

Report to: East Sussex Health and Wellbeing Board

Date: 23 July 2013

By: Cynthia Lyons, Acting Director of Public Health

Title of report: Health and Wellbeing Board Responsibility for Pharmaceutical Needs Assessment

Purpose of report: To outline the requirements and implications of the Health and Wellbeing Board's responsibility for Pharmaceutical Needs Assessment, update on actions undertaken by the Public Health Department on behalf of the Board and to seek approval for a process for considering pharmacy applications on behalf of the Board.

RECOMMENDATIONS

The Health and Wellbeing Board is recommended to:

- 1. Note that from 1 April 2013 the Board assumed responsibility for the Pharmaceutical Needs Assessments published by the East Sussex Downs and Weald and Hastings and Rother Primary Care Trusts and that it has to publish it's first Pharmaceutical Needs Assessment by April 2015.**
- 2. Note the ESCC Public Health Department has assessed the inherited Pharmaceutical Needs Assessments on behalf of the Board and concluded that they are fit for purpose.**
- 3. Note that due to the long planning cycle for production and because of the risks is to the Board, work on a developing a new Pharmaceutical Needs Assessment will begin now and expected to be concluded by July 2014.**
- 4. Approve the Public Health Department process for considering pharmacy applications within the 45 day prescribed time period and making a written representation as necessary on behalf of the Board.**

1. Background

1.1 If a person (a pharmacist, a dispenser of appliances, or in some circumstances and normally in rural areas, a GP) wants to provide NHS pharmaceutical services, they are required to apply to the NHS to be included on a pharmaceutical list. Pharmaceutical lists are compiled and held by NHS England. This is commonly known as the NHS 'market entry' system.

1.2 Under the NHS (Pharmaceutical 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 in the relevant list by proving they are able to meet a pharmaceutical need as set out in the relevant Pharmaceutical Needs Assessment (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.

1.3 'Pharmaceutical services' in relation to PNAs include:

- 'essential services' which every community pharmacy providing NHS pharmaceutical services must provide and is set out in their terms of service – dispensing, repeat dispensing, support for self care, signposting, clinical governance, public health and the disposal of unwanted medication
- 'advanced services' are services community pharmacy contractors and dispensing appliance contractors can provide subject to accreditation as necessary – these are

Medicines Use Reviews and new Medicines Services for community pharmacists and the Stoma Customisation Service for dispensing appliances contractors;

- 'locally commissioned services' are known as enhanced services commissioned by NHS England such as anti-coagulation monitoring, the provision of advice and support to residents and staff in care homes in connection with drugs and appliances, on demand availability of specialist drugs, and out-of-hours services.

1.4 It is important that PNAs comply with all the requirements of the regulations, follow due process in their development and are kept up-to-date.

1.5 PNAs were published by primary care trusts (PCTs) but on 1 April 2013, Health and Wellbeing Boards (HWB) assumed responsibility for these and the 2013 Regulations require each HWB to make a revised assessment as soon as is reasonably practicable after identifying changes to the need for pharmaceutical services which are of a significant extent and to publish its first PNA by 1 April 2015.

2. Duties on the East Sussex Health and Wellbeing Board

2.1 On 1 April 2013, the East Sussex HWB became responsible for the PNAs produced by East Sussex Downs and Weald and Hastings and Rother PCT. It is required by the regulations to publish a revised assessment where it identifies changes to the need for pharmaceutical services 'which are of a significant extent'. The only exception is where the East Sussex HWB is satisfied that making a revised assessment would be a disproportionate response.

2.2 On behalf of the HWB the ESCC Public Health Department has assessed the inherited PCT PNAs. It has reviewed how well the PNAs and supplementary statements published in February 2011 and March 2013 on the Joint Strategic Needs Assessment website (www.eastsussexjsna.org.uk) meet the regulations. A red, amber, green (RAG) rating tool based on the PNA requirements was used in assessing the fitness for purpose of the two PNAs. Each PNA was assessed as having the same singular 'red' rating in relation to the maps within the PNAs not having been updated to reflect changes in pharmaceutical service provision. However, the supplementary statements published alongside the PNAs in March 2013 highlight the changes in pharmaceutical service provision and mitigate against the red rating. The supplementary statements indicate that pharmaceutical service provision has not been affected by the one closure in the East Sussex Downs and Weald PCT area and that generally coverage is better following licensing of eleven more providers since the PNA was published. Based on this assessment, it is concluded that the existing PNAs and supplementary statements explaining changes are fit for purpose and that there are no changes which are of a significant extent.

2.3 The HWB must publish its first PNA by 1 April 2015 and although the assessment of the inherited PNAs has concluded that the PNAs and supplementary statements are fit for purpose, because of the timescales associated with the production of a new PNA and of the risks to the HWB, work on developing a new PNA will begin now.

2.4 Although the HWB does not have to publish its first PNA until April 2015, the planning cycle for production of the PNA is very long and is likely to take a year, there is a statutory requirement for a minimum 60 day period of public consultation and the PNA requires board-level sign-off.

2.5 Failure to comply with the regulatory duties and to produce a robust PNA as detailed in the 2013 Regulations could lead to legal challenges because of the PNAs relevance to decisions about commissioning services and new pharmacy openings, for example where a party believes that they have been disadvantaged following the refusal by NHS England of their application to open new premises.

2.6 For these reasons, work on developing a new East Sussex PNA will begin now and it is expected to be concluded by July 2014. Following this, the HWB will be required to publish a revised assessment within three years of publication of this first assessment (so by July 2017). The HWB will be required to publish a revised assessment as soon as 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 revision assessment would be a disproportionate response to those changes.

3. Notification of Pharmacy Applications to the HWB

3.1 Upon receiving a pharmacy application the Local Area Team of NHS England notifies interested parties of the application and since April 2013 HWBs are included as an interested party. The Local Area Team invites interested parties to make written representation within 45 days on the applications should they wish. It then considers all representations and arranges an oral hearing to determine the application if it identifies a matter on which it wishes to hear further evidence.

3.2 Since April, the HWB has been informed of 4 pharmacy applications to which the H&WB can make written representation on the applications to the Surrey and Sussex Area Team of NHS England. On behalf of the HWB, the ESCC Public Health Department has considered these applications against the inherited PNAs and has judged that a written representation has not been necessary as the application meets a pharmaceutical need as set out in the PNA or it is not appropriate to make a written representation, for example as it relates to a distant selling service. Approval is sought that the Public Health Department continue with this process on behalf of the Board.

4. Conclusion and reasons for recommendations

4.1 The HWB assumed responsibility for the PNA on 1 April 2013. The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 effective from then requires the HWB to publish a revised assessment where it identifies changes to the need for pharmaceutical services 'which are of a significant extent' and to publish its first PNA by 1 April 2015. Failure to comply with the regulatory duties and to produce a robust PNA as detailed in the 2013 Regulations could lead to legal challenges.

4.2 This paper outlines the requirements and implications of the Health and Wellbeing Board's responsibility for the PNA, updates on actions undertaken by the Public Health Department on behalf of the Board and seeks approval for a process for considering pharmacy applications on behalf of the Board.

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