

NHS England – Board Paper

Title:

Specialised Services Commissioning Committee (SSCC) Report

Lead Director:

Noel Gordon – Non-Executive Director and Chair of the SSCC

Purpose of Paper:

To update the Board on SSCC business.

The Board is invited to:

- note the work and key decisions of the SSCC;
- take a verbal update on any additional issues and decisions taken by the SSCC on 25 October 2017;
- endorse the updated Terms of Reference for SSCC (attached as annex 1); and
- note the recent High Court decision on an application for Judicial Review from the Association of the British Pharmaceutical Industry challenging three decisions made by the National Institute for Health and Care Excellence (attached as annex 2).

Specialised Services Commissioning Committee Report

Report to the Board from: Specialised Services Commissioning Committee
Committee Chair: Noel Gordon
Date of the Committee meeting: 25 October 2017

Committee meetings

1. This report covers the last Committee meeting, held on 25 October 2017.

Implementation

Horizon scanning for new technologies

2. The Committee received an outline of the current tools used to understand the pharmaceutical pipeline, and the estimate of likely financial impact on specialised commissioning.
3. The following points were made in discussion:
 - The Committee recognised the progress that had been made and discussed how the approach might be augmented to provide greater quantification of future pipeline.
 - The issue of how to create a similar approach for medical technology devices and diagnostics was raised. It was agreed that a paper on this would be brought back to a future discussion.
 - The Committee discussed the need to be able to compare the effectiveness of multiple drugs for the same indication. It was agreed that NHS England would explore the possibility of this approach with NIHR and NICE.
4. It was concluded that further work would need to be conducted to model longer horizon periods (eg 2-3 years) to see the longer-term financial impact of the pharmaceutical pipeline.

Finance and contracting

5. The Committee received an update on the 2017/18 planning position, including potential risks and associated mitigations to the delivery of an overall balanced plan, and the latest position on provider contracts.

Service change and configuration

6. The Committee received an update on the assessment that has taken place of the current service review programme.
7. The following points were made in discussion:
 - The Committee recognised the progress that had been made in establishing the programme and on accelerating the reviews over the past few months.
 - Further analysis was needed on the provider landscape and on the 'long tail' of provision, recognising that it would vary by clinical service.
 - A focus was needed on ensuring full implementation of service change at a local level.

8. The Committee concluded that the process for agreeing new service reviews needs to be updated ensuring that there is sufficient account taken of the implementation costs and benefits.

Individual Funding Requests policy

9. The Committee noted the paper on the revised Individual Funding Request (IFR) policy, and the actions that are being taken to support the IFR programme.
10. The Committee agreed to publication of the revised policy and supporting documentation, and to the proposed action plan.

Assurance

11. The Committee took updates on:
 - the September and October 2017 meetings of the Patient and Public Voice Assurance Group, where the following items were considered for assurance: Transforming Care implementation; genetic labs procurement; Haemoglobinopathies service review; and specialised complex urogynaecology conditions;
 - the Specialised Commissioning Oversight Group meeting in September 2017 (there was no meeting in August), including updates on clinical priorities, service reviews and Clinical Priorities Advisory Group recommendations, and whole genome sequencing; and
 - The Cancer Drugs Fund Investment Group.

Live issues

12. The PreP trial has gone live. At the time of the meeting eight clinics had begun, with 70 clinics on track to be running by the end of November and all of the clinics to be running by the end of April.

ANNEX 1



Terms of Reference

Specialised Services Commissioning Committee

Version: 1.2

Date: November 2017

Document file name: Terms of reference	
Directorate:	Specialised Commissioning
Document reference ToR - SSCC	
Owner	Status Approved
Author	Version 1.1
	Version issue date [Publish Date]

Document management

Revision history

Version	Date	Summary of changes
1.0	29/07/2016	Approved by SSCC
1.1	30/11/2017	Update to reflect organisational changes within NHS England and change of membership

Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
Noel Gordon		Non Executive Director & Chair of SSCC	29/07/2016	1.0

Related documents

Title	Owner	Location

Document control

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Contents

1.	Purpose.....	7
2.	Duties and Responsibilities	7
3.	Membership	7
	Attendees.....	7
	Quorum.....	8
4.	Governance and Administration	8
5.	Declaration of Interest	8
6.	Reporting.....	9
7.	Terms of Reference Review	9

Purpose

1. The Specialised Services Commissioning Committee purpose is to assure the Board that allocation for specialised commissioning in 2016/7 is utilised to maximise value, improve patient and population outcomes and ensure sustainability and transformation as part of wider programmes across the NHS.
2. The Committee's work programme should align with implementation of the required changes in how specialised services are to be commissioned and provided, specifically: delivery of place and population based systems of care, reforms at the national level to enable local flexibility, and ensuring financial sustainability

