

From: [REDACTED] ([REDACTED]) [REDACTED]
Sent: 10 June 2009 12:43
To: [REDACTED]
Subject: Final ACD and Evaluation Report: Psoriasis - ustekinumab

Thank you for giving the Welsh Assembly Government the opportunity to comment on the above appraisal. We are content with the technical detail of the evidence supporting the appraisal and have no further comments to make at this stage.

[REDACTED]
Clinical Governance Support and Development Unit/ Uned Cynorthwya a Datablygu Llwordraeth
Quality, Standards and Safety Improvement Directorate / Y Gyfarwyddiaeth Gwella Ansawdd, Safonau a Diogelwch
Department of Health and Social Services / Adran Iechyd a Gwasanaethau Cymdeithasol
Welsh Assembly Government / Llywodraeth Cynulliad Cymru
Tel / [REDACTED]
Fax / [REDACTED]
E-mail / [REDACTED]

From: [REDACTED] [mailto:[REDACTED]]
Sent: 11 May 2009 15:48
Subject: Final ACD and Evaluation Report: Psoriasis - ustekinumab
11 May 2009

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single technology appraisal (STA)

Ustekinumab for the treatment of moderate to severe psoriasis

Appraisal consultation document

Dear Consultee/Commentator,

You are invited to comment on the enclosed appraisal consultation document (ACD) and evaluation report for the above appraisal.

The Appraisal Committee is interested in receiving your comments on the ACD under the following general headings.

i) Do you consider that all of the relevant evidence has been taken into account?

ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence, and that the preliminary views on the resource impact and implications for the NHS are appropriate?

iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

iv) Are there any equality related issues that need special consideration that are not covered in the ACD?

If you wish to comment on the evaluation report, please do so under a separate heading from your comments on the ACD.

We prefer to receive comments in electronic format, either by email to TACommA@nice.org.uk or on compact or floppy disk. Please use Microsoft Office software products. Comments sent by post should be addressed to Bijal Chandarana Technology Appraisal Project Manager, at the above address.

Please note that your comments, along with a summary table of these comments and the action taken in response to them, will be released to consultees and commentators with the final appraisal determination (FAD) for this appraisal, and published on the Institute's website.

In line with the Guide to Technology Appraisals Process (April 2004; sections 4.5.2.7 and 4.5.2.10), we do not expect you to submit any information which is commercial in confidence or academic in confidence with your comments on the ACD and evaluation report.

In the light of comments received, the Appraisal Committee will reconsider the ACD at a meeting on 24th June 2009. In order for your views to be included in the papers for this meeting, your comments must be submitted before 5pm on 10th June 2009.

The ACD and evaluation report will be posted on the Institute's website on 19th May

2009. People who are not formal consultees or commentators for this appraisal can comment on the ACD through an email link on the website. However, we do not wish to receive comments from formal consultees and commentators via the website. Please send your comments directly to the Technology Appraisal Project Manager, either by email or by post.

Economic Model

The marketing authorisation holder has produced an economic model in support of their report. The Institute would like to offer consultees and commentators the opportunity to receive an executable version of the model by email.

An executable copy of the model will be released to you on the basis that you agree in writing to the following conditions for its use. If you wish to request a copy of the model please put your request in writing, together with your agreement of the conditions, Bijal.chandarana@nice.org.uk.

? This economic model enclosed and its contents are confidential and are protected by intellectual property rights, which are owned by Janssen-Cilag. It cannot be used for any other purpose than to inform your understanding of the appraisal. Accordingly, neither the model nor its contents should be divulged to anyone other than those individuals within your organisation who need to see them to enable you to prepare your response. Those to whom you do show the documents must be advised they are bound by the terms of the Confidentiality Acknowledgement and Undertaking Form that has already been signed and returned to the Institute by your organisation.

? You may not make copies of the file and you must delete the file from your records when the appraisal process, and any possible appeal, are complete. You must confirm to us in writing that you have done so. You may not publish it in whole or part, or use it to inform the development of other economic models.

? The model must not be re-run for purposes other than the testing of its reliability.

If you consider that changes need to be made, you should set out your argument in

writing, as part of your consultation response. You will be asked to set out your comments on reliability in writing providing separate justification, with supporting information, for each specific comment made. Where you have made an alteration to the model details of how this alteration was implemented in the model (e.g. in terms of programme code) must be given in sufficient detail to enable your changes to be replicated from the information provided. Please use the attached pro-forma to present your response. Comments on the model are welcomed as soon as possible to allow quicker consideration, you do not have to wait until comments on the ACD and evaluation report have been constructed to submit them.

I must emphasise that the documents enclosed with this letter, and their contents, are confidential until they are published on the Institute's website. They are released to you only for the purpose of informing the Appraisal Committee's consideration of this technology. Accordingly, the documents and their contents should only be divulged to those individuals within your organisation who need to see them to enable you to prepare your response. You must ensure that anyone who sees these documents is aware of their confidentiality.

The use of any information contained in the ACD to make investment decisions regarding any shares or other securities, or the passing of such information to someone else for such use, may constitute insider dealing, which is a criminal offence under section 52 of the Criminal Justice Act 1993. It may also be an offence to encourage someone else to deal in shares or securities, the price of which would be affected by the disclosure to the public of any information contained in the ACD.

Yours sincerely,

Dr [REDACTED]

Attached:

Appraisal consultation document (ACD)
Evaluation report
Pro-forma for comments on executable model

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chofnodi yn awtomatig am resymau cyfreithiol.

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Cafodd fersiwn gwreiddiol y neges e-bost hon ei sganio gan wasanaeth
gwrthfeirysau
Mewnrwyd Ddiogel y Llywodraeth (GSI) a ddarparwyd gan Cable&Wireless mewn
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oedd unrhyw
feirws yn gysylltiedig â'r neges hon.
Mae'n ddigon posibl y bydd unrhyw ohebiaeth drwy'r GSI yn cael ei logio,
ei monitro a/neu ei
chofnodi yn awtomatig am resymau cyfreithiol.

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