ANNEX A

Cancer Drugs Fund Consultation Report

Background to Consultation Process

1. NHS England undertook a four week public consultation from the 3rd October to 31 October 2014. A Consultation Guide was published explaining the proposed changes and outlining a series of questions for stakeholders to consider. Alongside this a draft revised version of the CDF SOP was published highlighting the proposed changes. Responses to the consultation could be made via an online portal and a dedicated consultation mailbox was set up to answer stakeholders questions and queries. The consultation was publicised via the NHS England website and through internal and external communication briefs. A direct mail to NHS England stakeholders (including NHS Organisations, Cancer Charities, Patient Organisations, Industry, Partner Organisations and Professional bodies) was also undertaken.

2. A workshop was held to help patient organisations and cancer charities understand the proposals, enabling them to respond formally to the consultation. A meeting was also held with the Association of British Pharmaceutical Industry to further explain the consultation proposals.

Reviewing Consultation Feedback

3. NHS England undertook quantitative analysis of consultation feedback.

4. In addition, "Participate", an independent provider of communications and engagement support to the health and social care sector, were commissioned to undertake thematic analysis of consultation feedback.

Responses Received

5. A total of 189 consultation responses were received through the consultation portal.

6. A breakdown of responses by stakeholder group is shown below:

Stakeholder Type	# Responses
Charity	23
NHS	104
NHS England	3
Organisation Not Provided	17
Other Organisation	8
Patient/Patient Group	9
Pharma	25

7. 104 responses came from a variety of NHS organisations, including many CCGs, provider organisations and responses from individual clinicians. In addition, 3 responses were received from employees of NHS England. The responses from Charity and Pharmaceutical companies were predominantly responses made on behalf of whole organisations.

8. A number of key stakeholders responded including the ABPI, All Party Parliamentary Group on Cancer, Cancer Research UK, Cancer 52, NICE, Rarer Cancers Foundation and The Royal College of Radiologists.

Overview Summary of Findings

9. The findings infer a general agreement that action is required in the short term to address immediate issues of sustainability relating to the CDF and good levels of support for a number of the proposals. There were also many detailed comments and questions raised regarding the proposals.

10. There was also a significant view that a more fundamental issue relating to the overall process of appraising, funding and sustaining routine access to new cancer medicines through the NHS needs addressing. Many respondents expressed disappointment that these wider issues were not mentioned within this consultation and that the proposed changes to the operation of the CDF were not linked to longer term solutions to these issues.

Feedback by Question

11. **Question 1**: **Do you agree with, or have any comment to make about, proposed change (A) – the implementation of a re-evaluation process which will assess the drugs on the current CDF list in respect of clinical benefit.**

Yes	No	Don't know	Not Answered
140	34	8	7
74%	18%	4%	4%

Stakeholder Type	Yes	No	Don't know	Not Answered	% Yes responses
Charity	17	2	4	0	74%
NHS	89	13	2	0	86%
NHS England	2	1	0	0	67%
Organisation Not Provided	10	3	2	2	59%
Other Organisation	4	2	0	2	50%
Patient/Patient Group	7	2	0	0	78%
Pharma	11	11	0	3	44%

12. There was majority agreement to this proposal (75% responded yes). Agreement was weakest amongst pharmaceutical company responses (44% responded yes).

13. Re-evaluation was seen as being required to ensure the CDF is able to offer access to new and clinically more beneficial cancer medicines.

14. Understanding more clearly how clinical benefit is measured was raised.

15. It was acknowledged as essential that patients who are already receiving a drug/indication which is to be removed from the CDF will continue to gain access to it. However, many were concerned that new patients could only gain access to "removed drugs" through what is perceived to be an overly restrictive Individual Funding Request Process. Many patient groups and charities responded to this

effect.

16. Many suggestions were made regarding the current scoring tool and how it might be further improved as a tool to measure "clinical benefit". However, the tool was also praised by many as bringing improved rigour to the CDF clinical evaluation process.

17. Respondents from pharmaceutical companies who did not support this proposal stated that they could only support it if it was implemented alongside an evolution to the NICE appraisal process allowing CDF medicines to undergo a rapid review through a new NICE value assessment process.

