

MEDICINES EVALUATION BOARD

Policy document: Objection procedure

MEB 9

5 November 2012

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1. Introduction

Pursuant to the General Administrative Law Act [*Algemene wet bestuursrecht*], the objection procedure is in nearly all cases a mandatory gateway to gain access to the administrative court. The objection procedure is arranged in chapters 6 and 7 of the General Administrative Law Act. Chapter 6 contains the general provisions and chapter 7 contains the special provisions.

The objection procedure gives citizens the opportunity to bring the accuracy of a decision up for discussion. The administrative authority (the Medicines Evaluation Board, the 'Board') can then, based on the citizen's objection, reconsider the primary decision and remedy any errors, without a court having to be involved. Based on the objection, the Board assesses whether amendment or revocation of the contested decision is appropriate. If the court is then involved after all, the outcome of the objection procedure will form an important starting principle for the appeal proceedings.

When a dispute is ultimately submitted to the administrative court, it will already have been discussed to such an extent that the case that is submitted is better defined and clearly elaborated. In addition, the objection procedure has even more functions: to reduce the number of appeals to the court, to offer legal protection, extended decision-making because a complete review must take place and, finally, to improve the quality of the board decision-making.

This policy document describes the legal framework of the objection procedure, from the receipt of the objection up to the final decision that the Board takes in respect of the objection. Chapter 2 discusses the confirmation of receipt, the requirements for the objection and the direct appeal. The next chapter focuses on the objection committee. Chapter 4 discusses the hearing, and the final chapter is about the decision, in which the substantiation, the decision term, the payment of the costs of the proceedings and the notification of the decision will be discussed.

2. The objection

2.1. Introduction

The main rule is that before the citizen can go to court, he must first file an objection with the administrative authority that has taken the decision which he is objecting against (Section 7:1(1) of the General Administrative Law Act). The General Administrative Law Act also states what 'filing an objection' means:

..."exercising the right conferred by law to request the administrative authority that took a decision to reconsider that decision"...

The objection must comply with a number of conditions, which will be discussed in this chapter. First and foremost, only an interested party can file an objection against a decision. The definition of the term interested party is stated in Section 1:2(1) of the General Administrative Law Act:

"Interested party' means a person whose interests are directly affected by a decision."

The definition of the term decision is stated in Section 1:3(1) of the General Administrative Law Act:

"Decision' means a written decision of an administrative authority constituting a public-law juridical act."

An interested party can only file an objection with the Board if this objection is aimed at a decision of the Board. If the objection is aimed at a decision of a different administrative authority, the Board must send this objection to the administrative authority in question.

2.2. Filing deadline

If an interested party wishes to file an objection against a decision, he must do so within a certain term. The term for filing an objection is six weeks. This means that, for six weeks after the day on which the decision was notified as prescribed by law, interested parties can file an objection (Section 6:7 and 6:8 of the General Administrative Law Act). The reason for the (short) objection deadline is the social interest that requires that every citizen should be able to rely on government decisions. An objection per post has been filed in time if it has been sent by post before the end of the deadline, and has been received not later than a week after the end of the filing deadline.

2.3. Confirmation of receipt

An objection can be filed by letter via post or electronic means. Communication by electronic means with an administrative authority is only possible if the administrative authority has stated that this means is available (Section 2:15 of the General Administrative Law Act). The Board has made this means available, provided that a scanned letter (the objection) with an autograph is attached to the electronic message.

Pursuant to Section 6:14(1) of the General Administrative Law Act, receipt of the objection must be confirmed in writing. An objection can only be filed if the decision that is objected against has been notified. If the case is handled by a representative, the Board will correspond with the representative (Section 6:17 of the General Administrative Law Act).

2.4. Requirements for the content

Section 6:5 of the General Administrative Law Act sets a number of conditions for the content of an objection. After receiving the objection, the Board will first check whether these conditions have been met, before assessing the contents of the objection. The objection must be signed and contain the name and the address of the person filing the objection, in addition to the date and a description of the decision that is objected against. The grounds of the objection must also be indicated (unless 'pro forma', see section 2.5). Finally, the objection must in principle be in Dutch. If this is not the case, the Board will give the person filing the objection the opportunity to submit an accompanying translation.

