state its intention of refusal directly in very exceptional circumstances where an entirely new serious concern only came to light during the second assessment round, which could not have been foreseen by either the MEB or the applicant during the first assessment round. The applicant will then be given the opportunity to respond to this new serious concern in an additional assessment round. If the applicant does not respond adequately during the third assessment round, the intention of refusal will then be released.

In order to remind applicants that the serious concerns from the first round must be resolved in the second round of assessments, the following standard sentence will be added to the letter for the first assessment round from now on. This text is as follows:

'For the record, I wish to inform you once more that an assessment procedure is divided into only two rounds. The concerns must be resolved after these two rounds. If this is not the case and the application is not withdrawn, the MEB will be forced formally to refuse the application.'

In the above text the term 'application' means the initial application or variation application.

4. Explanatory notes

First assessment round

The first assessment round consists of the time from receipt of the dossier for the application or variation to the announcement to the applicant of the MEB's stance after assessment of the submitted dossier.

If the MEB has any concerns regarding the dossier for the application or variation, the applicant will be given the opportunity to resolve these. The applicant will be asked to submit a response/amended dossier within a set period of time.

Second assessment round

The second assessment round consists of the time from receipt of the applicant's response to the announcement to the applicant of the MEB's stance after assessment of the response/amended dossier.

Two-round assessment policy

This policy means that serious concerns from the first assessment round must be addressed adequately in the second assessment round. In other words, the serious concerns must be resolved by the applicant's response to the first letter with concerns from the MEB.