18. **Question 2: Do you agree with, or have any comment to make on, proposed change (B) - the list will be re-evaluated taking into consideration both clinical benefit and cost?**

Yes	No	Don't know	Not Answered
109	62	11	7
57%	33%	6%	4%

Stakeholder Type	Yes	No	Don't know	Not Answered	% Yes responses
Charity	8	14	1	0	35%
NHS	78	17	8	1	75%
NHS England	2	1	0	0	67%
Organisation Not Provided	6	8	1	2	35%
Other Organisation	4	2	0	2	50%
Patient/Patient Group	5	4	0	0	56%
Pharma	6	16	1	2	24%

19. There was a majority agreement to this proposal (57% said yes). Only 35% of charities and 24% of pharmaceutical company responses said yes.

20. Respondents who agreed to this proposal commented that it would rightly allow the opportunity cost of cancer drugs to be considered within the CDF and would ensure greater fairness with other NHS funding mechanisms. Many qualified this view by stating that clinical benefit should be of greater importance than cost.

21. However there were also strong concerns expressed that this proposal would see the CDF duplicating what is perceived to be NICE's role in undertaking a full appraisal of cancer medicines.

22. Respondents who disagreed with this proposal stated that the CDF was not established to undertake value assessments and such a proposal would not be in line with the original objectives of the CDF.

23. *"Unless there is an unlimited budget then there has to be a financial component to CDF evaluation" (Cancer Charity)*

24. *"NICE is already looking at cost. The CDF should only be taking into account clinical benefit" (Individual respondent)*

25. *"Both NICE and the CDF should be speaking the same language" (NHS Clinician)*

26. **Question 3: Do you agree with, or have any comment to make about, proposal (C) – that drugs which are highly priced in relation to clinical benefit should be removed from the list?**

Yes	No	Don't know	Not Answered
88	64	27	10
47%	34%	14%	5%

Stakeholder Type	Yes	No	Don't know	Not Answered	% Yes responses
Charity	4	14	4	1	17%
NHS	68	19	16	1	65%
NHS England	2	0	1	0	67%
Organisation Not Provided	4	8	3	2	24%
Other Organisation	4	1	0	3	50%
Patient/Patient Group	3	5	1	0	33%
Pharma	3	17	2	3	12%

27. There was a smaller majority in favour of this proposal, with a higher number of don't know responses than proposals A&B (47% said yes, 14% don't know).

28. The findings demonstrate that there was a higher degree of uncertainty around this proposal. Many asked how "highly priced" would be defined. Again, the perceived duplication between the CDF and NICE processes was mentioned, alongside concerns over access to expensive drugs (removed from the CDF) via the Individual Funding Request Process.

29. Many respondents suggested that the CDF should look at the full opportunity cost impact of cancer drugs (including delivery costs/benefit, offset costs and costs/savings in treating toxicity) when assessing cost and not just direct drug costs.

30. *"In principle yes, but there needs to be clear criteria for determining the point at which affordable becomes unaffordable" (NHS respondent)*

31. *"With the caveat that these remain available to patients currently receiving treatment through the CDF and also that where there are no other treatment options for the condition the CDF funding may still remain" (NHS respondent).*

32. **Question 4**: **Do you agree with, or have any comment on, the proposal that, in order to protect current and potential future pricing arrangements between pharmaceutical companies and NHS England, which differ from the public list price of drugs, the proposed process should treat the scoring bands for assessment of drug cost and the individual cost scores of drugs as confidential.**

Yes	No	Don't know	Not Answered
72	63	44	10
38%	34%	23%	5%

Stakeholder Type	Yes	No	Don't know	Not Answered	% Yes responses
Charity	4	6	12	1	17%
NHS	50	30	23	1	48%
NHS England	0	0	3	0	0%
Organisation Not Provided	4	7	4	2	24%
Other Organisation	3	1	1	3	38%
Patient/Patient Group	4	4	1	0	44%
Pharma	7	15	0	3	28%

33. There was a very mixed response to this proposal. (38% said yes to this proposal, 34% no and 23% don't know)

34. The most common concern related to the need for transparency. Being more open rather than confidential was seen as essential in ensuring public confidence and trust in the process, recognising that the process involves spending considerable £millions of public money. However, many recognised that confidentiality could be acceptable if it enabled costs to be driven down by securing beneficial pricing arrangements with pharmaceutical companies. Even so, many respondents commented that the process by which cost is scored (i.e. the scoring bands) should be made public, or at least the process needed to be better explained to the public. In addition, pharmaceutical companies expressed the importance of knowing the detail of the process by which their drugs would be assessed.

