

HEALTH AND WELLBEING BOARD			
<b>Report Title</b>	The role and responsibility of the Health and Wellbeing Board for Pharmaceutical Needs Assessments		
<b>Contributors</b>	Dr Danny Ruta, Director of Public Health	Item No.	8
<b>Class</b>	Part 1	Date:19.09.13	

## 1. Purpose

- 1.1 This report outlines the requirements and responsibilities of the Health and Wellbeing Board's (HWB) for maintaining and publishing a Pharmaceutical Needs Assessment (PNA).
- 1.2 The report provides an update on the actions undertaken to date by the Council's Public Health Unit and sets out a proposed process for updating the existing PNA and for developing a plan to ensure that a revised PNA is presented for approval by the Health and Wellbeing Board before April 2015.
- 1.3 The report also proposes that the Director of Public Health is given responsibility for considering and commenting on any local pharmacy applications within the statutory consultation period.

## 2. Recommendations

Members of the Health and Wellbeing Board are recommended to:

- 2.1 Note that from 1 April 2013 the Health and Wellbeing Board assumed responsibility for the existing Pharmaceutical Needs Assessment - previously published by Lewisham Primary Care Trust - and that the Board must publish its own Pharmaceutical Needs Assessment by April 2015.
- 2.2 Note that, in 2012, NHS South East London assessed the inherited Pharmaceutical Needs Assessment and supplementary statements and concluded that the current Pharmaceutical Needs Assessment and the four supplementary statements are fit for purpose.
- 2.3 As set out in paragraph 7.1 below, note that a working group will be set up to review and identify any changes needed in local pharmaceutical services and undertake the preparation of a revised PNA which will be presented for approval to the Health and Wellbeing Board in Autumn 2014.
- 2.4 Approve the proposed process for preparing any necessary supplementary statements to ensure the current PNA remains fit for purpose.

- 2.5 Agree that the Public Health Director be given responsibility to consider any forthcoming pharmacy applications within the 45 day prescribed time period and to make any written representations as necessary on behalf of the Board.

### **3. Policy Context**

- 3.1 The activity of the Health and Wellbeing Board is focused on delivering the strategic vision for Lewisham as established in *Shaping our future – Lewisham's Sustainable Community Strategy* and in Lewisham's *Health and Wellbeing Strategy*.
- 3.2 The work of the Board directly contributes to *Shaping our future*'s priority outcome that communities in Lewisham should be *Healthy, active and enjoyable - where people can actively participate in maintaining and improving their health and wellbeing*.
- 3.3 The NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 set out the legislative basis and the full requirements of the Health and Wellbeing Board for developing and updating the Pharmaceutical Needs Assessment (PNA) together with the responsibility of the NHS Commissioning Board (now NHS England) in relation to market entry.

### **4. Background - Overview of Regulatory Framework**

- 4.1 The provision of NHS Pharmaceutical Services is a controlled market. 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. Since April 2013 Pharmaceutical lists are compiled and held by NHS England. This regulation of pharmacy sites is commonly known as the NHS 'control of entry' system.
- 4.2 The NHS (Pharmaceutical Services and Local Pharmaceutical Services) (amendment) Regulations 2010 placed each Primary Care Trust (PCT) under a duty to prepare and publish a PNA by 1st February 2011. The PCT was also required to publish any necessary supplementary statements to ensure that the PNA remained fit for purpose. This requirement of publishing a PNA was a prelude to major changes in the control of entry arrangements for community pharmacies.
- 4.3 In September 2012, the NHS (Pharmaceutical Services) Regulations 2012 came in to effect. These regulations replaced the previous control of entry system with a new system of market entry control, where applications to open new pharmacies, move existing premises or change hours or provide additional pharmaceutical services must be considered, by the PCT (now NHS England), against the PNA for the area in which the application is made.
- 4.4 The Health and Social Care Act 2012 transferred the statutory responsibility for the development and updating of the Pharmaceutical Needs Assessment

to Health and Wellbeing Boards (and the determination of applications to the National Commissioning Board – now NHS England).

