

# **THE INDEPENDENT REVIEW PANEL FOR BORDERLINE PRODUCTS**

Guidance on requesting a review of a Provisional Determination  
issued by the Borderline Section of the Medicines Control Agency.

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The Medicines Control Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ

## Guidance on requesting a review of a Provisional Determination

**This guidance should be read in conjunction with Guidance Note 8 *A guide to what is a medicinal product***

**The information contained in this guidance should not be taken as a complete or definitive statement of the law. It is not intended as a substitute for legal or other professional advice. The MCA accepts no liability for any loss or damage caused, arising directly, or indirectly, in connection with reliance on the contents of this guidance.**

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### 1 INTRODUCTION

- 1.1 Under Regulation 3A(1) of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (“the Marketing Regulations”), the Medicines Control Agency (“the MCA”), acting on behalf of the UK licensing authority, may serve a notice (“*provisional determination*”) on a person that the MCA is minded to determine that the product to which the notice refers is a medicinal product as defined in Article 1 of Directive 65/65/EEC and is therefore a *relevant medicinal product*. This note outlines the procedure for requesting a review of such a provisional determination by the Independent Review Panel for Borderline Products. This note should be read in conjunction with Guidance Note 8: *A guide to what is a medicinal product*. Both will be reviewed on a regular basis in the light of experience.
- 1.2 In many cases the MCA’s Borderline Section will have discussed the factors which they believe bring a product within the definition of a medicinal product with the company concerned before a provisional determination notice is issued.

#### Provisional Determination Notices

- 1.3 Provisional determination notices will be in writing, and will formally advise that the MCA are minded to determine that a product is a medicinal product within the first limb of the definition in Article 1 of Directive 65/65/EEC (*relating to presentation*), or within the second limb of that definition (*relating to function*), or within both limbs of that definition. The provisional determination notice will set out the reasons for the MCA’s position. The notice will also set out the options available to the company should they wish to request a review of the MCA’s provisional determination.

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### **2 THE INDEPENDENT REVIEW PANEL**

- 2.1 You may ask for a review of the provisional determination by an Independent Review Panel (“the Panel”). The role of the Panel is to advise the licensing authority whether or not it believes that a product is a medicinal product within the definition in Article 1 of Directive 65/65/EEC.
- 2.2 The Panel will consist of at least three persons, a legally qualified Chairman and two members, one or more of whom will have experience of the market area in which the product is placed, or intended to be placed. The Chairman and members do not represent external bodies or organisations, but will use their expertise and judgement in coming to their recommendations. Where the Chairman considers it appropriate the Panel may have additional members. The Chairman and Panel will be served by a Secretariat provided by the MCA but independent of the Borderline Section, where determinations that products are relevant medicinal products are made.
- 2.3 Panel members will have to declare any interest in any matter before the Panel and will have to withdraw from any matter in which they have, or may be seen to have, a conflict of interest. In this connection, the Panel members will be expected to follow the Code of Practice on Relations within the Pharmaceutical Industry and any further guidance issued by the MCA.

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### **3 REQUESTING A REVIEW**

- 3.1 If you have received a provisional determination notice that your product is a medicinal product and you disagree with that determination, you may ask the MCA to review its provisional determination. You have two options, either to ask for a review by way of making written representations to the Review Panel (written review) or to ask for a review by way of an oral hearing before the Panel (oral review). Whichever option you choose you must write to the Borderline Section requesting a review within four weeks of the date on which the provisional determination notice was served on you, and stating whether or not you are requesting an oral or written review.
- 3.2 The Borderline Section will alert the Secretariat to the Panel to your request and they will contact you to acknowledge your request for review. If you have asked for a review of the determination, whether involving the making of written representations or an oral hearing, you are not obliged to remove the product or its presentational material from the market.
- 3.3 If you fail to request a review within four weeks of the date of the provisional determination, the MCA shall, after further consideration of the matter, determine whether or not the product is a relevant medicinal product and shall inform you in writing of the determination and the reasons for it. The MCA shall also take this action where, having opted to have a review, you fail to submit written representations (for written review), or written submissions (for oral review) within the applicable time limit, or you fail to attend the hearing (oral review).
- 3.4 If you have any questions about the applicable procedures, you should contact the Panel Secretariat.

