

MEDICINES EVALUATION BOARD

Policy document

**Written and verbal opinion procedure for a proposed primary
judgement by the MEB**

**MEB 18
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1. Introduction

This policy document provides an explanation of the course of events surrounding the various opinion procedures at the MEB. Please refer to the General Administrative Law Act (Algemene wet bestuursrecht [Awb]) for more details regarding the legal framework.

The Medicines Act (Geneesmiddelenwet [Gmw]) and the Medicines Act Regulation (Regeling Geneesmiddelenwet) include stipulations regarding the grounds on which the MEB has to grant a (parallel) marketing authorisation. The Medicines Act also stipulates the grounds on which a marketing authorisation can be revoked, amended or suspended.

The MEB distinguishes between four situations that afford an affected party the opportunity to present their opinion:

A Opinion of the applicant in the event that the MEB intends to refuse an application (art. 4:7 Awb).

This relates to an application for a national marketing authorisation for medicinal products, including homeopathic medicinal products, traditional herbal medicinal products, as well as parallel marketing authorisations. An application for variation of a national marketing authorisation also falls under this category, including requests for amendment of the dispensing status.

B Opinion of Notified Body in the case of an envisaged negative opinion regarding a medical device.

The applicant (the Notified Body in this case) will also be given the opportunity to submit an opinion in the case of a proposed negative opinion for a consultation procedure for medical devices. Also refer to A. Please note that such opinions are not judgements in the sense of the Awb.

C Opinion of the “addressee” in the case of a proposed judgement by the MEB, where the initiative lies with the MEB (“official judgement”) and which the addressee is expected to object to (art. 4:8 Awb).

The “addressee” is usually the holder of a (parallel) marketing authorisation on which the MEB intends to make a decision. For example, suspension, revocation, amendment of the dispensing status.

D Opinion of a third party relating to a proposed judgement by the MEB (art. 4:8 Awb)

Any person who can be considered a third party in a proposed decision can submit his/her opinion before this decision is taken.

This policy document must be read in conjunction with the policy document “Two-round assessment policy for national procedures”. Finally, the “Advisory Committee on primary decisions MEB” and the “Advisory Committee on medical devices MEB” determine the composition of the advisory committee. These regulations are published on the MEB website.

2. Opinion of the applicant in the event that the MEB intends to refuse an application (art. 4:7 Awb)

2.1. Legal framework

Please refer to the Medicines Act for the legal framework that the MEB uses to arrive at a decision (marketing authorisation extension or refusal).

2.2. The opinion procedure

2.2.1. Introduction

The role of the opinion procedure is to ensure careful preparation of judgements.

Pursuant to article 4:7 Awb, the applicant must be granted the opportunity to submit his opinion if the MEB intends to make a (partially) unfavourable ruling that rests on facts and interests that involve the applicant. In such situations, the MEB and the affected party must be in contact, in order to ensure that the governing body (the MEB) bases its decisions on the correct facts and data and assigns a correct weight to the interests. In addition, the opinion procedure gives the opportunity to clarify stances and exchange ideas.

The applicant must provide the MEB with all the data required to make a decision on the application. The opinion procedure provides a last opportunity for this. The burden of evidence for the decision in question lies with the applicant.

Article 4:9 Awb offers the applicant the choice to present the opinion in writing or verbally.

2.2.2. Grounds for exception

Article 4:11 Awb formulates three grounds for exception in which the opportunity to submit an opinion can be omitted.

Based on article 4:11 Awb, sub-section a, the application of article 4:7 Awb can be omitted if the required urgency forms a barrier. This ground for exception applies in the case of objective urgency (the urgency must be evident). This will be stated in the decision. If the decision-making period of the application is in danger of being exceeded, this does not form a reason to prevent the applicant from presenting his opinion.