Duties and Responsibilities

3. The Committee operates on behalf of and reports to the Board. The following summarises the scope of responsibilities of the Committee:
 - Agree NHS England's work programme for specialised services and receive assurance about its delivery, with associated risks identified and mitigated
 - Oversee NHS England's work programme for direct commissioning of services for Health and Justice, and Armed Forces and their families
 - Ensure alignment of Specialised Commissioning strategy and implementation wider sustainability and transformation work across the overall commissioning system
 - Assure in-year and end-of-year financial balance, and to ensure necessary action – internally and with external bodies – is taken to ensure financial sustainability
 - Assure the work of the Specialised Commissioning Oversight Group (SCOG), Public and Patient Voice Assurance Group (PPVAG), and the Cancer Drugs Fund Investment Group (CDFIG)

Membership

13. The following members of the Specialised Services Commissioning Committee have been appointed by the Board.
14.
 - Paul Baumann (Chief Financial Officer)
 - Professor Sir John Burn (Non-Executive Director) Deputy Chair
 - Ian Dodge (National Director: Strategy & Innovation)
 - Noel Gordon (Non-Executive Director) Chair
 - Professor Sir Bruce Keogh (National Medical Director)
 - Michelle Mitchell (Non-Executive Director)
 - Simon Stevens (Chief Executive Officer)
 - John Stewart (Acting Director of Specialised Commissioning)

Attendees

- Gareth Arthur (Acting Director of Strategy and Policy, Specialised Commissioning) Committee secretariat
- James Palmer (Medical Director, Specialised Commissioning)

15. The Committee may ask any other officials of the organisation to attend and assist it with its discussions on any particular matter;
16. The Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

Quorum

17. The meeting will be quorate if at least two or more Non-Executive Directors and one National Director are present.

Governance and Administration

18. The Committee will be provided with a secretariat function by a member of the specialised commissioning team.
19. They will ensure that minutes of the meeting are taken and provide appropriate support to the Chair and members. Duties will include:
 - Committee meetings shall be set before the start of the financial year
 - Meeting administration, agreement of agenda with Chair and attendees and collation of papers
 - ensuring that minutes are taken and keeping a record of matters arising and issues to be carried forward
 - timely distribution of papers before each meeting, usually a minimum of five working days
 - record of actions and other matters arising or issues to be carried forward;
 - The Secretariat will prepare an attendance register for each meeting and ensure that the attendance/non-attendance of all individuals is correctly recorded at each meeting
20. The Board or the CEO/Accounting Officer may ask the Committee to convene further meetings to discuss particular issues on which they want the Committee's advice.

Declaration of Interest

21. All members and attendees of the Committee must declare any relevant personal, non-personal, pecuniary or potential interests at the commencing of any meeting. The Chair of the Committee will determine if there is a conflict of interest such that the member and/or attendee will be required to not participate in a discussion.
22. All potential conflicts of interest must be declared and dealt with in line with NHS England's policies/procedures for handling conflicts of interest. All declarations of interest will be minuted.
23. The Board Secretary can provide advice on this matter and in addition, guidance on reporting Declaration of Interests can be found at [SO9.1 of the Standing Orders and Standards of Business Conduct](#). A template for the Declaration of Interest can be found [here](#).

Reporting

24. The Committee will report in writing to the Board and CEO/Accounting Officer after each meeting.
25. The Committee will provide the Board and CEO/Accounting Officer with an Annual Report in July each year, timed to support finalisation of the accounts and the Governance Statement, summarising its conclusion from the work it has done during the year.

Terms of Reference Review

26. The Committee Terms of Reference will be reviewed as a minimum on an annual basis.



**In the High Court of Justice
Queen's Bench Division
Administrative Court**

CO Ref: CO/2936/2017

In the matter of an application for Judicial Review

The Queen on the application of THE ASSOCIATION OF THE BRITISH
PHARMACEUTICAL INDUSTRY

versus

THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

interested parties

- (1) THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD
- (2) SECRETARY OF STATE FOR HEALTH

**Application for permission to apply for Judicial Review
NOTIFICATION of the Judge's decision (CPR Part 54.11, 54.12)**

Following consideration of the documents lodged by the Claimant and the
Acknowledgement of service filed by the Defendant and Interested Party

Order by the Honourable Mrs Justice Elisabeth Laing DBE

Permission is hereby refused.

