Dear Carole,

Bristol-Myers Squibb Pharmaceuticals Ltd. (BMS) writes to notify you of our intention to appeal against the above FAD; a formal Appeal Notice is attached. Our appeal is brought under each of the three permitted grounds: procedural unfairness, perversity, and excess of powers, and we request an oral hearing to determine the issues raised.

In our view, the appraisal of abatacept for treatment of RA lacked transparency in a number of critical respects and this has hampered our ability to understand the basis for the conclusions reached or verify the ERG’s results. This is not conducive to either transparency or confidence in the process and must therefore cast doubt on the reliability of the FAD.

Ground One: The Institute has failed to act fairly and in accordance with its published procedures

Our appeal under Ground One relates firstly to NICE’s failure to identify and rectify procedural unfairness relating to the conduct of the Evidence Review Group (ERG). In particular, BMS believes that the ERG has gone beyond their remit, as stipulated in the STA Process Guide, to conduct additional analysis of BMS data without consultation with the manufacturer. BMS believes that the importance of the manufacturer being involved in additional analyses is very high in the STA process where there is no opportunity for the manufacturer/sponsor to comment on the ERG Report before it is considered by the Appraisal Committee.

Secondly, there has been lack of transparency throughout this appraisal, both in terms of the evidence base relied upon by the Appraisal Committee in formulating its recommendations and the reasoning of the Committee in reaching the conclusions expressed in the FAD. BMS is particularly concerned that the lack of detail surrounding the methodology and results of the analyses conducted by the ERG, and accepted by the Appraisal Committee, has considerably prejudiced our ability to participate fully in the appraisal process.

Further, BMS is concerned that the Appraisal Committee did not take into account all available evidence on HAQ progression rates from previous appraisals of biologics for RA when recommending on the rates to be used in estimating cost-effectiveness of abatacept.

Ground Two: Perversity

Under Ground Two, BMS argues that the Appraisal Committee has perversely accepted analyses and opinions of the ERG, which represented an overly pessimistic view of the cost effectiveness of abatacept. This is particularly
concerning given that the decision, if upheld as Guidance, would effectively deny access to abatacept to patients who have no other effective treatment options.

BMS considers that the Appraisal Committee’s decision not to recognize the BMS utility-mapping algorithm as more robust than alternative approaches and its reliance on the ERG’s re-estimate of abatacept’s efficacy is perverse.

**Ground Three: The Institute has exceeded its powers**

Finally, BMS appeals on the basis that the Institute has exceeded the powers delegated to it. The Appraisal Committee has produced a determination which would effectively impose a ban on access to abatacept; this is a power that should be reserved to Government and subject to statutory safeguards.

Yours sincerely,
I. History of the appraisal

Abatacept (Orencia®) is a selective T-cell co-stimulation modulator indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an insufficient response or intolerance to other disease-modifying anti-rheumatic drugs including at least one tumour necrosis factor (TNF) inhibitor. Abatacept was discovered and developed by BMS and is the subject of a marketing authorisation granted by the European Commission under the centralised procedure on 21st May 2007, following a favourable decision by the CHMP issued on 22nd March 2007.

Abatacept was referred to NICE by the Department of Health and the Welsh Assembly Government as part of the Institute's 12th wave work programme on 25 August 2006. The Department of Health remit for the appraisal was “to appraise the clinical and cost effectiveness of abatacept for the treatment of rheumatoid arthritis”. Abatacept was appraised as part of the Single Technology Appraisal (STA) process.

The appraisal of abatacept began in October 2006. BMS submitted the Decision Problem (Section A) to NICE on 09 November 2006, following up with the full submission on 19 March 2007. NICE commissioned the Liverpool Reviews & Implementation Group (Evidence Review Group, ERG) to appraise the BMS submission critically and produce the ERG report, which together with the rest of the evidence submitted to NICE, was forwarded to the members of the Appraisal Committee.

The Appraisal Committee met for the first time on the 11th July 2007. The Appraisal Consultation Document (ACD) was issued to consultees on the 26th July 2007 for the 4-week consultation period. On 14th August 2007, during the consultation period, BMS wrote a letter to Andrew Dillon, chief executive of NICE, highlighting our concerns in relation to the way in which the appraisal had been conducted, the fact that additional analyses had been carried out by the ERG without discussion with BMS, contrary to the stated process, and the lack of clarity regarding the methodology of the analyses conducted by the ERG and relied upon by the Appraisal Committee. On 21st August 2007, a teleconference took place between BMS and the NICE technical team, during which our questions about methodological details were recorded by NICE, to be forwarded for clarification to the ERG. BMS provided a written response to the ACD on the 23rd August 2007. On the 29th August 2007, BMS received a letter from the ERG (via NICE) with additional information, to which we responded on 5th September 2007.