Based on article 4:11 Awb, sub-section b, the application of article 4:7 Awb can be omitted if the affected party has previously been given the opportunity to present his opinion and no new facts or circumstances have occurred in the interim. One can also drop an opinion procedure if an applicant has already presented an opinion for a similar decision. If new facts or circumstances present, that relate to the applicant, then the applicant will once again be given the opportunity to present his opinion. The MEB will ask the applicant to motivate this in writing.

Based on article 4:11 Awb, sub-section c, the application of article 4:7 Awb can be omitted if the aim envisaged by the decision can only be achieved if the affected party was not already informed of this in advance. This ground for exception of article 4:11 Awb can be applied if a hearing would negate the aim of the decision because the applicant would be informed of the proposed decision in advance. This will be stated in the decision.

A decision not to hear an affected party is a decision in preparation of a decision and - pursuant to article 6:3 Awb - is not plausible for appeals, unless the affected party is directly affected by this decision separately from the proposed decision.

2.2.3. *The Advisory Committee on primary decisions MEB*

The Advisory Committee on primary decisions MEB (hereafter: advisory committee) advises the MEB about the opinion and the decision that needs to be taken. An advisory committee is appointed for both written and verbal opinion procedures. Article 3, section 1 of the Regulations for the Advisory Committee on primary decisions MEB stipulates that the advisory committee must consist of at least four members: the chairman, who is a member of the MEB, a Second Secretary, a case manager from the PT group and a lawyer (working at the MEB Agency). The advisory committee receives administrative support from a case manager who is employed by the Policy, Government and Regulatory Affairs unit and the management support services of this unit. Article 3, section 5 of the Regulations of the Committee on opinion procedure for primary decisions MEB 2013 stipulates that the advisory committee can appoint other members and that the advisory committee can be assisted by experts. This can involve both internal and external members and experts.

2.2.4. *Language of the opinion procedure*

Article 2:6 Awb stipulates that the governing bodies and the individuals that work under the responsibility of the governing body use the Dutch language in communication between citizens and the governing body. Deviation from this is permitted if the use of another language is more effective and is not disproportionately disadvantageous to the interests of third parties. This article relates to both the verbal and written use of a language.

In general, the Dutch language will be used during a verbal opinion procedure (hearing). A deviation is permitted if the applicant submits a request to present the opinion in the English language. At the start of the hearing, the chairman of the hearing will ask if the affected party wishes to use the English language. This is done to avoid discourteous treatment by the MEB of the applicants for the ordinance.

The written opinion can be drafted either in Dutch or in English. If it is drafted in another language, the applicant will be asked to submit a Dutch or English translation.

2.2.5. *Further data*

In the case of a verbal opinion procedure, all data submitted prior to and during the hearing will be incorporated in the decision-making process. However, from a practical perspective, it is better to submit as much data as possible in advance of the hearing (preferably 10 days prior to the hearing). Data submitted just prior to the processing of the verbal (hearing) or written opinion will still be included in the processing of the verbal and written opinion. It is possible that the applicant will refer to data during the verbal or written opinion procedure that were not submitted and that the applicant now wishes to submit these data. The governing body must inform the applicant, if the applicant fails to submit all essential data and this forms a reason to reject the application. The MEB must grant the applicant the opportunity to supplement these data. During the hearing the chairman can ask the affected party to submit the missing data.

During a written opinion procedure this request will be submitted in writing. The chairman of the advisory committee will decide on the deadline for submission of these data. In general, the applicant will be granted two weeks - unless this period is unreasonable - starting from the day after the day on which the hearing took place, to submit these data. If the applicant misses the deadline for submission of these data, the MEB can decide not to include these data in the decision-making process.

2.2.6. *Public access to the hearing*

A hearing will be scheduled for a verbal opinion procedure. In the case of a proposed refusal of a (marketing authorisation) application, the hearing will only be accessible to the applicant. This allows the applicant to submit and discuss commercially sensitive data during the hearing, which form part of the authorisation dossier.

As a result, the hearing and the documents involved will not be accessible to third parties. The hearing will not be announced on the MEB website. If the applicant requests a public hearing, the head of the Policy, Government and Regulatory Affairs unit - in his capacity as Second Secretary - will decide on this matter.

