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BOARD PAPER - NHS ENGLAND

Title: Future Delivery of the Cancer Drugs Fund (CDF)
From: Sir Bruce Keogh, National Medical Director Paul Baumann, Chief Financial Officer
Purpose of Paper: To inform the Board of activity to date and proposed next steps in developing proposals for future delivery of the CDF.
The Board is invited to: 1. Note that proposals developed for future delivery of the CDF will be subject to a public consultation in September 2015. Public consultation is required to take place at the latest in September to allow sufficient time for responses to be analysed, orderly transition from the existing scheme to be implemented and the new CDF to be operational from 1 April 2016. 2. Agree to delegate authority from the Board to the Chair and to the Chief Executive, who may act jointly and or individually (where either of them is unavailable), for approval of the public consultation document on the proposals for future delivery of the CDF and the future process post-consultation.

Future Delivery of the Cancer Drugs Fund (CDF)
Board Meeting – 23 July 2015

1.0 INTRODUCTION AND CONTEXT

1.1 Since its inception in 2010, the Cancer Drugs Fund (CDF) has provided access to treatment for patients whose individual circumstances suggest that they will benefit from drugs that have not been adopted for routine use in the NHS. This includes drugs which have not been approved by the National Institute for Health and Care Excellence (NICE), are for rare cancer licensed drug indications not selected for NICE appraisal, or are planned to be used off-label.

1.2 The budget for the Fund was initially set at £200m; however, this has been increased twice, most recently to £340m for 2015/16. However, and as recognised by the Cancer Taskforce in their recent report, while the Cancer Drugs Fund has helped to unlock access to new treatments for a large number of patients, its implementation under the current model does not enable access to innovative drugs in a smart or sustainable way. England is currently allocating an increasing share of the cancer budget to treatments that are less cost-effective, towards the end of life, and the impacts of this are being felt further down the cancer pathway.

1.3 The arrangements for the current Fund are due to end in March 2016, providing a useful opportunity to take stock of current arrangements. In light of this, and the escalating overspend under current arrangements, the Board requested that proposals be developed for a new CDF operating model, to be introduced from April 2016, following a public consultation.

1.4 The new operating model should be co-designed by NHS England, patients and NICE, in a way that does not allow the budget to grow any further, recognising that other areas of investment will deliver greater benefits.

2.0 CDF WORKING PARTY

2.1 A Working Party was established in December 2014, under the chairmanship of Sir Bruce Keogh, with representation from NHS England, cancer charities, the pharmaceutical industry, NICE and the Department of Health (DH). The Working Party was commissioned to collaborate in identifying potential solutions for a longer term sustainable way of evaluating and commissioning cancer drugs.

2.2 The Working Party has met five times and has been extremely effective in galvanising and strengthening the commitment of stakeholders to working with NHS England in the development of a collaborative solution. The Working Party established a number of workstreams and has collectively agreed a valuable set of high level principles.

2.3 Taking the valuable insights from the CDF Working Party's activity as a starting point, detailed and rapid discussions have been taking place between NHS England, DH and NICE to shape the proposal for the future delivery of the CDF, which will go out to public consultation in September 2015. It is proposed that NHS England and NICE meet with a representative group of stakeholders immediately prior to publication of the public consultation to demonstrate *inter alia* how the CDF Working Party input has been considered in the final proposals.

2.4 The independent Cancer Taskforce's report, *Achieving World Class Cancer Outcomes: A Strategy for England 2015-20,* made the following recommendations on the Cancer Drugs Fund, which we propose to accept:

"Section 5.3.3.1 Access to innovative drugs
The Cancer Drugs Fund has helped more than 72,000 cancer patients in England access the drugs their doctors think they need in the absence of NICE approval. It has enabled pull through of innovative drugs into routine NHS use. However, because it has also enabled some pharmaceutical companies to bypass NICE cost-effectiveness assessments, it is widely acknowledged that it is no longer sustainable or desirable for the Cancer Drugs Fund to continue in its current form. In its place a solution is needed that ensures patients have routine access to a greater range of cancer drugs, including earlier access to innovative drugs, while ensuring that cost-effectiveness is maintained. A process is under way to find such a solution and it is anticipated that this will be agreed by summer 2015. Part of the solution will continue to be a national fund to make new cancer treatments available prior to NICE assessment or which are subject to a conditional approval."

