

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Proposed Single Technology Appraisal**

**Certolizumab pegol for the treatment of rheumatoid arthritis**

**Consultee and commentator comment form**

Please use this form for submitting your comments on the draft remit, draft scope and provisional matrix of consultees and commentators. It is important that you complete and return this form even if you have no comments otherwise we may chase you for a response.

**Enter the name of your organisation here: British Pain Society**

**Comments on the draft remit and draft scope**

The draft remit is the brief for a proposed appraisal, given to the Institute by the Department of Health. Appendix A contains the draft remit. The draft scope, developed from the draft remit outlines the question that the proposed appraisal would answer.

Please submit your comments on the draft remit and draft scope using the table below. **Please take note of any questions that have been highlighted in the draft scope itself** (usually found at the end of the document).

**If you have been asked to comment on documents for more than one proposed appraisal, please use a separate comment form for each topic, even if the issues are similar.**

If you do not have any comments to make on the draft remit and draft scope, please state this in the box below.

No comments

**Comment 1: the draft remit**

| Section         | Notes                                                                                                                                                                                                                                                                        | Your comments |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Appropriateness | <i>It is important that appropriate topics are referred to NICE to ensure that NICE guidance is relevant, timely and addresses priority issues, which will help improve the health of the population. Would it be appropriate to refer this topic to NICE for appraisal?</i> |               |

| Section                                    | Notes                                                                                                                                                                                                     | Your comments |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Wording                                    | <i>Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider? If not, please suggest alternative wording.</i> |               |
| Timing Issues                              | <i>What is the relative urgency of this proposed appraisal to the NHS? Is the suggested timing for submission of evidence (see cover letter) appropriate?</i>                                             |               |
| Any additional comments on the draft remit |                                                                                                                                                                                                           |               |

**Comment 2: the draft scope**

| Section                      | Notes                                                                                                                                                                                         | Your comments |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Background information       | <i>Consider the accuracy and completeness of this information.</i>                                                                                                                            |               |
| The technology/ intervention | <i>Is the description of the technology or technologies accurate?</i>                                                                                                                         |               |
| Population                   | <i>Is the population defined appropriately? Are there groups within this population that should be considered separately?</i>                                                                 |               |
| Comparators                  | <i>Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared? Can this (one of these) be described as 'best alternative care'?</i> |               |
| Outcomes                     | <i>Will these outcome measures capture the most important health related benefits (and harms) of the technology?</i>                                                                          |               |
| Economic analysis            | <i>Comments on aspects such as the appropriate time horizon.</i>                                                                                                                              |               |

| Section                                    | Notes                                                                                                                                                                                                                                                                                                                                              | Your comments |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Equality                                   | <p><i>Suggestions for factors which may help promote equality and eliminate unlawful discrimination.</i></p> <p><i>These may include issues with the intended use of the technology (including factors relating to assessment, delivery and follow up) amongst e.g. people of different race, disability, religion and sexual orientation.</i></p> |               |
| Other considerations                       | <p><i>Suggestions for additional issues to be covered by the proposed appraisal are welcome.</i></p>                                                                                                                                                                                                                                               |               |
| Questions for consultation                 | <p><i>Please answer any of the questions for consultation if not covered in the above sections. If appropriate, please include comments on the proposed process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).</i></p>                                        |               |
| Any additional comments on the draft scope |                                                                                                                                                                                                                                                                                                                                                    |               |

**Comment 3: provisional matrix of consultees and commentators**

The provisional matrix of consultees and commentators (Appendix B) is a list of organisations that we have identified as being appropriate to participate in this proposed appraisal. If you have any comments on this list, please submit them in the box below.

As NICE is committed to promoting equality and eliminating unlawful discrimination we are keen to know if we have missed any important organisations from the lists contained within the matrix and which organisations we should include who have a particular focus on relevant equality issues.

If you do not have any comments to make on the provisional matrix of consultees and commentators, please cross this box: x

Comments on the provisional matrix of consultees and commentators

**Comment 4: regulatory issues (for manufacturers to complete)**

| Section                                     | Notes                                                                                                                                                                                                                                               | Your comments |
|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Remit                                       | <i>Does the wording of the remit reflect the current or proposed marketing authorisation? If not, please suggest alternative wording.</i>                                                                                                           |               |
| Current or proposed marketing authorisation | <i>What are the current indications for the technology?</i>                                                                                                                                                                                         |               |
|                                             | <i>What are the planned indications for the technology?</i>                                                                                                                                                                                         |               |
|                                             | <b>FOR EACH PLANNED INDICATION:</b>                                                                                                                                                                                                                 |               |
|                                             | <i>What is the target date (mm/yyyy) for regulatory submission?</i>                                                                                                                                                                                 |               |
|                                             | <i>Which regulatory process are you following?</i>                                                                                                                                                                                                  |               |
|                                             | <i>What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable) and regulatory approval?</i>                                                                                                                                     |               |
|                                             | <i>Please indicate whether the information you provide concerning the proposed marketing authorisation is in the public domain and if not when it can be released. All commercial in confidence information must be highlighted and underlined.</i> |               |

Please return this form, preferably by e-mail, to **Christopher.Feinmann@nice.org.uk** by **10<sup>th</sup> February 2009**.

Where email is not possible, please copy this completed form onto a CD-ROM and send to: Christopher Feinmann, Project Manager, NICE, Level 1A, City Tower, Piccadilly Plaza, Manchester, M1 4BD to arrive on or before the deadline. Further contact details are (☎ 0161 870 3147, fax 0207 061 9832).