2.2.7. *Date of the opinion procedure*

The MEB aims to facilitate a procedure as soon as possible after the opinion has been submitted. In the case of a verbal opinion (hearing), please allow for a period of 4 - 6 weeks from the moment that the company indicates which method it wishes to use (verbal or written). In the case of a written opinion, the company must submit this opinion no later than 4 weeks after the moment at which it indicated which method is required.

2.2.8. *Duration of the hearing (in the case of a verbal opinion)*

In general, the duration of the hearing is one hour. In order to ensure that the applicant is given sufficient opportunity to be heard, the chairman of the hearing can decide during the hearing to extend the duration of the hearing. The chairman can also decide during the hearing to suspend the hearing.

2.2.9. *Reporting (in the case of a verbal opinion)*

The MEB will draft a verbatim report of the hearing and - if requested by the applicant - the report will be provided to the applicant as soon as it is ready. If the applicant does not specifically request the report, then the report will be supplied to the applicant at a later stage, together with the decision that was made. The relevant legal deadlines for the underlying procedure are used as a starting point for the deadline for the decision-making process. In addition to the report, the agreements that were made will be recorded in writing and supplied to the applicant after the hearing.

2.2.10. *After the hearing (in the case of a verbal opinion)*

The applicant will be informed that the advisory committee intends to advise the MEB.

3. Opinion procedure for a proposed negative opinion during the consultation procedure for a medical device

Article 9, section 1, sub-section i, of the Medicines Act (Gmw) stipulates that the MEB is charged with providing advice pertaining to an integrated active component of a medical device, the so-called consultation procedure. The product-specific guidelines of the European Medicines Agency (EMA) and the general guidelines relating to the quality, the safety and the use that apply to the awarding of marketing authorisations for medicinal products form the testing framework for this assessment.

In determining their advice, the MEB is not legally required to grant the applicant for advice the opportunity to submit his opinion. The stipulations of the General administrative law act (Awb) do not apply, as this advice is not a judgement in the context of the first section of article 1:3 Awb. The abovementioned also applies to advice to be provided by the MEB to a Notified Body as part of the consultation procedure. Nor does section 3.3 of the Awb apply to the advice provided by the MEB in relation to the active components of medical devices, because the CE quality mark of the Notified Body should not be classified as a decision.

However, the MEB has chosen - in the case of a proposed negative opinion - to give the Notified Body the opportunity to submit their opinion. Where possible, the procedure will be analogous to the application for a marketing authorisation for a medicinal product. Therefore, please refer to chapter 2 for the opinion procedure during the consultation procedure, but taking note of the following:

- The advisory committee that acts in such cases is the Advisory Committee on Medical Devices MEB.
- The communication in this procedure will be conducted with the Notified Body. In the case of a hearing, the Notified Body can be accompanied by the manufacturer of the medical device, the manufacturer of the active component or a consultant. This is at the discretion of the Notified Body, however, the advice by the MEB will be issued to the Notified Body.
- A definitive advice will be issued at the end of the procedure and not a judgement in the context of the Awb.

Please refer to chapter 2 for more information.

4. Opinion of the “addressee” in the case of a proposed judgement by the MEB, where the initiative lies with the MEB (“official judgement”) and which the addressee is expected to object to (art. 4:8 Awb)

4.1. Legal framework

Please refer to the Medicines Act for the legal framework that the MEB uses to arrive at a decision to amend a marketing authorisation and which type of variations this can include. In short, this includes the variations, revocations and suspensions of (parallel) marketing authorisations. For example, variations include changes to the legal status of supply. In addition, other variations to the authorisation dossier, including variations in the product information (for example, the therapeutic indication of the medicinal product). It should be noted that - with exception to the variation in legal status of supply - the MEB formally cannot implement a variation in an authorisation dossier. However, the MEB can suspend or revoke a marketing authorisation of its own accord (“officially”). If the MEB deems it essential from a public health perspective to amend an authorisation dossier, then the MEB will ask the marketing authorisation holder to submit the relevant variation application. If the marketing authorisation holder does not want to honour this request, the consequence could be that the MEB concludes that the marketing authorisation cannot be maintained, after which an intention to suspend or revoke the marketing authorisation can be announced. The marketing authorisation holder will then be given the opportunity to submit his opinion first, before the MEB enters the decision-making process. The latter also applies to other situations in which the MEB intends to take an official decision regarding a (parallel) marketing authorisation.