2.5. Pro forma

In situations in which the person filing the objection is not yet able to (fully) substantiate an objection, the filing deadline can be preserved by filing a 'pro forma' objection. That is an objection that includes a start of the grounds for objection. The Board must give the person filing the objection a term within which the grounds must have been supplemented (Section 6:6 of the General Administrative Law Act). The Board applies a term of eight weeks for filing the supplementary grounds. If the person filing the objection already advances a number of grounds in his objection with the notice that he will supplement these, the Board must also set a term within which the supplementary grounds must have been filed (within eight weeks).

2.6. Rectifying an omission

In case the requirements for the objection are not met, the Board will give the person filing the obligation the opportunity to rectify these omissions. The possibility to rectify an omission is offered in cases in which it concerns an omission that can be rectified. A term must be set for this, with a term of two to four weeks being reasonable. During this term to rectify the omission, the decision period is postponed. The term is postponed starting on the day on which the person filing the obligation is requested to rectify an omission up to the day on which the omission is rectified or the term set to do so has expired (Section 7:10(2) of the General Administrative Law Act). If the person filing the obligation continues to fail to rectify the omission, the Board can declare the objection to be inadmissible (Section 6:6 of the General Administrative Law Act).

2.7. Direct appeal

In order to gain access to the court, the objection procedure must first be followed. The General Administrative Law Act makes a number of exceptions to this rule. Pursuant to Section 7:1a of the General Administrative Law Act, the objection procedure can be passed over and a direct appeal may be instituted with the administrative court if the consent of all parties has been acquired. The intention is that the possibility of a direct appeal contributes to the simplification and shortening of administrative proceedings. The direct appeal is in particular intended for cases in which the parties have already exchanged ideas in detail prior to the decision to such an extent that it is certain in advance that a reconsideration of that decision will not change much or anything at all. The same can apply in cases in which a pure legal issue is keeping the parties separate, for example the interpretation of a legal provision in a specific case.

The request for a direct appeal must be made in the objection. The decision to such a request is a decision within the meaning of Section 1:3 of the General Administrative Law Act, but has been excluded from objection and appeal in Section 8:4 of the General Administrative Law Act. The Board can only agree to a request for direct appeal if all persons filing an objection against a specific decision can agree to this. The Board will decide on the request as soon as possible. In case the request is honoured, the Board will hand the objection to the competent court.

3. The objection committee

3.1. Introduction

The Board attaches importance to a careful reconsideration of its decisions in objection and it therefore assigns the preparation of a decision on the objection to a number of members of the Board and officers who have been employed by the MEB Agency. Together, they form the objection committee. 'MEB Agency' means the secretariat of the Medicines Evaluation Board as referred to in Section 8 of the Medicines Act (Gmw).

The Board's objection committee is an internal committee, meaning the members have been recruited from the organisation itself. Section 7:5(1) of the General Administrative Law Act gives the possibility to do so. The objection committee is composed as soon as the objection has been filed. This is also the case if no hearing takes place, but the person filing the objection files a written opinion.

3.2. Composition

Article 2 of the Objection Committee Regulations [*Reglement Bezwaarschriftencommissie*] determines that the objection committee consists of at least three members, including a chair, who is a member of the Board. There must therefore be at least one member of the Board on the objection committee. If possible, two members of the Board have a seat on the objection committee. The Second secretary will compose the objection committee in consultation with the head of the Policy, Administrative and Regulatory Affairs unit (BBR). They will decide which member of the Board will act as chair of the objection committee (and will therefore lead the hearing).

The MEB appoints, suspends or dismisses the members, in consultation with the director of the MEB Agency. Suspension or forced redundancy will only take place as a result of unsuitability for the post or as a result of other compelling reasons in connection with the person involved. Dismissal can also take place at the request of the person involved. If the appointment of a member of the objection committee with the Board or the MEB Agency ends, the membership of the objection committee will also end. The members are appointed for a period of four years. The retiring members may be reappointed (Article 3 of the Objections Committee Regulations). The objection committee is administratively supported by a case manager, employed at the BBR unit.

The members of the objection committee do not take part in the handling of an objection if their impartiality may be at issue.

The members of the objection committee will take joint decisions as much as possible. In case of differences of opinion, the decision will be taken by voting. In case of equal votes, the chair's vote will be decisive.

