



The Royal College of **Pathologists**

Pathology: the science behind the cure

Response from the Royal College of Pathologists to Consultation ECR0165 from the National Chemo- therapy Board on the Cancer Drugs Fund

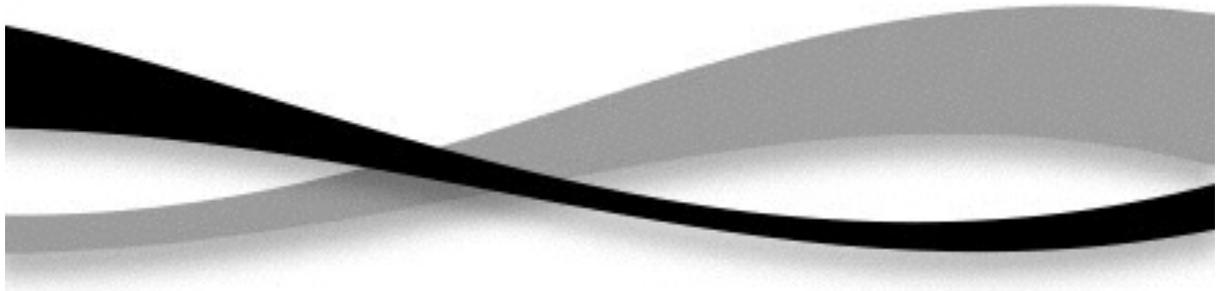
The Royal College of Pathologists' written submission

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1 About the Royal College of Pathologists

1.1 The Royal College of Pathologists (RCPATH) is a professional membership organisation with charitable status. It is committed to setting and maintaining professional standards and to promoting excellence in the teaching and practice of pathology. Pathology is the science at the heart of modern medicine and is involved in 70 per cent of all diagnoses made within the National Health Service. The College aims to advance the science and practice of pathology, to provide public education, to promote research in pathology and to disseminate the results. We have over 10,000 members across 19 specialties working in hospital laboratories, universities and industry worldwide to diagnose, treat and prevent illness.

1.2 The Royal College of Pathologists comments were made by members of the College Council during the consultation which ran from 4th January 2016 until the 4th February 2016 and collated by Dr Rachael Liebmann, Registrar.

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2.1 Council members considered that the Cancer Drugs Fund was an important facility for enabling treatment of patients who met certain criteria and who fell outside 'normal' cancer presentation and progression patterns and who would benefit from new and often expensive drugs. However, since it was not possible to provide a convincing answer to the question: 'What is the justification for treating the funding of cancer treatment differently to the treatment of other serious illnesses?' there was a view that the existence of the cancer drugs fund was justified on political rather than ethical grounds.

2.2 Council members responded to the specific questions as follows:

2.2.1 Do you agree with the proposal that the CDF should become a 'managed access' fund for new cancer drugs, with clear entry and exit criteria?

(Yes) Agree

2.2.2 Do you agree with the proposal that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal?

(Yes) Agree

2.2.3 Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs?

(Yes) Agree

2.2.4 Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of the NICE Technology Appraisal Committee's evaluation would be a set of recommendations falling into one of the following three categories:

- i. Recommended for routine use;
- ii. Recommended for use within the Cancer Drugs Fund;
- iii. Not recommended.

(Yes) Agree

2.2.5 Do you agree with the proposal that “patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation” be removed from the criteria for the higher cost effectiveness threshold to apply?

(Yes) Agree

2.2.6 Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?

There was a mixed response from College respondents to this question.

2.2.7 Do you agree with the process changes that NICE will need to put in place in order for guidance to be issued within 90 days of marketing authorisation, for cancer drugs going through the normal European Medicines Agency licensing process?

(Yes) Agree

2.2.8 Do you agree with the proposal that all drugs that receive a draft NICE recommendation for routine use, or for conditional use within the CDF, receive interim funding from the point of marketing authorisation until the final appraisal decision, normally within 90 days of marketing authorisation?

(Yes) Agree

2.2.9 What are your views on the alternative scenario set out at paragraph 38, to provide interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not yet been produced, given that this would imply lower funding for other drugs in the CDF that have actually been assessed by NICE as worthwhile for CDF funding?

College respondents did not think that such funding should be supported.

2.2.10 Do you have any comments on when and how it might be appropriate for the CDF in due course to take account of off-label drugs, and how this might be addressed?

College respondents did not see how off-label drugs could easily be supported.

2.2.11 Do you agree with the proposal to fix the CDF annual budget allocation and apply investment control mechanisms within the fixed budget as set out in this consultation document?

(Yes) Agree

2.2.12 Do you consider that the investment control arrangements suggested are appropriate for achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the budget? Are there any alternative mechanisms which you consider would be more effective in achieving those aims?

Yes

2.2.13 Are there any other issues that you regard as important considerations in designing the future arrangements for the CDF?

None proposed by College respondents.

2.2.14 Do you agree that, on balance, the new CDF arrangements are preferable to existing arrangements, given the current pressures the CDF is facing?

(Yes) Agree