

## **Rapid re-consideration of drugs currently funded through the Cancer Drugs Fund**

### **Introduction**

- 1 All cancer drugs that are funded through the current Cancer Drugs Fund (CDF) will be considered in line with the proposed new CDF criteria.
- 2 This document sets out the proposed rapid reconsideration process necessary to support the re-consideration of drugs that have previously been appraised by NICE and are currently funded through the CDF.
- 3 In order to allow for the transition of drugs currently in the CDF to take place before 31 March 2017, NICE needs to prepare for the re-consideration in parallel with consultation on the new CDF arrangements, without prejudging the outcome of that consultation. The proposals in this paper are therefore provisional and subject to change if the proposed CDF arrangements are amended after the consultation.

### **Rapid re-consideration process**

#### Scope and evidence submission

- 4 The scope for re-consideration will remain the same as the final scope used for the published guidance. NICE will re-issue the scope at the start of the re-consideration process.
- 5 A decision problem meeting (see 3.2.2 of the Guide the processes of technology appraisal) will be held only on request from a company, and NICE will judge the need for a meeting taking into account the details of the request.
- 6 The company evidence submission should focus on cost effectiveness analyses using the new cost of the drug, either as a consequence of an amendment to the

existing patient access scheme or as a 'commercial access agreement' (see proposed new paragraphs 5.31 – 5.33).

- 7 The analyses included in the evidence submission must use the assumptions that determined the most plausible incremental cost effectiveness ratio as presented by the Appraisal Committee in the published guidance. Only in exceptional circumstances and with prior agreement with NICE should new clinical evidence be included. Submission of new clinical evidence must not lead to structural changes in the approach to cost effectiveness.
- 8 The submission should take account of the proposed changes to NICE's methods of technology appraisal set out in the CDF consultation, in particular those concerning the appraisal of life-extending products at the end of life (proposed amended paragraph 6.2.10), and including those for use through the Cancer Drugs Fund (proposed new paragraphs 6.5.1 – 6.5.4).
- 9 If the evidence submission is to include a new patient access scheme, an amendment to an existing patient access scheme, or a commercial access arrangement, each of these must have been formally agreed with the relevant organisation (that is, the Department of Health or NHS England), by the time the Appraisal Committee meets.
- 10 Companies will have the opportunity to change their evidence submissions to NICE in case substantial changes are required to the proposals currently included in the CDF consultation.
- 11 Statements from non-company consultees will be requested.
- 12 The Evidence Review Group (ERG) critically evaluates the evidence submission.
- 13 NICE sends the ERG report to the company before it is presented to the Appraisal Committee. The company has 5 working days from the date of sending to check that the report (including confidential information provided by the company) does not contain factual errors, for example, errors in the figures, incorrect quotes from the evidence submission or text that does not describe the facts accurately. NICE prepares a document highlighting any factual errors for the

Appraisal Committee and publishes the document on its website as part of the committee papers. The company cannot submit additional evidence during the evidence review phase unless NICE has agreed to this before the main evidence submission, or NICE asks for more evidence. The company is also required to check that the ERG has accurately marked confidential information within the report. This again provides an opportunity for the company to reconsider and update the confidential status of information before the Appraisal Committee meeting.

14 All other relevant sections of the Guide to the processes of Technology Appraisal apply.

#### Appraisal Committee

15 The Appraisal Committee used for the re-consideration of CDF products will be drawn from the 4 Appraisal Committees with the same membership composition as the existing Committees. The terms of reference and standing orders for this Appraisal Committee will be available separately.

16 The Committee discussion will be held in public in as much as is possible. Considering the likely commercial nature of the discussion, it will be necessary to hold the discussions largely in private, with only company and evidence review group representatives attending.

17 Clinical experts, patient experts and NHS commissioning experts will be invited to attend the Appraisal Committee meeting.

18 The Appraisal Committee can make one of the following recommendations:

- **Recommended for routine commissioning**
- **Not recommended**
- **Recommended for use within the CDF**

19 Scheme proposals submitted through the rapid re-consideration process are treated by NICE as commercial in confidence and all matters about the proposed

scheme (except the existence of the scheme proposal) will usually remain confidential unless consideration by the Appraisal Committee results in a change to guidance recommendations. In this situation, NICE will issue an Appraisal Consultation Document (ACD) for consultation (see section 3.7.21 onwards in the Guide to the processes of technology appraisal) or a Final Appraisal Determination (FAD) for appeal. NICE releases information during the ACD consultation or FAD for appeal consideration so that the proposed scheme and its impact on the clinical effectiveness, cost effectiveness and the recommendations can be understood.