The second meeting of the Appraisal Committee took place on 13th September 2007. On 8th October 2007 we received a written response from Andrew Dillon to our letter of 14th August 2007. The Final Appraisal Determination (FAD) was issued to consultees on 19th October 2007 and published on 26th October 2007.
II. Notification of Intention to Appeal

Bristol-Myers Squibb Pharmaceuticals Ltd (BMS) has considered the FAD prepared by the Institute and provides formal notification of our intention to appeal. We request an oral hearing before NICE’s Appeal Panel for the determination of this appeal.

This Notice of Appeal does not repeat all of the submissions and information provided by BMS earlier in the appraisal process. We therefore respectfully request the Appeal Panel to consider all of our previous submissions, in particular, the following:

- The original BMS submission dated 19 March 2007
- BMS responses to NICE’s clarification letters dated 24 April 2007 and 29 May 2007
- BMS response to the ACD dated 23 August 2007
- Letter from ERG with additional technical information dated 29 August 2007
- BMS response to the ERG letter dated 05 September 2007
- Letter from BMS to Andrew Dillon dated 14 August 2007
- Letter from Andrew Dillon to BMS dated 01 October 2007
- BMS response to the letter from Andrew Dillon dated 19 October 2007

III. Grounds of Appeal

BMS appeal against the draft guidance in the FAD on the following grounds:

1. The Institute has failed to act fairly and in accordance with its published procedures.
2. The FAD is perverse in the lights of evidence submitted.
3. The Institute has exceeded its powers.

Ground One: The Institute has failed to act fairly and in accordance with its published procedures

1.1 The Evidence Review Group (ERG) has gone beyond its remit of a critical appraisal of the BMS submission and conducted further analyses without reference to BMS, contrary to NICE’s procedures. These analyses have then been relied upon by the Appraisal Committee.

The STA procedure requires discussion between the ERG and the manufacturer (through the Institute) with respect to any further analyses that are required. NICE’s Guide to the STA process provides in paragraph 3.3.2:

“A technical review of the manufacturer/sponsor’s evidence submission is undertaken by an external group, the ERG. Their remit is to critically evaluate the submission and identify gaps in the evidence base that could lead the Institute to request further clarification from the manufacturer/sponsor ...”.

BMS was concerned to find that significant analyses were undertaken by the ERG in this case, without reference to the Company, contrary to process and even though we had emphasised with our submission that we would wish to be consulted if further analyses were thought to be necessary.
We believe the involvement of manufacturers in any additional analyses is an essential component of a fair STA procedure, in view of the fact that manufacturers are not, as a matter of practice, invited to meetings of the Appraisal Committee and, in contrast to other stakeholders, have no opportunity to consider the ERG’s work with the Committee before preliminary guidance is formulated.

The harm to BMS resulting from the failure to consult the Company in relation the additional analyses is substantial. The ERG exceeded its remit to evaluate the submission critically; they re-estimated the efficacy of abatacept by running a linear regression analysis, which, based on what BMS was told by the ERG, used imprecisely-measured variables that introduced bias. Further, the new estimates of efficacy were applied by the ERG in the “gender reconciliation” step, the methodology of which has not been fully explained and which BMS cannot replicate or verify.

This failure to discuss such additional work with BMS and to ask the company to conduct relevant additional analyses is not only inconsistent with the Guide to the STA Process, it is also inconsistent with the way the same ERG acted during a parallel appraisal of rituximab for RA\(^1\). Moreover, Meindert Boysen expressly recognised the requirement to involve the manufacturer in additional analyses in his letter to BMS dated 05 April 2007\(^2\).

We raised these issues in our letter to Andrew Dillon dated 14 August 2007 with the hope that our concerns could be resolved through discussion with the Institute. However, Mr Dillon responded, by letter dated 01 October, stating that “it was always envisaged that the ERG groups would undertake additional analyses to support the opinion they give to the Institute...”. BMS cannot accept that this statement represents an accurate reflection of NICE’s written procedures, which anticipate that additional analyses, if required at all, would be requested of and conducted by the manufacturer.

