



Bristol Clinical Commissioning Group

Agenda Item No. 7(b)

Bristol Health & Wellbeing Board

Pharmaceutical Needs Assessment: process for acting on new information

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Report for Action

1. Purpose of this Paper

This paper for decision proposes a system whereby the Health and Wellbeing Board (HWB) will meet requirements to receive and act upon information from NHS England on changes to pharmaceutical services.

2. Executive Summary

The HWB needs a system to decide whether changes in local pharmaceutical services should lead to publication of a new Pharmaceutical Needs Assessment (PNA) or issue of a supplementary statement to the current PNA.

A robust system is needed to ensure that NHS England Area Team decisions on new applications to provide pharmaceutical services can be made with reference to a sufficiently accurate assessment of how local needs are being met. This is necessary to reduce the risk of legal challenge to NHS England and the HWB.

This paper proposes that the HWB delegates authority to a senior officer to assess information on changes in services on its behalf. Notifications will be received by the delegated officer from NHS England via the Democratic Services Team's In-box. The officer will be responsible for deciding proportionate responses to notifications of service changes.

To assure the quality of decision-making, it is proposed that the delegated officer participates in annual audit with counterparts in neighbouring authorities.

3. Context

The Health and Social Care Act 2012 transferred responsibility for the developing and updating of PNAs to HWBs. The NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 set out the legislative basis for developing and updating PNAs (¹, Appendix 1).

Responsibility for using PNAs as the basis for determining market entry to a pharmaceutical list transferred from PCTs to NHS England from 1 April 2013. There are five types of market entry application (known as routine applications):

- current need
- future need
- improvements or better access
- future improvements or better access; and
- unforeseen benefits (where the applicant provides evidence of a need that was not foreseen when the PNA was published).

HWBs are required to produce their first PNA by 1 April 2015 and to publish a revised assessment within three years of publication of their first assessment. Furthermore, HWBs will be required to publish a revised assessment as soon as is reasonably practical after identifying significant changes to the availability of pharmaceutical services since the publication of its PNA, unless it is satisfied that making a revised assessment would be a disproportionate response to those changes. If revision of the PNA is judged disproportionate, the HWB may decide to issue a supplementary statement to the current PNA.

3. Proposed system for receiving and acting upon notifications of changes in pharmaceutical services

Under the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations (“the 2013 Regulations”), a person who wishes to provide NHS pharmaceutical services must generally apply to NHS England to be included on a relevant list by proving that they are able to meet a pharmaceutical need as set out in the relevant PNA. There are exceptions to this, such as applications for needs not foreseen in the PNA or to provide pharmaceutical services on a distance-selling (internet or mail order only) basis.

The flowchart provided in appendix 2 sets out the process whereby the NHS England Area Team receives and considers applications and notifications of changes by providers of pharmaceutical services. The diagram shows that NHS England may notify the HWB:

¹ For further information see <http://www.dh.gov.uk/health/2013/02/pharmaceutical-services-regulations/>.

- Immediately, for changes that might be significant to meeting needs eg notification of an opening or of closure of a local community pharmacy; major changes in opening hours.
- Routinely, by providing updated lists of changes unlikely to be significant eg move of premises only a short distance from those currently occupied; minor adjustments to opening hours.

To ensure that there is a robust system for receiving and acting on these notifications, it is proposed that:

- Notifications are sent by NHS England to Bristol City Council's Democratic Services Team's In-box;
- The Democratic Services Officer responds by passing the notification to the officer with responsibility (delegated by HWB) for assessing the notifications;
- The officer with delegated responsibility will review each change to determine whether it will impact on how local needs are met – and on how future applications should therefore be considered.

Where the officer judges that the changes do not have a significant impact on availability of services and are not relevant to the consideration of future applications, it will be sufficient to include information on the changes in the PNA when next revised.

Where the officer judges that service availability is affected and that consideration of future applications will need to take this into account, then a decision will be needed on whether to immediately revise the PNA in full or to publish a supplementary statement to the current PNA, explaining the changes. The officer will need to choose a proportionate response taking account of the scale of the change that has been notified.

- To assure the quality of decision-making, it is proposed that the delegated officer participates in annual audit with counterparts in neighbouring authorities. This would complement periodic reporting to HWB on the delegated duty.