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### **4 WRITTEN REPRESENTATIONS PROCEDURE**

- 4.1 If you have said that you wish to make written representations to the Panel, six copies of your representations must be submitted to the Secretariat to the Panel. The Secretariat will contact you beforehand, informing you of the date by which your representations are required (this date will be not less than six weeks from the date of the provisional determination notice). This time period may be extended, where the Secretariat, having consulted both parties, concludes that an extension of time is warranted owing to exceptional circumstances or the nature or complexity of the issues in the case. If an extension is agreed, you will be notified by the Secretariat of the new deadline for lodging representations.
- 4.2 Your written representations should set out why you believe your product is not a medicinal product within the definition. It may be helpful to do this by responding to each of the reasons why the MCA believes that the product is a medicinal product. You should also include any additional material and information which you consider supports your views.
- 4.3 Once you submit your written representations to the Secretariat, they will automatically send a copy to the Borderline Section. If you make written representations and have included any relevant material which has not already been seen by the Borderline Section and which could affect the provisional determination, the Borderline Section will reconsider the matter. If appropriate, the MCA may withdraw its provisional determination completely or issue a revised one. If the Borderline Section withdraws its provisional determination completely there will be no need for the case to proceed to the Review Panel. If the Borderline Section revise the provisional determination notice, the notice will be served on you afresh, and the time limits referred to in paragraphs 3.1 and 4.1 will start to run again.
- 4.4 Where the Borderline Section are still of the opinion that the product is a medicinal product within the definition, and do not revise the provisional determination notice, the Panel will set a date when it will meet to consider the status of the product. The Panel Secretariat will notify you of this date. Subject to any agreement which may be reached between both parties and the Panel, the date will not be earlier than four weeks following the receipt of your representations.
- 4.5 No later than two weeks before the meeting date, the MCA will lodge with the Panel a written submission, commenting on your written representations, which may be accompanied by any supporting material. The submission and any supporting material will be copied to you by the Panel Secretariat.
- 4.6 You, or the MCA, may lodge additional material with the Panel up to one week before the date of the meeting (which will be notified to you). The Panel may call for further material from either party or from an independent expert. Any additional material lodged with the Panel will be made available to both parties.

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- 4.7 The Panel may, where necessary, having consulted both parties, extend the time for the MCA to lodge a written submission with supporting papers, or the time for either party to lodge further material. It may also postpone the date of its meeting if it needs longer to consider any material. You will be notified of any postponement and told the reasons for it.

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### 5 ORAL HEARING PROCEDURE

- 5.1 If you have requested an oral hearing, the Secretariat will set a date for the hearing and will notify both parties of the date and time set. The date will, subject to any agreement which may be reached between both parties and the Secretariat, not be earlier than six weeks following the date on which the Borderline Section receives notice from you that an oral hearing is requested. The Secretariat may alter the date set to a different date where they consider that this is warranted owing to exceptional circumstances or the nature and complexity of the issues in the case. Before doing so, they shall consult both parties and the Panel.
- 5.2 No later than four weeks before the date of the hearing, you must lodge with the Panel Secretariat written submissions in support of your case, together with any supporting material, and any application to the Panel for leave to call witnesses or be represented by Counsel at the hearing, together with the grounds for such an application. Any application for leave to call witnesses must set out the names of the witnesses it is desired to call. The Secretariat will copy your written submissions, any supporting material and any application to call witnesses or be represented by Counsel to the MCA.
- 5.3 No later than two weeks before the date of the hearing, the MCA must lodge with the Panel a written submission in support of its case, together with any supporting material, and any application to call witnesses, or to be represented by Counsel at the hearing, together with the grounds for any such application. Any application to call witnesses must set out the names of the witnesses it is desired to call. The Secretariat will copy to you the MCA's written submissions, any supporting material and any application to call witnesses or be represented by Counsel.
- 5.4 The Panel will as soon as possible after receiving an application relating to witnesses or Counsel consider whether or not to accede to the request. In connection with the calling of witnesses, the Panel will accede to the request where it considers that it is necessary to call the witnesses in question in order to clarify any matter or otherwise so as to ensure fairness. It is not intended that the parties will routinely be represented by independent Counsel, and the Panel will only accede to a request to be so represented if it concludes that, without Counsel, a party would not be able to present its case to the Panel with sufficient clarity, or that it is otherwise necessary for a party to be so represented so as to ensure fairness (e.g. where the Panel has agreed that the other party can be so represented).
- 5.5 The Panel may where necessary, and having consulted both parties, extend the time for either party to lodge material with the Panel. The Panel Secretariat will inform the parties of any new deadlines set.
- 5.6 Both you and the MCA may attend the hearing and make oral representations. Where any witnesses are called by either party, they may be cross examined by the other party, and questioned by the Panel. The Panel may request witnesses to attend where it considers this to be appropriate, whether or not a party has requested their attendance, and any such witness may be examined by either party or the Panel.

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- 5.7 Hearings will be held in private with support from the Panel Secretariat. The Panel may adjourn a hearing on application or on its own initiative where this seems necessary or appropriate.