In his letter to BMS, Andrew Dillon also sought to explain the actions by the ERG on the basis of timing: “...we designed the STA process to provide a rapid appraisal mechanism and for it to achieve that objective, we need to offer the ERG groups reasonable latitude to test the assumptions in the models they receive without necessarily referring to others for permission or agreement to do so”. While NICE has not explained why it concluded that the STA timetable would not be met if BMS had been asked to carry out the additional analyses, BMS strongly believes that the fairness and proper procedure should, in any event, take precedence over the speed of the appraisal.

1.2 The appraisal has lacked transparency throughout its duration, which has prejudiced BMS’s ability to participate fully in the process

From its inception, NICE has accepted the requirement for transparency in its procedures\(^1\), both as a matter of fairness, but also to ensure that guidance issued to the NHS is credible and may be acted upon. BMS supports this principle and believe this approach should be adhered to in all appraisals.

This requirement for transparency necessitates firstly the disclosure to consultees of evidence relied upon by the Appraisal Committee in formulating its guidance (unless there is some exceptional reason why such evidence may not be made available) and also sufficient reasoning to enable consultees (and subsequently those seeking to apply NICE guidance) to test the decision making process and to understand the Institute’s analyses, conclusions, recommendations and advice. In
the absence of proper transparency, the basis for the guidance issued is unclear, consultees are prejudiced in their ability to engage with the appraisal process and clinicians seeking to implement the guidance, will be unable to assess the extent to which it may properly apply to their patients.

Despite these requirements, the appraisal of abatacept for treatment of RA lacked transparency in a number of important respects and this has hampered our ability to understand the basis for the conclusions reached. The ERG’s approach is so unclear that BMS is unable to replicate or verify its results. This is not conducive to either transparency or confidence in the process and must therefore cast doubt on the reliability of the guidance.

1.2.1 NICE did not ensure that the ERG provided sufficient details with regard to the methods and parameters used in their analysis in time for BMS, or any third party, adequately to assess its validity.

In their critical appraisal of the BMS submission, the ERG made a number of changes to assumptions and parameters used in the cost-effectiveness model. These changes led to a significant increase in the incremental cost effectiveness ratio (ICER) for abatacept, and were seemingly relied upon by the Appraisal Committee in deciding not to recommend abatacept. However, the rationale and methodology underlying these changes were not sufficiently described in the ERG Report. The lack of sufficient detail was recognised by NICE, and, as described above, a conference call was arranged with NICE to clarify BMS’s request to the ERG for additional details. Although the ERG did provide further information in their letter sent to BMS on the 29 August 2007 (see Appendix I for timelines), the details provided were still not sufficient for BMS to replicate and properly understand the ERG’s approach to key changes such as the “gender reconciliation”.

Furthermore, the additional details supplied by the ERG in response to BMS’s request were received by BMS after the deadline for responses to the ACD. While BMS was permitted to submit comments on the additional material after the deadline, we had little time in which to consider this new information and were prevented from submitting a comprehensive response to the ACD, by the ERG’s failure to provide proper information at the appropriate time.

1.2.2 The Institute has acted unfairly in failing to provide BMS with a copy of the ERG version of the BMS economic model upon request.

BMS requested a copy of the BMS model revised by the ERG and the results of the regression analysis underpinning the additional analyses (letter to Andrew Dillon dated 14 August 2007). The result of this lack of transparency is that the revised analysis, upon which NICE’s proposed Guidance is based, has not been peer reviewed by anyone outside the NICE team. From BMS’s perspective, the fact that we did not have access to this material significantly prejudiced our ability to respond to the ERG’s amendments relied upon by the Appraisal Committee, during the period of consultation on the ACD.

NICE’s response that we could only receive the model if we agreed to its disclosure to other consultees (letter from Andrew Dillon dated 01 October 2007) is unacceptable. The additional analyses conducted by the ERG use highly confidential BMS patient-level data; therefore NICE’s condition places BMS in an impossible position whereby the only way our legitimate
demand for clarity can be satisfied is by sacrificing our right to have commercially-confidential information withheld from third parties. This situation would not have arisen if proper procedures had been followed and the additional analyses had been carried out by BMS rather than the ERG.

1.2.3 The reference used to estimate disease related costs, relied upon by the Appraisal Committee, was not made available to BMS and other consultees.