4. Key risks

If the PNA is not sufficiently up to date, NHS England will be unable to use it as a reliable source of information on how well needs are met and the case for changes in service provision in localities. NHS England and the HWB may be subject to legal challenge, by an applicant whose application has been turned down on the basis of a PNA that no longer provides an accurate assessment of needs and how they are met.

Production of the PNA to meet the precise requirements of the Regulations is a significant undertaking. The timeline for production of the 2015 Bristol PNA is approximately 15 months.

It is therefore important that the HWB adopts a reliable system for receiving and acting on notifications of changes and that careful judgement is exercised with respect to proportionate responses. Mitigation of the above risks can include:

- Robust system for ensuring applications are received and processed within the Council;
- Delegation to a named senior officer, with authority to assess and decide action on each notification.
- Participation in annual audit with counterparts in neighbouring authorities.

6. Financial and legal implications

As noted above, if the PNA is not sufficiently up to date, NHS England and the HWB may be subject to legal challenge, by an applicant whose application has been turned down on the basis of a PNA that no longer provides an accurate assessment of needs.

No financial implications have been identified for setting up and running the proposed system for receiving and making decisions on notification of changes. Notifications of changes from NHS England have been received less than quarterly since April 2013. Changes notified to-date have been minor and accommodated in the drafting of the 2015 Bristol PNA. Based on experience to-date, the hours of officer time that might be needed to fulfil the delegated role for HWB would be of the order of up to 2 working days per annum.

The issue of a supplementary statement to a current PNA is expected to be accommodated within existing resources for updating the HWB webpage. Producing updated maps of services providers is expected to be feasible through partnership working within the HWB, as has been the case in producing the current PNA.

In the event of it being decided that rewriting of the PNA is needed, significant resources would be needed. This would in effect bring forward work that will be needed to publish the next Bristol PNA, due for publication by April 2018.

7. Conclusions

The HWB must agree a process for receiving and acting on new information relating to the Bristol PNA. It is proposed that the HWB delegates this responsibility to an officer and that a secure process for receiving and acting

upon information is implemented. In keeping with the arrangements for PNA production to date, it is proposed that responsibility is delegated to the DPH.

No new resources are requested to implement the system of delegation and publication of supplementary statements to the PNA.

8. Recommendations

It is recommended that:

The HWB delegates to a lead officer responsibility for receiving and acting upon new information relating to the PNA.

9. Acknowledgement: this paper draws on information from 'Pharmaceutical needs assessments. Information Pack for local authority Health and Wellbeing Boards' (Dept of Health 2012)

Appendix 1

**Extract from 'The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
2013 No. 349 PART 2 Regulation 6'**

Subsequent assessments

6.

- (1) After it has published its first pharmaceutical needs assessment, each HWB must publish a statement of its revised assessment within 3 years of its previous publication of a pharmaceutical needs assessment.
- (2) A HWB must make a revised assessment as soon as is reasonably practicable after identifying changes since the previous assessment, which are of a significant extent, to the need for pharmaceutical services in its area, having regard in particular to changes to—
 - (a) the number of people in its area who require pharmaceutical services; .
 - (b) the demography of its area; and .
 - (c) the risks to the health or well-being of people in its area, .

unless it is satisfied that making a revised assessment would be a disproportionate response to those changes.