Reasons:

1. The Claimant challenges three decisions made by the Defendant on March 15 2017, after consulting relevant bodies (between October 2016 and January 2017), including the Claimant. The Defendant is a statutory body. Its functions are described in the National Institute for Health Care and Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 ('the 2013 Regulations'). The decisions took effect on 1 April 2017. The Defendant has published three documents based on the decisions, and had, at the date of its summary grounds, assessed nine submissions under the framework established by the decisions.
2. One of the Defendant's functions is to appraise the benefits and costs of a health technology. If it makes a positive recommendation about such a technology, then after a date specified in the recommendation by the Defendant, relevant health bodies must fund that technology (see regulations 7 and 8 of the 2013 regulations read with the definitions in regulation 1).
3. The challenged decisions were
 - a. to introduce, from 1 April 2017, a budget impact threshold ('BIT') when, after an appraisal, it makes a positive recommendation about a health technology ('a TAR') or about a highly specialised technology ('HSTR') and

- b. to change the way it assesses how cost-effective HSTs are (the Claimant refers to this as the 'QALY Cap decision').

4. The Claimant argues that

- a. the BIT decisions
 - i. are ultra vires regulations 7 and 8 of the 2013 regulations and/or
 - ii. are flawed because the consultation preceding them was deficient (it is said that consultees were not given enough information to enable them to consider, and respond to, the Defendant's proposals), and
- b. the QALY Cap decision
 - i. is a reversal of the Defendant's previous policy and that change is unexplained, unjustified and arbitrary, so that that decision is irrational, or inadequate reasons have been given for it, and/or
 - ii. was made in breach of the duty imposed by section 149 of the Equality Act 2010 ('the 2010 Act') and/or
 - iii. was preceded by an unlawful consultation.

The BIT decisions

(1) Vires

5. In sum, the vires argument is that relevant words in regulations 7 and 8 of the 2013 regulations (which are in material respects the same) distinguish between money and 'logistics', and that the Defendant can only exercise its power to lengthen the period after which relevant health bodies must comply with a recommendation if it has a 'logistical' justification for doing so. It is said that the Defendant cannot, as it has decided it will do in the future, exercise that power for financial reasons alone.
6. This argument depends on reading the phrase 'other appropriate health service resources include staff' as excluding money. I do not consider that this is an arguable interpretation of that phrase, for two reasons. First, 'resources' is almost invariably used in the public sector (and elsewhere) to mean 'money'. Second, it is difficult to see, given the structure of regulations 7(5) and 8(5), what 'resources' means if it does not mean 'money'.
7. That approach is supported by the distinct argument relied on by the first interested party, NHS England. This draws on the transitional provisions in the 2013 regulations which reflect the language of the 1999 Direction which governed the Defendant before the enactment of the Health and Social Care Act 2012. NHS England argues, with some force, that if the relevant phrase in regulations 7 and 8 does not include 'money' that would represent a significant departure from the way in which the word 'resources' had previously been understood in the context of the Defendant's functions. But there is no sign in the

drafting of the 2013 regulations of any intention to depart from the previous use of 'resources'.

8. I consider that its phrase is not arguably ambiguous. But it were, I would consider that the Claimant's reading produces an absurd result, which is that, having appraised the costs and benefits of a health technology, and having decided to make a positive recommendation about it, the Defendant would be obliged to make a positive recommendation, which would take effect within three months, and which would require relevant health bodies to fund the technology, even if the Defendant knew that the relevant health bodies would not have the money to fund the technology by the end of that period.
9. I do not consider that the word 'administered' or the phrase 'in place' arguably detract from these points. They are not exclusively concrete in meaning, and do not only mean giving a treatment to a patient.

(2) Consultation

10. Nor do I consider it arguable that the consultation about the BIT decision was defective. The Claimant did not, in its thorough and considered response to the consultation, indicate that it did not understand what the Defendant was proposing, or that it needed more information to respond, nor did it make the points now made in the Claimant's grounds. The criticisms in the grounds address points of detail, rather than the proposed new approach, on which the Defendant did consult.

The QALY Cap decisions

(1) Irrationality/lack of reasons

11. It is not arguable, for the reasons given in NHS England's summary grounds, that the QALY Cap decision is a wholesale reversal of the Defendant's previous policy. It is clear both that the Defendant has not replaced a humane and balanced approach with a narrow utilitarian calculation, and that the new way of making an HSTR is not the same as that for making a TAR. In any event, the Defendant is an expert body. Deciding how to assess, and assessing, the costs and benefits of treatments inherently involves the exercise of difficult technical and moral judgments, and the Defendant necessarily has a wide discretion at both stages. I do not consider that the new approach is arguably irrational.
12. Nor do I consider that it is arguably flawed by a failure to give reasons. It is adequately explained. For the reasons given in both sets of summary grounds, no EU obligation to give reasons is arguably engaged.