The ERG used an unpublished analysis of data from the NOAR database submitted by Roche during the appraisal of rituximab for RA (referenced incorrectly in the ERG Report and identified by BMS in the rituximab submission as “Roche, data on file”) to estimate RA related direct medical costs. The Appraisal Committee accepted these estimates over the ones submitted by BMS (Section 4.18), derived from a published and peer-reviewed report from the same database. The details of the Roche report were not disclosed to BMS (or other consultees) and therefore our ability to verify and respond to the ERG’s estimates was considerably prejudiced.

We believe NICE should have made the report available to consultees and commentators with the ACD so that we could have considered this in the context of our submission during the consultation period. The approach followed by NICE, providing the report only with the FAD, recognised the significance of the data, but deprived us of the possibility of effective consultation. The fact that we may review the data before submitting an appeal does not correct the procedural flaw resulting from the earlier failure to disclose in view of the fact that NICE’s procedures do not permit an appeal based simply on the merits of a decision unless this reaches the perversity threshold.

Further, BMS believes the Appraisal Committee should explain why it has chosen to rely upon unpublished data, emanating from a competitor company, which cannot be properly verified, when other peer reviewed and published data are available. In this context the explanation that the unpublished data are “more detailed” is inadequate in circumstances where there is no indication that the Appraisal Committee has properly considered the marginal benefits from the increased detail provided, against the risks of reliance on unpublished material.

1.2.4 It is unclear why the Appraisal Committee’s failed to take into account zero HAQ progression rates, consistent with other appraisals.

In the final analysis underpinning the recommendations of the AC, the Committee failed to consider a “zero HAQ progression rate” for abatacept. This is inconsistent with the appraisal of anti-TNF agents and therefore requires explanation.

The Appraisal Committee rejected both the BMS and ERG proposed rates for underlying HAQ progression in patients suffering from RA, and used instead the progression rates associated with other biologic treatments for RA from previous appraisals. However, the Appraisal Committee appeared to be selective in their choice of the individual rates; for example, they did not take the “no progression rate” into account for abatacept, even though it was considered a valid option for a biologic in the appraisal of anti-TNF agents: “the Committee considered it appropriate to primarily examine the estimates of cost effectiveness based on the assumption of no HAQ
progression while on TNF α inhibitor therapy, while acknowledging the effects on the estimates of incorporating different assumptions of HAQ progression”.

No explanation is provided for the inconsistent approach followed by the Appraisal Committee in this appraisal and BMS is therefore unable to understand why zero HAQ progression rates have not been considered. This is particularly concerning to BMS as we were specifically requested by NICE to conduct additional cost-effectiveness analysis using the “zero progression rate” for abatacept; the results of these analyses were provided to NICE in the BMS response to the clarification letter.

1.3 The Appraisal Committee’s failed to take account of the ERG’s belated acceptance that BMS’ cost-effectiveness model was appropriate

The BMS cost-effectiveness model was based on changes in HAQ scores as a result of treatment. In estimating abatacept’s efficacy, BMS applied a simulated distribution of percentage change in HAQ score across the patient population, thus accounting for the variation between individual patients; this approach is similar to the one applied in the BRAM model (anti-TNF appraisal). In the ERG report (section 5.4.2, page 63) the ERG criticised this approach as “erroneous” and “potentially liable to substantial and unpredictable bias”. The ERG therefore chose to re-estimate abatacept’s efficacy by conducting a series of regression analyses using the BMS patient-level data. In the ACD, the ERG’s conclusion was relied upon by the Appraisal Committee in concluding that the ERG’s calculations were appropriate (paragraph 4.7).

However, the ERG subsequently revised its view of BMS’ modelling and stated that “the original [BMS] assumption of forcing the regression line through the origin was acceptable”. Nevertheless, there is no indication in the FAD, that the Appraisal Committee took into account, the ERG’s subsequent acceptance that its criticisms of the BMS model were inappropriate. Instead it appears to have continued to rely on the ERG’s original view of the BMS model.

The fact that the Appraisal Committee were misled into believing that the approach followed in the BMS model was erroneous is clearly procedurally unfair. The fact that, as a result of the inaccurate criticisms by the ERG, the Committee was persuaded to rely on the ERG re-estimate, rather than the BMS estimate is particularly damaging to BMS given that, as argued in paragraph 1.1, the ERG’s own analysis was subject to statistical bias. (The ERG regression analysis assumed that the outcome (change in HAQ score at day 169 versus baseline HAQ) is measured with error and the independent variable (baseline HAQ) is measured without error, which is not the case.)