- 4.6 Thus under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulation 2013 (the 2013 Regulations) a person who wishes to provide NHS pharmaceutical services must now apply to NHS England to be included in the relevant list by proving they are able to meet (fill a gap in) a pharmaceutical need as set out in the relevant Pharmaceutical Needs Assessment (PNA). There are two exceptions to this, one for services provided only by distant selling (internet or mail – order only) basis; the second is an application for needs not foreseen in the PNA.
- 4.7 NHS England must maintain up to date lists of persons within an area offering a pharmaceutical service. NHS England must consult, giving 45 days for a response, the relevant Health and Wellbeing Board when an application for a new pharmacy or change to existing pharmacy is received within 2km of the area served by a Health and Wellbeing Board.
- 4.8 Pharmaceutical Services covered by the Pharmaceutical Needs Assessment are those services listed within the NHS (Pharmaceutical Services) Regulations 2013.  
[The NHS \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013](#)

## **5. Responsibilities of Health and Wellbeing Boards**

In summary, the Health and Wellbeing Board responsibilities are to:

### 5.1. Publish its first PNA by 1 April 2015

The Regulations set out the minimum information which must be included within the PNA: the matters which must be considered when making the assessment: and the process to be followed (including formal consultation with specific stakeholders for a minimum of 60 days) in preparation of the PNA.

In the interim period, the PNA published by a Health and Wellbeing Board's former PCT(s) will be used, by NHS England, to inform market entry decisions.

### 5.2. Maintain and keep up-to-date the PNA

In response to changes in the availability of pharmaceutical services, there is a requirement for the Health and Wellbeing Board to determine whether or not it needs to revise the PNA or, where this is thought to be a disproportionate response, to issue a supplementary statement setting out the change(s). As a minimum, a new PNA must be published every 3 years. In addition, the Health and Wellbeing Board is required to keep up-to-date a map of provision of NHS Pharmaceutical Services within its area.

### 5.3. Consultation by a neighbouring Health and Wellbeing Board

- 5.4 The Regulations require that, when consulted by a neighbouring Health and Wellbeing Board on a draft of their PNA, the Health and Wellbeing Board must consult with the Local Pharmaceutical Committee (LPC) and Local Medical Committee (LMC) for its area (unless the areas are served by the same LPC and/or LMC) and have regard for the representations from these committee(s) before making its own response to the consultation.

## **6. Current Position for Lewisham**

- 6.1 The Lewisham Health and Wellbeing Board has assumed responsibility for the PNA originally approved by Lewisham PCT (and with it 4 additional statements). The NHS Lewisham PNA 2011 is accessible on:  
<http://www.lewisham.gov.uk/myservices/socialcare/health/Pages/Pharmaceutical-Needs-Assessment.aspx>
- 6.2 A high level review of the PNA was commissioned by NHS South East London in 2012 for all its constituent PCTs. The purpose of the review was to ensure that each PNA was fit for purpose to inform market entry decisions and for subsequent transfer to the relevant Health and Wellbeing Board.
- 6.3 The review identified that Lewisham PCT's PNA either met or partially met all but two of the requirements set out in the 2010 Regulations (the Regulations prevailing at the time the document was written). One of the non-compliant areas (defining localities) has been resolved (to being met) by the preparation of a (clarifying) additional supplementary statement (supplementary statement 4). The second area is related to "benefits of reasonable choice" which was not explicitly addressed in the PNA. Recent guidance has outlined that a PNA should be explicit in defining benefits to the population (or part of the population), and as far as is reasonable when, for example the closure or relocation of a pharmacy would change significantly the availability of the service. The issue will be addressed in the H&WB PNA. The PNA was then assessed by NHS South East London as being a low risk in relation to potential complaints and/or judicial review in relation to market entry decisions made against future pharmacy applications. The review provides assurance to the Health and Wellbeing Board that it is not necessary to update the inherited PNA because of failure to comply with Regulations.

## **7. Process and Timetable for the Development of a new PNA**

- 7.1 Although the Health and Wellbeing Board does not have to publish its first PNA until 1 April 2015 and the assessment of the inherited PNA has concluded that the PNA with its supplementary statements is fit for purpose, a work group, chaired by the Director of Public Health, will be formed by end September 2013 to ensure the timetable for producing a new PNA can be met.
- 7.2 The group will be supported with pharmaceutical advice provided from NHS Lewisham Clinical Commissioning Group and input as necessary from NHS England.