3.3. Authorities

The objection committee is charged with handling objections. The objection committee hears the interested parties on behalf of the Board and advises the Board regarding the handling of the objections filed with the Board, on request or otherwise. The Board will take the final decision on the objection. Objections that are clearly inadmissible will in principle not be submitted to the objection committee for advising.

In connection with the preparation of the handling of the objection, the members of the objection committee are authorised to make enquiries directly (Article 6 of the Objection Committee Regulations).

4. Hearing or written opinion

4.1. Introduction

The general rule is that the administrative authority with which an objection is filed will give the interested parties the opportunity to be heard (Section 7:2 of the General Administrative Law Act). The interested parties can choose to be heard orally, in the form of a hearing, or submit a written opinion to the Board.

The purpose of the hearing is to offer the interested parties the option of advancing their opinion and making it credible that they have information that may give the Board cause to review the decision. There is also the opportunity to receive an explanation from the Board of its decision, if it is unclear to the interested parties. Moreover, not just substantive aspects can be discussed during the hearing, but procedural aspects as well.

An interested party can appear at the hearing themselves, but can also authorise someone in writing to do so. An interested party can also be assisted by experts.

Based on the information advanced during the hearing or in the written opinion, the objection committee will advise the Board on the decision to be taken on the objection. Based on this advice, the Board will take a decision.

4.2. Exceptions to the obligation to hear

Section 7:3 of the General Administrative Law Act contains four grounds for exceptions based on which the providing of an opportunity to give a written or oral opinion can be omitted:

- The objection is manifestly inadmissible; if it can immediately be established that there are formal impediments to deal with the objection or the substance of the objection.
- The objection is manifestly unfounded; if it can be assumed, based on the law and settled case law, that the interested party's objection will have no chance of succeeding at all;
- The interested parties have stated that they do not wish to exercise the right to be heard.
- The objection is satisfied in all respects and this cannot prejudice the interests of other interested parties.

Section 7:12(1) of the General Administrative Law Act obliges the administrative authority to state the reasons in the decision on the objection for the decision not to hold a hearing of the interested parties.

4.3. Submitting further information prior to the hearing

Interested parties may file documents until ten days before the hearing (Section 7:4(1) of the General Administrative Law Act). For documents filed later, it will be assessed whether these have still been submitted in time to take them into account in the decision on the objection. These documents may not unnecessarily delay the handling of the objection. In the assessment of whether the documents are submitted in time, it is relevant to what extent the decision on the objection can affect the interests of third parties. In cases in which there is no chance of third parties wanting to respond to documents submitted later, the documents that are submitted at the hearing will be taken into account in the preparation of the decision on the objection, provided that these documents substantiate the objections. However, in cases which do involve the interests of third parties, documents that were submitted too late can only be taken into account if other interested parties were reasonably able to respond to them.

4.4. Making documents relating to the case available for inspection

At a public hearing, the objection and all other documents relating to the case will be made available for inspection at least one week before the hearing. The making available of documents for inspection can only be omitted in the following cases:

- All interested parties agree that the making available of documents for inspection will be omitted.
- The parties do not wish to be heard.

- In so far this is required for serious reasons, all or part of the documents can be made confidential. It is up to the Board to make that decision. If all or part of the documents are made confidential, the interested party must be informed of this.

4.5. Duration

The duration of the hearing is in principle one hour. In order to guarantee that interested parties are given sufficient opportunity to be heard, the objection committee can decide at the hearing to extend the duration of the hearing. It can then also decide to suspend the hearing.

4.6. Public nature

The starting principle is the public nature of the hearing, insofar as it does not concern the taking of decisions concerning commercially confidential data and documents. This is at the discretion of the Board. Interested parties can request the Board to have the hearing in public or not. It is then the Board's duty to decide – on its own initiative or on request – whether a certain case can be heard in private.

Prior to and during the hearing, an interested party can make a request for a private hearing. If a request is made during the hearing, the chair of the objection committee will suspend the hearing, so that the committee can deliberate on the matter. If the request is granted, the interested party will be heard separately (Section 7:6 of the General Administrative Law Act).

A public hearing will be announced on the Board's website as soon as the date of the hearing is known.

4.7. Language

Section 2:6 of the General Administrative Law Act prescribes that administrative authorities and persons under their responsibility will use the Dutch language in the communications between the citizen and the administrative authority. This can be deviated from if the use of another language is more effective and does not disproportionately harm the interests of third parties. This section relates to both oral and written use of the language.