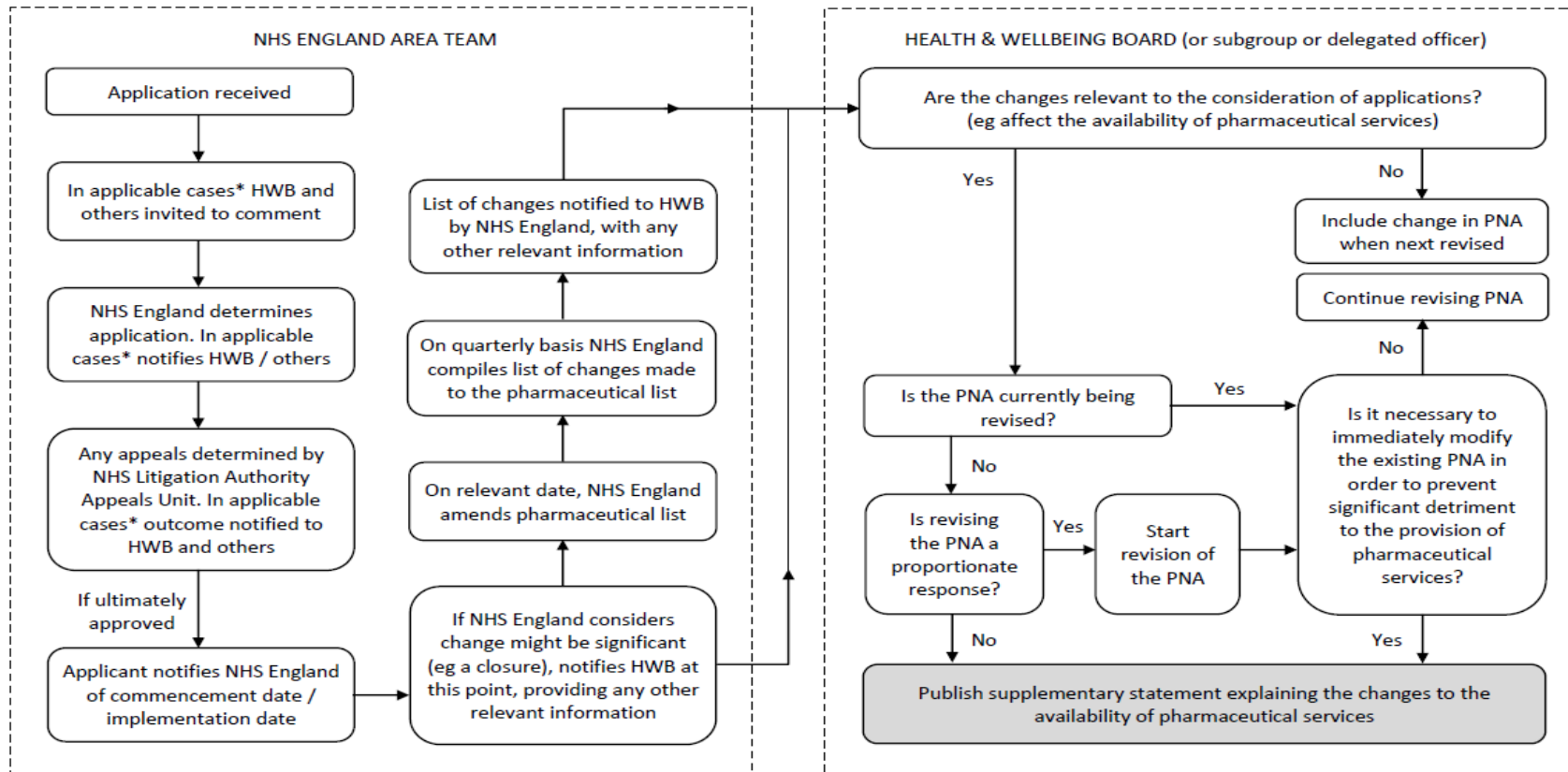
- (3) Pending the publication of a statement of a revised assessment, a HWB may publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of its or a Primary Care Trust's pharmaceutical needs assessment (and any such supplementary statement becomes part of that assessment), where -
 - (a) the changes are relevant to the granting of applications referred to in section 129(2)(c)(i) or (ii) of the 2006 Act; and
 - (b) the HWB -
 - (i) is satisfied that making its first or a revised assessment would be a disproportionate response to those changes, or .
 - (ii) is in the course of making its first or a revised assessment and is satisfied that immediate modification of its pharmaceutical needs assessment is essential in order to prevent significant detriment to the provision of pharmaceutical services in its area.

Appendix 2

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NHS ENGLAND – BNSSSG AREA TEAM

PROCESS FOR NOTIFICATION OF CHANGES TO THE PHARMACEUTICAL LIST AND ISSUE OF SUPPLEMENTARY STATEMENTS TO PHARMACEUTICAL NEEDS ASSESSMENTS



* Applicable cases are notifiable routine or excepted applications. Applications to change opening hours are not notifiable.

H&WB part of flowchart based on flowchart in *Revising PNAs and Supplementary Statements, Primary Care Commissioning, October 2012*