- 7.3 The group will create a timetable to:
- Assess current pharmaceutical services; updating the current information as necessary and preparing any supplementary statement.
  - Use the updated assessment of current services, with relevant information in the JSNA and the local strategic directions for the health and wellbeing of the Lewisham population to develop a new Pharmaceutical Needs Assessment.
- 7.4 Once prepared, the new PNA will be circulated for consultation as outlined in the Regulations. A final version will be presented for consideration of approval at the Health and Wellbeing Board in autumn 2014.

## **8. Supplementary Statements and PNAs of Neighbouring Boroughs**

- 8.1 In relation to the Health and Wellbeing Board's responsibilities as set out in 5(b) and 5(c) above, it is proposed that the Health and Wellbeing Board delegate to the Director of Public Health responsibility to:
- Approve supplementary statements which ensure that the current PNA remains fit for purpose;
  - Respond to any consultations on PNAs being developed by neighbouring Health and Wellbeing Boards; and
  - Respond, as necessary, on any consultations received from NHS England on changes to existing pharmacies or application for new pharmacies within the Borough and within 2 km of the borough boundary.
- 8.2 The Director of Public Health will ensure that significant risks and/or issues are escalated to the Health and Wellbeing Board, as appropriate, and will, in Autumn 2014, submit with the new PNA a summary report of any actions that were undertaken.

## **9. Financial implications**

- 9.1 The development work to produce the new PNA the administration, any management time required to ensure that the PNA remains fit for purpose and the production of any additional statements will all be undertaken within existing Public Health budgets.
- 9.2 The financial implications of any changes to services proposed as a result of the needs assessment will be considered in future reports.

## **10. Legal implications**

- 10.1 As highlighted in the body of this report, the Health and Wellbeing Board has a number of statutory duties and responsibilities in relation to PNAs. Failure to comply with the regulatory duties and to produce a robust PNA following the 2013 Regulations could lead to legal challenges because of the PNA

relevance to decisions about issues such as the opening of new pharmacies, the commissioning of (pharmaceutical) services etc. For example a party may believe that they have been disadvantaged following a decision made by NHS England based on the information within the PNA and may consider challenging the process ( if not robust) of preparation, consultation and approval of the PNA.

- 10.2 Members of the Board are reminded that under Section 195 Health and Social Care Act 2012, health and wellbeing boards are under a duty to encourage integrated working between the persons who arrange for health and social care services in the area.

## **11. Crime and Disorder Implications**

There are no specific implications arising from this report.

## **12. Equalities Implications**

- 12.1 The Regulations require Health and Wellbeing Board to have regard (in so far as is practicable) to the outcome of its assessment of compliance with its duties under Chapter 1 of Part 11 of the Equality Act 2010(a) specifically in relation to the protected characteristics.
- 12.2 The assessment undertaken by NHS South East London assessed the current PNA as partially meeting these specific areas.
- 12.3 The PNA to be presented in Autumn 2014 will have regard ( as far as is practicable) to being fully compliant with duties under Chapter 1 of Part 11 of the Equality Act 2010.

## **13. Environmental Implications**

There are no specific implications arising from this report.

## **14. Conclusion**

- 14.1 The Health and Wellbeing Board assumed responsibility for the PNA on the 1 April 2013. The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 - effective from 1 April 2013 - requires the Health and Wellbeing Board 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.
- 14.2 This report outlines the requirement and responsibility of the Health and Wellbeing Board's to maintain and produce a PNA, and outlines the actions to be undertaken on behalf of the Health and Wellbeing Board by the Director of

Public Health, both in relation to maintaining the existing PNA and in preparing a new PNA by Autumn 2014.

## Background Documents

[Lewisham PNA and 4 supplementary statements](#)

[The Lewisham Heat map assessment](#)

[The NHS \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013](#)

If there are any queries on this report please contact Danny Ruta, Director of Public Health on 020 8314 9094