Decisions executed by the MEB based on decisions by the European Commission are exempt from this. These decisions have an immediate effect. This is not an intention by the MEB that can be changed by an opinion from the addressee.

4.2. The opinion procedure

4.2.1. Introduction

Article 4:8 of the General administrative law act (Awb) stipulates that a written or verbal opinion procedure must take place if the MEB intends to make an official (i.e. without application or request from an affected party) unfavourable decision that this affected party is expected to object to. In addition, the facts and interests that underpin the decision must also relate to the affected party. If the abovementioned conditions have been met, then an affected party must be granted the opportunity to submit their opinion. In theory, the burden of evidence for the decision in question lies with the MEB. This is different in the case that the affected party claims that the opposite is true. In such a situation, the affected party must submit evidence to prove the opposite.

Article 4:9 Awb offers the marketing authorisation holder the choice to present the opinion in writing or verbally.

4.2.2. *Grounds for exception*

Article 4:11 Awb formulates three grounds for exception in which the opportunity to submit an opinion can be omitted.

Based on article 4:11 Awb, sub-section a, the application of article 4:8 Awb can be omitted if the required urgency forms a barrier. This ground for exception applies in the case of objective urgency (the urgency must be evident). This will then be stated in the decision.

Based on article 4:11 Awb, sub-section b, the application of article 4:8 Awb can be omitted if the affected party has previously been given the opportunity to present his opinion and no new facts or circumstances have occurred in the interim. One can also drop an opinion procedure if a marketing authorisation holder has already presented an opinion for a similar decision. If new facts or circumstances present, that relate to the marketing authorisation holder, then the marketing authorisation holder will once again be given the opportunity to present his opinion. The MEB will then ask the marketing authorisation holder to motivate this in writing.

Based on article 4:11 Awb, sub-section c, the application of article 4:8 Awb can be omitted if the aim envisaged by the decision can only be achieved if the affected party was not already informed of this in advance. This ground for exception of article 4:11 Awb can be applied if a hearing would negate the aim of the decision because the applicant would be informed of the proposed decision in advance. This will be stated in the decision.

A decision not to hear an affected party is a decision in preparation of a judgement and - pursuant to article 6:3 Awb - is not plausible for appeals.

4.2.3. *The Advisory Committee on primary decisions MEB*

The Advisory Committee on primary decisions MEB (hereafter: advisory committee) advises the MEB about the opinion and the decision that needs to be taken. An advisory committee is appointed for both written and verbal opinion procedures. Article 3, section 1 of the Regulations for the Advisory Committee on primary decisions MEB stipulates that the advisory committee must consist of at least four members: the chairman, who is a member of the MEB, a Second Secretary, a case manager from the PT group and a lawyer (working at the MEB Agency). The advisory committee receives administrative support from a case manager who is employed by the Policy, Government and Regulatory Affairs unit and the management support services of this unit. Article 3, section 5 of the Regulations of the Committee on opinion procedure for primary decisions MEB 2013 stipulates that the advisory committee can appoint other members and that the advisory committee can be assisted by experts. This can involve both internal and external members and experts.

4.2.4. *Language of the opinion procedure*

Article 2:6 Awb stipulates that the governing bodies and the individuals that work under the responsibility of the governing body use the Dutch language in communication between citizens and the governing body. Deviation from this is permitted if the use of another language is more effective and is not disproportionately disadvantageous to the interests of third parties. This article relates to both the verbal and written use of a language.