1.4 The Appraisal Committee’s reasons for criticising the structure of the model submitted by BMS are unfair and no explanation has been provided for the conclusion that abatacept would be less cost effective if usage was considered sequentially

BMS’ economic model did not include any estimate of the cost-effectiveness of abatacept when used in a sequence of treatments. There were and are no robust efficacy data to permit such modelling to be carried out with sufficient accuracy. Nevertheless, the ERG concluded that this was a limitation of the BMS model and went so far as to advise the Appraisal Committee that it believed that abatacept would be less cost-effective when used in a sequence of treatments (ACD, section 4.5). This advice was seemingly accepted by the Appraisal Committee, who
stated that it was “mindful of the possible limitations of the model structure as it examined the estimates of cost-effectiveness”.

However, the alleged limitations in the BMS model were unavoidable given the absence of data and it is therefore unfair to criticise the model on that basis. Furthermore, the evidence or reasoning relied upon by the Appraisal Committee for its conclusion that abatacept would be less cost effective when used in a sequence of treatments has not been provided. While BMS believes such a conclusion is not valid, the Company was unable properly to respond to the ACD (or the FAD) in the absence of any explanation for the Committee’s views.

Ground Two: NICE has prepared guidance which is perverse in light of the evidence submitted.

We believe that the additional analyses conducted by the ERG represented a perverse interpretation of available evidence.

2.1 The Appraisal Committee’s refusal to accept the BMS utility-mapping algorithm and to use less reliable data is perverse

The BMS cost-effectiveness model linked changes in HAQ scores (clinical outcome from clinical trials), to Quality-Adjusted Life Years gained (QALYs). As no published data on societal utility weights for quality of life in RA were identified to inform the model, the approach adopted, consistent with other RA economic models, was to link the changes in HAQ scores to utility, a process known as “utility mapping”. Several algorithms for mapping HAQ changes to utility were identified by BMS and the merits of each were assessed carefully. The algorithm based on data from the National Databank of Rheumatic Diseases was chosen because it was considered the most robust and most relevant to the NICE Reference Case.

The decision by the Appraisal Committee not to rely on the HAQ-utility mapping algorithm used by BMS (paragraph 4.17 of the FAD) and to use instead the algorithm referenced by the ERG is perverse as it disregards aspects of the BMS-proposed algorithm that make it a more rational and sound basis for decision-making. Moreover, the Appraisal Committee’s decision is at odds with NICE’s own recommended utility methodology. The flaws in the Appraisal Committee’s approach were outlined in the BMS response to the ACD:

- The BMS-proposed algorithm is based on data from a more representative and larger RA population, than the trial-based algorithm used by the ERG. The algorithm used in the BMS submission is based on patient data from the largest data set of rheumatic patients in the world (National Databank for Rheumatic Disease in the US, NDRD) – currently with nearly 24,000 patients. The analysis itself was based on 18,380 patients distributed across HAQ categories (0-3). In contrast, the Bansback et al data, relied upon by the Appraisal Committee, derived their HAQ-utility function from data of 2,000 adalimumab patients, all with HAQ scores of around 1.5.

- The BMS-proposed algorithm was developed using the NICE Reference Case-recommended EQ5D with UK weights, whereas Bansback et al used an alternative health-related quality of life questionnaire, HUI3 (which is not NICE’s preferred measure), with Canadian weights, making it less applicable to the UK setting. The Appraisal Committee appeared not to recognise that the BMS proposed algorithm was therefore consistent with
the utility methodology recommended by NICE in the Reference Case, whereas the Bansback approach was not.

- The BMS-proposed algorithm is the only one considered to capture the non-linear relationship between HAQ and utility, due to a large dataset underpinning the analysis. This feature of the HAQ-utility relationship was recognised in the recent appraisal of anti-TNF agents for RA\(^8\) where the Appraisal Committee stated that "the HAQ scoring system (...) may have a non-linear relationship to utility scores" (Section 4.3.10).