During the hearing, the Dutch language will be used in principle. This can be deviated from if the interested parties request to have the hearing held in the English language. At the start of the hearing, the chair of the objection committee will ask whether the interested parties wish to use the English language. This prevents the Board from acting carelessly.

4.8. Reporting

The Board will draw up a verbatim report of the hearing. The hearing will be recorded. The sound file of the hearing will be destroyed when the Board has taken a decision on the objection and has adopted the verbatim report.

5. The decision on objection

5.1. Introduction

An objection having been made, the administrative authority that made a decision is requested to reconsider the decision. It is therefore this administrative authority that must decide on the objection. The objection committee advises the Board on the decision to be taken on the objection. The Board makes the decision in the Board meeting. This chapter focuses on that decision.

5.2. Substantiation

The decision on the objection must be founded on proper substantiation, which is stated in the announcement of the decision. If, pursuant to Section 7:3 of the General Administrative Law Act, the administrative authority has decided not to hear interested parties, the reasons for this will also be stated (Section 7:12(1) of the General Administrative Law Act).

It is possible to give other reasons for the decision on the objection than for the original decision. If, for example, the primary decision has an incorrect ground for refusal, this can be rectified in the decision on the objection. The statutory rules on which the decision is based must be stated in the decision on the objection. The objection procedure gives interested parties the opportunity to advance arguments and facts, which an interested party may have failed to advance or was simply unable to advance in the primary decision-making process. It is also possible that arguments that emerged in the primary decision-making process may return in the objection stage. The administrative authority must take all relevant facts and circumstances into account in the decision on the objection. All these relevant facts and circumstances must be taken into consideration, insofar as they have been submitted in time.

The substantiation requirement only weighs less heavy if all the objections are met and if no interests of third parties are at stake. But this does not mean that the substantiation can be ignored. For example, there may be reason to indicate which facts and circumstances have led to a decision being taken in the first instance that cannot be upheld. It is in all cases important that the substantiation is readable and understandable for all interested parties. The wording must show that the decision was carefully made.

5.3. Decision period

Section 7:10 of the General Administrative Law Act provides terms within which the decision on the objection must be made. This term is six weeks in principle. The end of the objection deadline is decisive for the commencement of the decision period (and not the day of receipt of the objection). The decision may be postponed for six weeks at most.

The objection committee and the parties involved in the objection are often unable to appear at a hearing at short notice. Moreover, it often concerns complex cases. Furthermore, the decisions on the objection must be placed on the agenda of the Board meeting, which takes place only once a month, as a result of which the terms of the General Administrative Law Act are exceeded nearly by default.

5.4. Compensation of costs

An administrative authority will only compensate an interested party, at their request, for the costs which they were reasonably required to incur in connection with the objection procedure if the challenged decision is revoked on the ground that the decision was taken unlawfully, and that the administrative authority is responsible for this. The request will be made before the administrative authority has decided on the objection. The administrative authority will give its decision on the request together with the decision on the objection (Section 7:15(1), (2) and (3) of the General Administrative Law Act).

5.5. Notification and communication

The Board will make the decision on the objection. The decision on the objection will be drawn up in Dutch. The substantiation of the contents of the decision may be attached to the decision as an appendix in English. The notification and communication of the decision on the objection is subject to the special arrangement of Section 7:12(2) - (4) of the General Administrative Law Act. The notification will be made

by sending or delivering it to the persons to whom it is addressed, i.e. the person filing the objection. If a representative has been instituted, the decision will be sent or delivered to that representative. At the same time as or as soon as possible after this notification to the person filing the objection it must also be communicated to interested third parties who expressed their opinion in the objection procedure or prior to the establishment of the primary decision (Section 7:12(3) of the General Administrative Law Act). With a view to the start of the appeal period, the communication will clearly state when the decision was notified to the person filing the objection.

After the decision has been notified to the person filing the objection and any interested third parties, the decision on the objection will be published on the website of the Board and in the Government Gazette (if a public hearing took place). The verbatim report of the hearing will not be published on the Board's website. For interested parties, the verbatim report will be attached as appendix to the decision on the objection. On request, the (non-confidential part of the) verbatim report will be made available for third parties.

The notification of the decision on the objection will state the possibility to lodge an appeal against this decision. It will indicate who can lodge an appeal, with which party and until when.