35. Many respondents suggested other ways in which the process could be made more transparent, including the publishing of forecasted and actual costs on a regular basis and clarification of what information the CDF would make public.

36. *"The current proposals do not provide sufficient information to ensure that the cost analysis would promote transparency." (APPG)*

37. *"The panel should ensure that all clinical information considered is published in full, so that there is evidence to help the public to understand whether clinical or cost factors were pivotal to decisions." (CRUK)*

38. *"At least the price bands can be made public and the actual price can be kept confidential" (NHS Respondent).*

39. *"We agree that drug costs proposed by manufacturers should stay confidential, similarly we believe that the price scoring systems (or bands) should be confidential and the corresponding scores not published, but it should be made clear to the manufacturer applying to the CDF the scores associated with each band" (Pharma Company)*

40. **Question 7: Should the proposed process allow a pharmaceutical company the option of making an appropriate and confidential adjustment to its drug price to allow the drug/indication to remain in the CDF?**

Yes	No	Don't know	Not Answered
129	18	28	14
68%	10%	15%	7%

Stakeholder Type	Yes	No	Don't know	Not Answered	% Yes responses
Charity	16	1	5	1	70%
NHS	75	13	12	4	72%
NHS England	2	0	1	0	67%
Organisation Not Provided	9	1	6	1	53%
Other Organisation	1	0	2	5	13%
Patient/Patient Group	5	2	2	0	56%
Pharma	21	1	0	3	84%

41. There was a majority agreement to this proposal (68% said yes).

42. Many stated that as long as this meant that good drugs were supported that would bring the greatest value to patients then they agree. Some respondents felt that price needed to always be open and transparent.

43. *"Clearly any solution that resulted in visibility of commercial arrangements or discounts offered by companies would be unacceptable" (Pharmaceutical Company)*

44. *"With the public in the form of the tax-funded NHS being the consumer who surely has the right to know costs of goods their taxes are purchasing?" (NHS Respondent).*

45. **Question 6**: **Are there any other considerations that you think should be addressed in developing a process for prioritising drugs for inclusion within the CDF list?**

46. A considerable number of ideas and questions for clarification were raised, which have been recorded and are being reviewed. Key suggestions and comments included:

47. The risk that rare cancers would be disadvantaged through the process due to both the more limited evidence bases for rarer cancers and the higher costs associated with drug development in rarer cancers.

48. Similar concerns were raised regarding Paediatric Cancer, alongside the need to include greater paediatric cancer expertise within the CDF Panel.

49. The need for clarification on the definition of unmet need and / or the broadening of the CDF definition of unmet need (to include where there are high mortality rates or where there are limited treatment options\-

50. The need for clarity on the definition of "drugs that are the only proven drug treatment therapy for a particular condition" (which therefore would not be removed from the CDF list in the event of re-evaluation).

51. **Question 7: Please provide any comments that you may have about the potential impact on health inequalities which might arise as a result of the**

proposed changes that we have described. Please also comment on any impact you consider there may be on equality matters more broadly.

52. A number of comments were received that the CDF in itself results in inequality by establishing a separate funding mechanism for cancer medicines. Secondly, a number of comments were received that an emphasis on cancer drugs over other treatments for cancer was unwarranted inequality.

53. A number of respondents asked why innovative and effective radiotherapy treatments could not be funded through the CDF.

54. Some stated that removing access to drugs previously funded via the CDF would create inequality, as those that are able to pay privately will still get access.

55. Some commented that the use of a dynamic / changing threshold for CDF entry and removal would create inequity in that access to some medicines would depend on timescale of diagnosis or time of the required clinical need for the drug.

56. CRUK raised concern regarding the financial sustainability of the CDF and the potential detrimental impact on other cancer treatments of a continuing CDF overspend.