(2) Section 149 of the 2010 Act

13. The duty imposed by section 149 is a duty to give 'due regard' to the listed statutory needs. It is not a duty to achieve a result, or to have regard to remote possibilities. Rather, it is a

duty to have due regard to the equality needs most obviously engaged by the decision in question. The Defendant specifically consulted on the equality impacts of the decisions, and had regard to the consultation responses in making the decisions. In those circumstances, given the high-level nature of the decisions and the continuing nature of the duty, I do not consider that the Defendant arguably failed to have due regard to any of the listed equality needs in making the decisions.

(3) *Consultation*

14. Again, the Claimant was able to, and did, respond to the consultation on this proposal. It did not ask for more information, or complain that it was not able to make an intelligent response. For the reasons given in the summary grounds, the detailed various criticisms of the consultation are not arguable.

Promptness

15. The claim was lodged right at the end of the three-month period for making an application for judicial review. The Claimant's account of what happened in that time is vague '...its decision-making procedures ...can reasonably be expected to be somewhat more involved and lengthy than those of an individual business'.

16. Time taken to comply with the pre-action protocol is not a satisfactory excuse for delay; in any event, the pre-action protocol letter was not sent until over two months after the decisions were made. Had I considered the claim arguable, I might well have refused permission on the grounds of delay. If the application for permission to apply for judicial review is to be renewed, the Claimant would be well advised to provide a fuller explanation for the time it took to lodge the claim.

- The costs of preparing the acknowledgment of service are to be paid by the claimant to the defendant, in the sum of £ 14000. The costs of preparing the acknowledgment of service are to be paid by the claimant to the first interested party, in the sum of £ 7000. This is a final order as to costs unless within 14 days the claimant notifies the court and the defendant, in writing, that he objects to paying costs, or objects to the amount now ordered to be paid, in either case giving reasons. If he does so, the defendant has a further 14 days to respond to both the court and the claimant, and the claimant the right to reply within a further 7 days, after which the defendant's claim for costs and any submissions in relation to it will be put before a judge to be determined on the papers, or at a hearing to reconsider the application for permission.



~~• A renewed application is no bar to removal in the absence of a further order~~

- Where the claimant seeks a reconsideration of the application for permission the above order now made as to costs will be final unless the Claimant files the written representations referred to above or further order is made by the Court either at a permission hearing or as a consequence of the parties settling the claim and reaching agreement as to costs.



Signed

Mrs Justice Elisabeth Laing

The date of service of this order is calculated from the date in the section below

Sent / Handed to the claimant, defendant and any interested party / the claimant's, defendant's, and any interested party's solicitors on (date): 04/10/2017
Solicitors: Arnold & porter (UK) LLP
Ref No.

Notes for the Claimant

If you request the decision to be reconsidered at a hearing in open court under CPR 54.12, you must complete and serve the enclosed FORM (86B) within 7 days of the service of this order. A fee is payable on submission of Form 86B. **For details of the current fee please refer to the Administrative Court fees table at <https://www.gov.uk/court-fees-what-they-are>**. Failure to pay the fee or submit a certified application for fee remission may result in the claim being struck out. The form to make an application for remission of a court fee can be obtained from the Justice website <https://www.gov.uk/get-help-with-court-fees>



**In the High Court of Justice
Queen's Bench Division
Administrative Court**

CO Ref no: CO/2936/2017

In the matter of a claim for Judicial Review

The Queen on the application of

**ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY
(ABPI)**

**versus NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Notice of RENEWAL of claim for permission to apply for Judicial Review (C P R 54. 12)

- 1. This notice must be lodged in the Administrative Court Office, by post or in person and be served upon the defendant (and interested parties who were served with the claim form) within 7 days of the service on the claimant or his solicitor of the notice that the claim for permission has been refused.*
- 2. If the claim was issued on or after 7 October 2013, a fee is payable on submission of Form 86B. Failure to pay the fee or lodge a certified Application for Fee remission may result in the claim being struck out. The form for Application for Remission of a Fee is obtainable from the Justice website <http://hmctsformfinder.justice.gov.uk/HMCTS/FormFinder.do>*
- 3. If this form has not been lodged within 7 days of service (para 1 above) please set out below the reasons for delay:*

- 4. Set out below the grounds for seeking reconsideration:*

5. Please supply

COUNSEL'S NAME:

COUNSEL TELEPHONE NUMBER:

Signed

Dated

Claimant's Ref No.

Tel.No.

Fax No.

To the Administrative Court Office, Royal Courts of Justice, Strand, London, WC2A 2LL