In general, the Dutch language will be used during a verbal opinion procedure (hearing). A deviation is permitted if the external parties present submit a request to conduct the hearing in the English language. At the start of the hearing, the chairman of the hearing will ask if the delegation from the marketing authorisation holder wishes to conduct the hearing in the English language. This is done to avoid discourteous treatment by the MEB of the addressees for the ordinance.

The written opinion can be drafted either in Dutch or in English. If it is drafted in another language, the marketing authorisation holder will be asked to submit a Dutch or English translation.

4.2.5. *Further data*

In the case of a verbal opinion procedure, all data submitted prior to and during the hearing will be incorporated in the decision-making process. However, from a practical perspective, it is better to submit as much data as possible in advance of the hearing (preferably 10 days prior to the hearing). Data submitted just prior to the processing of the verbal (hearing) or written opinion will still be included in the processing of the verbal and written opinion. It is possible that the marketing authorisation holder will refer to data during the hearing that were not submitted and that the marketing authorisation holder now wishes to submit these data. The MEB must grant the marketing authorisation holder the opportunity to supplement these data. During the hearing the chairman can ask the affected party to submit the missing data. During a written opinion procedure this request will be submitted in writing. The chairman of the advisory committee will decide on the deadline for submission of these data. In general, the marketing authorisation holder will be granted two weeks - unless this period is unreasonable - starting from the day after the day on which the hearing took place, to submit these data.

These data must be submitted within the set deadline. If the deadline for submission of these data expires, the MEB can decide not to include these data in the decision-making process.

4.2.6. *Public access to the hearing*

A hearing will be scheduled for a verbal opinion procedure. The obligation to facilitate a hearing for a proposed amendment, revocation or suspension of a marketing authorisation is limited to the marketing authorisation holder. This allows the marketing authorisation holder to submit and discuss commercially sensitive data during the hearing, which form part of the authorisation dossier.

If there are several marketing authorisation holders involved in a similar decision, the advisory committee can decide - for reasons of efficiency - to organise one joint hearing. If the affected parties submit a request for an individual section of the hearing, in which company and manufacturing information will be discussed, then the advisory committee will determine whether this request can be honoured.

As a result, the hearing and the documents involved will not be accessible to third parties. The hearing will not be announced on the MEB website. If the marketing authorisation holder requests a public hearing, the head of the Policy, Government and Regulatory Affairs unit - in his capacity as Second Secretary - will decide on this matter.

4.2.7. *Date of the opinion procedure*

The MEB aims to facilitate a procedure as soon as possible after the opinion has been submitted. In the case of a verbal opinion (hearing), please allow for a period of 4 - 6 weeks from the moment that the company indicates which method it wishes to use (verbal or written). In the case of a written opinion, the company must submit this opinion no later than 4 weeks after the moment at which it indicated which method is required.



4.2.8. *Duration of the hearing (in the case of a verbal opinion)*

In general, the duration of the hearing is one hour. In order to ensure that the applicant is given sufficient opportunity to be heard, the chairman of the hearing can decide during the hearing to extend the duration of the hearing. The chairman can also decide during the hearing to suspend the hearing.

4.2.9. *Reporting (in the case of a verbal opinion)*

The MEB will draft a verbatim report of the hearing and - if requested by the marketing authorisation holder - the report will be provided to the marketing authorisation holder as soon as it is ready. If the marketing authorisation holder does not specifically request the report, then the report will be supplied to the marketing authorisation holder at a later stage, together with the decision that was made. The relevant legal deadlines for the underlying procedure are used as a starting point for the deadline for the decision-making process. In addition to the report, the agreements that were made will be recorded in writing and supplied to the marketing authorisation holder after the hearing.

4.2.10. *After the hearing (in the case of a verbal opinion)*

The marketing authorisation holder will be informed that the advisory committee intends to advise the MEB.