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### 6 PUBLICATION OF ADVICE AND FINAL DETERMINATIONS

- 6.1 Whether or not there is an oral hearing the Panel will consider the product and its status under medicines legislation having regard to the legal definition of a medicinal product, the criteria set out in Guidance Note 8 and any relevant legal precedent. They will take into account any written or oral representations tendered by either party and any evidence given to, or lodged with, the Panel. The Panel may request clarification from either party to enable it to give its advice. The Panel will settle its advice, if necessary, by majority verdict. The Panel's advice will be put in writing giving full reasons, and the papers returned to the Secretariat.
- 6.2 Following the advice from the Panel, the licensing authority will make a final determination of whether or not the product is a medicinal product within the definition and therefore a *relevant medicinal product*. You will be advised of the final determination and the reasons for it, normally within 14 days of the date of the hearing. A copy of the Panel's advice will accompany the final determination. It will specifically point out any divergence between the MCA's determination and the Panel's advice, and give the reasons for this. Where the MCA determine that the product is a *relevant medicinal product*, it may, by notice served on you, require that you stop marketing the product from a date specified in the notice or that you shall not place the product on the market.

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### 7 WHAT IF I STILL DISAGREE?

- 7.1 There is no right of appeal against the making of a final determination that a product is a *relevant medicinal product*, or the service of a notice requiring you to stop marketing the product or not to place it on the market. You may, however, seek a judicial review of the determination or notice. Where a product is a *relevant medicinal product* and the MCA serve a notice on you requiring you to stop marketing the product or not to place it on the market, the marketing of the product without a marketing authorisation is a criminal offence.

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### **8 PUBLICATION OF ADVICE AND FINAL DETERMINATIONS**

- 8.1 The advice of the Review Panel and the final determination on the status of a product will be published. Persons affected will be advised of the text to be published and allowed to comment. The MCA will take note of those comments in the final text to be published where possible.

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### **9 FURTHER INFORMATION**

9.1 Further advice about policy on the Borderline can be obtained from:

Mr David Carter  
Manager, Borderline Section  
The Medicines Control Agency  
16-141 MT  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7273 0613  
Fax: 020 7273 0439

9.2 Further advice about the Independent Review Panel and its processes can be obtained from the Panel Secretariat:

Mr Sean Fletcher  
16-149 MT  
The Medicines Control Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7273 0878  
Fax: 020 7273 0121

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### Appendix 1

#### Terms of Reference for the Chairman of the Panel

1. Together with Members of the Panel, to objectively review the provisional determinations issued by the Borderline Section of the Medicines Control Agency that a product is a medicinal product as defined in Article 1 of Directive 65/65/EEC and therefore a *relevant medicinal product*. The Panel should also have regard to legal precedent, and any submissions or evidence of the licensing authority and person(s) marketing, or proposing to market, the product. The Panel may also have regard to the guidance provided by the Medicines Control Agency in its Guidance Note 8: *A guide to what is a medicinal product*.
2. To advise the Licensing Authority in writing whether the Panel does or does not agree that a product so reviewed is a *relevant medicinal product*. The advice to the Licensing Authority will reflect the opinions and views of a majority of the Panel members. The chairman shall have a casting vote in the case of a tied decision.
3. To assist the Licensing Authority in its regulatory role by advising, when requested, on the status of a product which is not yet on the market, as to whether any presentational material or ingredient would bring the said product within the definition of a medicinal product. The advice to the Licensing Authority will reflect the opinions of a majority of the Panel members. Where the Panel cannot come to a unanimous decision, the advice to the Licensing Authority shall state this and give brief details of the alternative views expressed.
4. To assist the Panel Secretariat in the work of scheduling and arranging the meetings of the Review Panel.
5. To select (from those Members nominated) who shall sit with him to review a provisional determination and to decide the number of Panel Members he wishes to assist him. As a minimum, the Panel shall be three (Chairman and two Members), but in any case where the Chairman considers it appropriate, additional Members may be selected.
6. To preside over Panel meetings, and ensure full consideration and a fair hearing of the cases under review. The Chairman will look to the Secretariat for assistance in matters of procedure.

#### Terms of Reference for Panel Members

1. To objectively review the provisional determinations issued by the Borderline Section of the Medicines Control Agency that a product is a medicinal product within the definition set out in Article 1 of Directive 65/65/EEC and therefore a *relevant medicinal product*. The review should be made having regard to that definition, to the criteria set out in Guidance Note 8 *A guide to what is a medicinal product*, any legal precedent and the information provided by the manufacturer or marketer of the product.
2. To advise the Licensing Authority whether or not they believe that a product, which has been the subject of the provisional determination, is a *relevant medicinal product*.
3. To assist the Licensing Authority in its regulatory role by advising, when requested, whether, in respect of a product which is not yet on the market, any presentational material or ingredient would bring the said product within the definition of a medicinal product in Article 1 of Directive 65/65/EEC.