and

"Recommendation 31: NHS England should work with NICE, the Government, the pharmaceutical industry and cancer charities to define a sustainable solution for access to new cancer drugs. This updated process should enable NHS England to confirm clinical utility, whilst managing within a defined budget, and should be aligned with NICE appraisal processes. The new process should be published for consultation in summer 2015, with a view to implementation from April 2016. The solution should set out reforms to NICE processes to make them more flexible for cancer drugs.
In recent years, a number of immunotherapy drugs have been developed, and are showing significant promise. They could be 'game changers' due both to the magnitude and durability of their effect in some patients and the number of different tumour types implicated. We will have to handle adoption of these therapies within the NHS carefully, as they have a different profile of toxicities and side effects to many of the treatments currently in use. There could also be major implications for the training and size of the medical oncology workforce and how some cancer services are delivered."

3.0 THE EMERGING PROPOSAL – KEY PRINCIPLES

3.1 We are developing arrangements for the operational management of a new fund, aligned with adapted NICE processes, including revisions to the current End of Life Criteria.

3.2 The emerging proposal is that in future the CDF should become a 'managed access' fund for new cancer drugs, with clear entry and exit criteria. It would be used to resource those drugs which appear promising, but where NICE indicates that there is insufficient evidence to support a recommendation for routine commissioning, and where additional evidence would be likely to enable a more informed NICE appraisal decision. Instead of a simple failure to recommend, the drug would be given 'conditional approval' by NICE and provided through the Fund for a defined period, whilst further evidence from 'real world' use was collected. At the end of this period, the drug would go through an abbreviated NICE appraisal, using this additional evidence and the company's offer price, and then either attract a NICE positive recommendation (at which point it would move out of the Fund into mainstream commissioning) or a NICE negative recommendation (at which point it would move out of the Fund and become available only on the basis of individual patient referral). New mechanisms will also need to be built into the fund to enable expenditure to be controlled within the allocated budget.

3.3 This approach would enable the money in the Fund to be more effectively managed, as well as providing a new pathway for innovative drugs to be assessed on a more robust evidence base and made available to patients.

3.4 It will clearly be important to ensure that our final proposal on the CDF is not inconsistent with the Accelerated Access Review's developing thinking about how we design a single accelerated access pathway.

4.0 BENEFITS FOR PATIENTS

4.1 Patients will benefit from access to treatments for which there are insufficient data to support routine use but which may, nevertheless be the right choice for them.

5.0 BENEFITS FOR THE NHS

5.1 The NHS will benefit from a careful process which contains cost and will select only those drugs where there is reason to believe that additional data, collected either through the CDF or from clinical studies already underway, may plausibly result in a decision to move the drug into routine commissioning.

6.0 BENEFITS FOR THE PHARMACEUTICAL INDUSTRY

6.1 Pharmaceutical companies will benefit from a transparent and contestable process, with NICE involvement, which will make clear the basis on which their products will be selected for use in the NHS, including the circumstances in which they may be eligible for time limited access to funding through the CDF.

7.0 PUBLIC CONSULTATION

7.1 As per the Board's previous request, the emerging proposal will be subject to public consultation. Public consultation is required to take place at the latest in September, to allow for sufficient time for responses to be analysed, orderly transition from the new scheme to be implemented and the new CDF to be operational from 1 April 2016. The intention is for NHS England to develop consultation documentation during August, in collaboration with the DH and NICE, and to meet with a representative group of stakeholders in advance of the public consultation being published in September.

7.2 NICE will also seek to consult in parallel on any changes to NICE methodology as a result of the emerging proposal.

8.0 RECOMMENDATIONS AND ACTIONS REQUESTED

8.1 The Board is asked to:

i. Note that proposals developed for future delivery of the CDF will be subject to a public consultation in September 2015. Public consultation is required to take place at the latest in September to allow sufficient time for responses to be analysed, orderly transition from the existing scheme to be implemented and the new CDF to be operational from 1 April 2016.

ii. Agree to delegate authority from the Board to the Chair and to the Chief Executive, who may act jointly or individually (where either of them is unavailable), for approval of the public consultation document on the proposals for future delivery of the CDF and the future process post-consultation.

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