5. Opinion of a third party relating to a proposed judgement by the MEB (art. 4:8 Awb)

5.1. Legal framework

Please refer to the previous sections for the legal framework that the MEB uses to arrive at a decision for a marketing authorisation for medicinal products. The legal framework for the option to submit an opinion by a third party as described below is described in the General administrative law act (Awb).

5.2. The opinion procedure

5.2.1. Introduction

In addition to hearing the addressee of an official decision, article 4:8 of the General administrative law act (Awb) also provides for the written or verbal hearing of a third party, if the MEB intends to honour an application to take a negative decision that a third party is expected to object to. The facts or interests that form the basis of the decision must relate to the third party. Finally, the intention to take a negative decision must actually exist (in other words, there must be a pending application).

According to set jurisprudence, under certain conditions a competitor can be classified as a third party. The competitive interest is directly involved in a proposed decision, if the interests of a competitor are affected as a result of that decision. A condition for this is that the affected company must be active in the same market segment (i.e. an overlapping of indications for both medicinal products) and active within the same geographical care area. Other legal entities (foundations and associations) can also be classified as third parties based on their statutory objectives.

If the abovementioned conditions have been met, then an affected party must be granted the opportunity to submit their opinion. The burden of evidence lies with the third party. The third party must submit evidence that demonstrates that the MEB cannot go on to make the decision. If the MEB adopts the opinion of the third party, then the MEB will adopt it as objection and submit this to the applicant of the decision, who will then be given the opportunity to submit his opinion.

Article 4:9 Awb offers the third party the choice to present the opinion in writing or verbally.

5.2.2. Grounds for exception

Article 4:11 Awb formulates three grounds for exception in which the opportunity to submit an opinion can be omitted.

Based on article 4:11 Awb, sub-section a, the application of article 4:8 Awb can be omitted if the required urgency forms a barrier. This ground for exception applies in the case of objective urgency (the urgency must be evident). This will then be stated in the decision.



Based on article 4:11 Awb, sub-section b, the application of article 4:8 Awb can be omitted if the affected party has previously been given the opportunity to present his opinion and no new facts or circumstances have occurred in the interim. One can also drop an opinion procedure if a third party has already presented an opinion for a similar decision. If new facts or circumstances present, that relate to the third party, then the third party will once again be given the opportunity to present his opinion. The MEB will then ask the third party to motivate this in writing.

Based on article 4:11 Awb, sub-section c, the application of article 4:8 Awb can be omitted if the aim envisaged by the decision can only be achieved if the affected party was not already informed of this in advance. This ground for exception of article 4:11 Awb can be applied if a hearing would negate the aim of the decision because the third party would be informed of the proposed decision in advance. This will be stated in the decision.

A decision not to hear a third party is a decision in preparation of a judgement and - pursuant to article 6:3 Awb - is not plausible for appeals.

5.2.3. *The Advisory Committee on primary decisions MEB*

The Advisory Committee on primary decisions MEB (hereafter: advisory committee) advises the MEB about the opinion and the decision that needs to be taken. In the case of opinions as part of a proposed marketing authorisation extension (4:8 Awb), this only applies to a request to submit a *verbal* opinion (hearing). If the third party wishes to submit their opinion exclusively *in writing*, then this written opinion will be included in the assessment procedure of the product for which the proposed marketing authorisation extension applies. Article 3, section 2 of the Regulations for the Advisory Committee on primary decisions MEB stipulates that the advisory committee in such cases must consist of at least three members: a Second Secretary, a case manager from the PT group and a lawyer (working at the MEB Agency). The advisory committee receives administrative support from a case manager who is employed by the Policy

Government and Regulatory Affairs unit and the management support services of this unit. Article 3, section 5 of the Regulations of the Committee on opinion procedure for primary decisions MEB 2013 stipulates that the advisory committee can appoint other members and that the advisory committee can be assisted by experts. This can involve both internal and external members and experts.