- Finally, the ERG’s criticism that the BMS approach had the steepest downward gradient does not accurately reflect the data; the BMS algorithm does not have the steepest gradient at all levels of disability. Contrary to the ERG’s comments, the BMS-proposed algorithm is not an outlier: if a linear regression is fitted, the slope of the BMS-proposed algorithm (0.304) lies between the ERG-proposed Bansback algorithm (0.28) and the Hurst algorithm (0.327) used in the Birmingham RA Model (BRAM) developed for the MTA of anti-TNF agents\(^9\). Moreover, the increase in changes in utility values at higher levels of disability is entirely reasonable and provides more information than the other algorithms, which appear more simplistic and less representative of the complexities of the disease.

**Ground Three: The Institute has exceeded its powers**

3.1 **The proposed recommendations have the effect of acting as an unlawful restriction on the prescription of abatacept**

Directive 89/105/EEC (the Transparency Directive) requires governments of Member States to notify to the European Commission a series of criteria which are used to restrict the range of medicinal products covered by National Health systems. The criteria notifies by the UK Government in accordance with these requirements do not include clinical and cost effectiveness.

BMS believes that guidance issued by NICE constitutes a measure within the scope of the Transparency Directive. The fact that NICE’s determinations are characterised as “guidance” is irrelevant in this context, because their effect is to lead to a de facto restriction on the prescription of medicinal products within the NHS in England and Wales. Furthermore, measures have been put in place which provides penalties for a failure to adhere to the Institute’s determinations. These measures are described at Section 5 of the FAD and in guidance issued by the Healthcare Commission. Standards, set by the Department of Health, together with NICE and set out in the publication “Standards for Better Health” issued in July 2004, provide that one of the core standards by which NHS organisations will be assessed is compliance with NICE’s guidance. In addition, Directions issued by the Department of Health make funding for technologies recommended by NICE mandatory, with the effect that where a product such as abatacept is not so recommended, funding will not be made available.

Therefore, a determination by NICE that abatacept should not be recommended for use in combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an insufficient response or intolerance to other disease modifying anti-rheumatic drugs including at least one TNF alpha inhibitor, is unlawful in Community law, because it restricts the use of the product, based on criteria that have not been notified to the European Commission.
IV. Requested actions

BMS respectfully request the Appeal Panel to:

- Return this Appraisal to the Appraisal Committee for further consideration and receipt of submissions
- Provide BMS with proper disclosure of the supplemental ERG analyses (and their results) as well as the BMS model as modified by the ERG
- Ensure that any future ACD/FAD be fully reasoned in line with the comments raised above.
## Appendix I: Chronology of the NICE appraisal of abatacept for RA.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>BMS submission</td>
<td>19 March 2007</td>
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<tr>
<td>Clarification letter 1</td>
<td>10 April 2007</td>
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<tr>
<td>BMS response to Clarification Letter</td>
<td>24 April 2007</td>
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<tr>
<td>Clarification letter 2</td>
<td>03 May 2007</td>
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<tr>
<td>BMS response to Clarification Letter 2</td>
<td>29 May 2007</td>
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<tr>
<td>Appraisal Committee meeting 1</td>
<td>11 July 2007 (evidence sent to the AC ~2 weeks before)</td>
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<tr>
<td>ACD received</td>
<td>26 July 2007</td>
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<tr>
<td>BMS letter for A.Dillon</td>
<td>14 August 2007</td>
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<tr>
<td>Teleconference between BMS and NICE Technical Team</td>
<td>21 August 2007</td>
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<tr>
<td>End of ACD consultation</td>
<td>23 August 2007</td>
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<tr>
<td>ERG clarification letter received</td>
<td>29 August 2007</td>
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<tr>
<td>BMS response to ERG Clarification Letter</td>
<td>05 September 2007</td>
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<tr>
<td>Appraisal Committee meeting 2</td>
<td>13 September 2007</td>
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<tr>
<td>A.Dillon response to BMS letter</td>
<td>Received 08 October 2007 (letter dated 01 October 2007)</td>
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<td>BMS response to Dillon</td>
<td>19 October 2007</td>
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<td>FAD received</td>
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<tr>
<td>FAD published</td>
<td>26 October 2007</td>
</tr>
<tr>
<td>Deadline for appeal</td>
<td>09 November 2007</td>
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3 Evidence of Sir Michael Rawlins to House of Commons Health Select Committee, February 1999 “the most important thing is for us to gain the confidence of the professions, of the public, of Parliament, of Ministers, of the Department as a whole…..we will do that by being transparent in so far as is humanly possible”