20 Appeals following the rapid re-consideration of guidance, when consideration of the impact of patient access scheme/commercial access arrangement proposals on current guidance has resulted in a change to the guidance, will only be accepted on points relating to the new or amended patient access scheme or commercial access arrangement proposal. The Appeal Panel will not consider points previously raised or points that could have been raised at earlier appeals. Subject to any appeal by consultees, the FAD forms the basis of NICE guidance on the use of the technology.

**Table 1 Expected timelines for the rapid reconsideration process\*:**

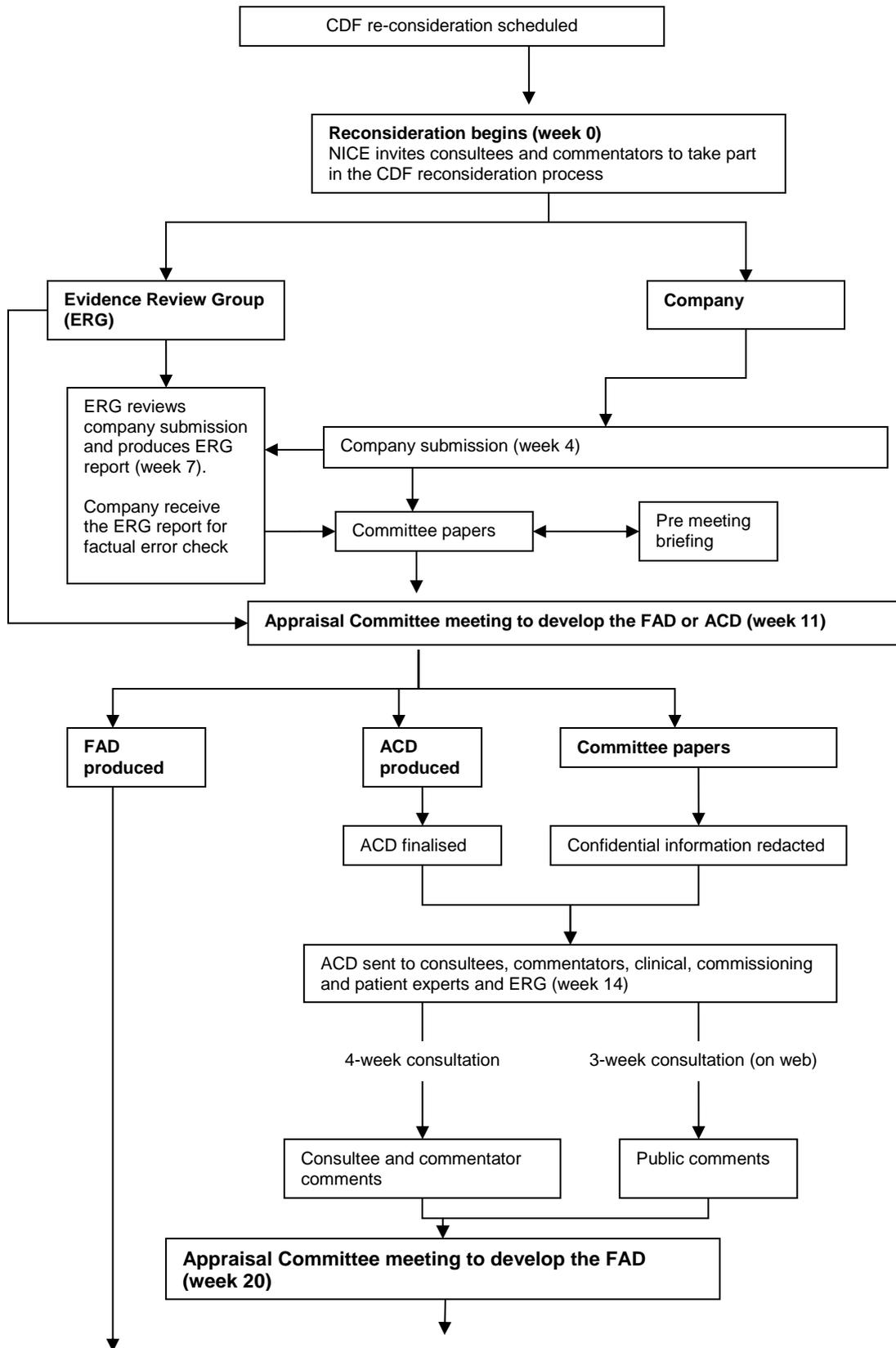
		<b>Weeks (approx.) since process began</b>
<i>Step 1</i>	<i>NICE invites organisations to participate in the rapid CDF re-consideration process as consultees or commentators – including requests for expert nominations, and evidence submissions</i>	<i>0</i>
<i>Step 2</i>	<i>NICE receives evidence submissions from company and non-company consultees</i>	<i>4</i>
<i>Step 3</i>	<i>NICE invites clinical experts, patient experts, commissioning experts and company representatives to attend the Appraisal Committee meeting</i>	<i>4</i>