5.2.4. *Language of the opinion procedure*

Article 2:6 Awb stipulates that the governing bodies and the individuals that work under the responsibility of the governing body use the Dutch language in communication between citizens and the governing body. Deviation from this is permitted if the use of another language is more effective and is not disproportionately disadvantageous to the interests of third parties. This article relates to both the verbal and written use of a language.

In general, the Dutch language will be used during a verbal opinion procedure (hearing). A deviation is permitted if the external parties present submit a request to conduct the hearing in the English language. At the start of the hearing, the chairman of the hearing will ask if the delegation from the marketing authorisation holder wishes to conduct the hearing in the English language. This is done to avoid discourteous treatment by the MEB of the third parties in the proposed decision.

5.2.5. *Further data*

Data submitted just prior to the hearing will still be included in the hearing. It is possible that the third party will refer to data during the hearing that were not submitted and that the third party now wishes to submit these data. The third party can submit the data until the moment at which the decision on the application will be taken.

In its capacity as a concerned member state (CMS) during the mutual recognition procedure or decentralised procedure, the MEB will send the presented opinion and submitted data to the reference member state (RMS). The above only applies to the type of opinion as stated in this section 5. For the opinions described in sections 2 and 4, the European process in which RMS and CMS countries form a judgement will already have been completed. The procedure as described in section 3 does not involve RMS and CMS countries.

5.2.6. *Public access to the hearing*

A hearing will be scheduled for a verbal opinion procedure. The hearing obligation for a proposed decision is limited to the third party; this allows the third party to submit and discuss commercially sensitive data during the hearing, which form part of the authorisation dossier of the third party.

As a result, the hearing and the documents involved will not be accessible to anyone other than the third party. The hearings will also not be announced on the MEB website.

Any written opinions that are submitted and any data submitted by third parties - with the exception of company and manufacturing data - will be made accessible for inspection during an appeals procedure.

5.2.7. *Date of the hearing*

A hearing for third parties will be scheduled at a time that allows any reservations (following the first assessment round) to be communicated to the applicant; in general, the hearing will be scheduled before the first clock-stop of the assessment procedure (to which the application pertains). This allows the MEB to include any (weighty) objections in the assessment process. This means that the interests of both the third party and the applicant will not be affected.

5.2.8. *Duration of the hearing*

In general, the duration of the hearing is one hour. In order to ensure that the applicant is given sufficient opportunity to be heard, the chairman of the hearing can decide during the hearing to extend the duration of the hearing. The chairman can also decide during the hearing to suspend the hearing.

5.2.9. *Reporting*

A hearing will be scheduled for a verbal opinion procedure. Although not a requirement stipulated by the Awb, the MEB will provide a verbatim report of the hearing. If requested by the third party, the report will be provided to the third party as soon as it is ready. If the third party does not specifically request the report, then the report will be supplied to the third party at a later stage, together with the decision that was made. The relevant legal deadlines for the underlying procedure are used as a starting point for the deadline for the decision-making process.



5.2.10. *After the hearing / publication of the decision*

As soon as a decision has been made regarding the application, the MEB will announce this decision to the third party and the governing body will grant the third party the opportunity to submit their opinion.

6. List of abbreviations and terms used

Awb: General administrative law act

MEB: Medicines Evaluation Board

Notified Body: Authority tasked with the certification of medical devices, refer to regulations on medical devices

“Proposed primary decision”: This describes the situation in which a governing body (the MEB in this case) has announced the intention to make a decision. “Primary” refers to the fact that this is the “first” decision in this case. This in contrast to a “decision in re-examination” (“decision on appeal”), which the MEB needs to make if an “appeal” is lodged against the primary decision. A different procedure applies to this.

Appendix 1: Document check

| Version | Date | Concurrence |
|----------------|-----------------|--|
| 1.0 | 29 October 2014 | Opened for public consultation |
| 1.1 | 2 March 2015 | Comments from public consultation taken into consideration |
| 1.2 | 30 April 2015 | Confirmed by MEB |