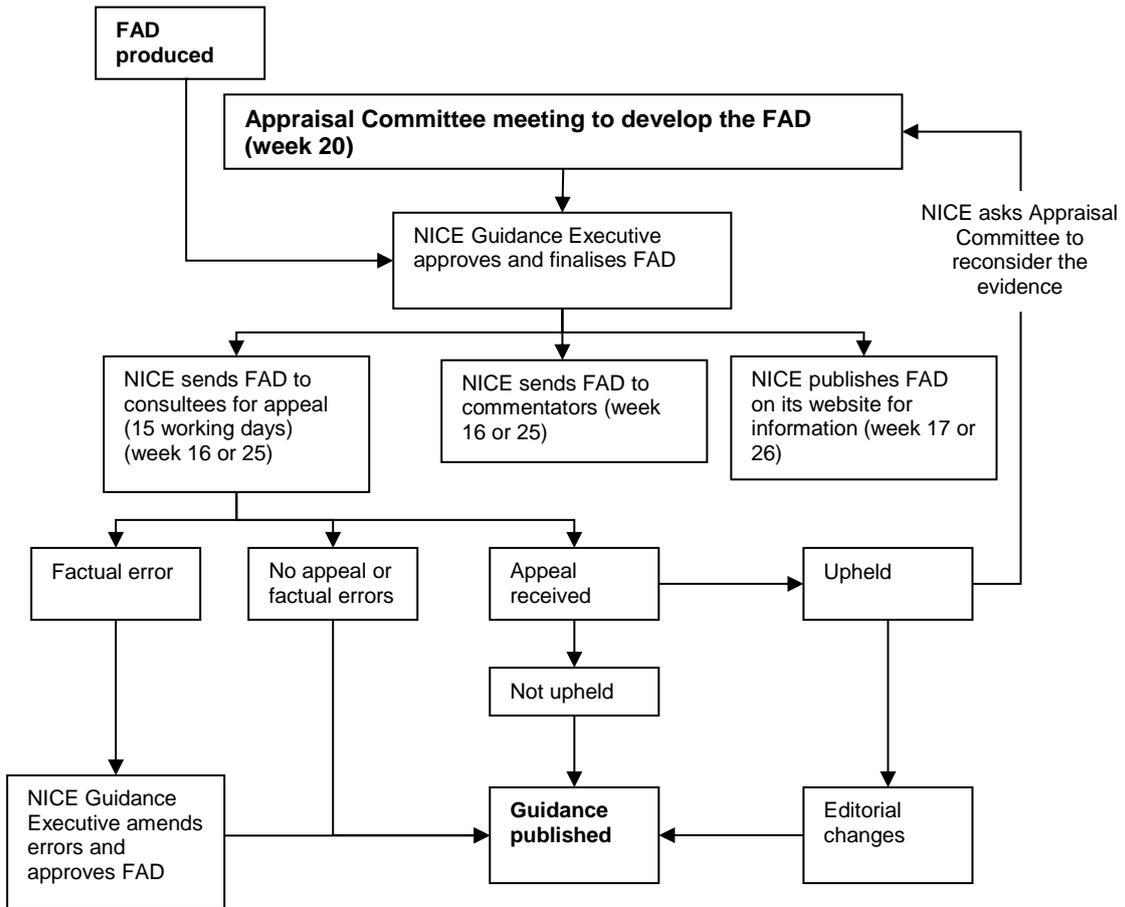
Step 4	<i>ERG delivers the critique of the company submission to NICE</i>	7
Step 5	<i>NICE sends the ERG report to the company for fact checking</i>	8
Step 6	<i>NICE compiles the supporting documentation (see section 3.7.3 of the Guide to the processes of technology appraisals) and sends it to the Appraisal Committee</i>	9
Step 7	<i>Appraisal Committee meeting</i>	11
Step 8	<i>The ACD is produced. NICE distributes the ACD and publishes it on the website 5 working days later</i>	14
Step 9	<i>Fixed 4-week consultation period on the ACD</i>	14-18
Step 10	<i>Appraisal Committee meeting to consider comments on the ACD from consultees and commentators, and comments received through the consultation on the NICE website. Appraisal Committee agrees the content of the FAD</i>	19/20
Step 11	<i>The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later</i>	25
<i>*Timelines may change in response to individual appraisal requirements.</i>		

**Table 2 Expected timelines for the rapid reconsideration process if an ACD is not produced\***

		<b>Weeks</b>
Step 7	<i>Appraisal Committee meeting to develop a FAD</i>	11
Step 8	<i>The FAD is produced. NICE distributes the FAD and publishes it on the website 5 working days later</i>	16
<i>*Timelines may change in response to individual appraisal requirements.</i>		

Figure 1 – Summary of the reconsideration process





**NICE March 2016**