

## AGENDA ITEM

### REPORT TO HEALTH AND WELL BEING BOARD

12 FEBRUARY 2014

### REPORT OF DIRECTOR OF PUBLIC HEALTH

## PHARMACEUTICAL NEEDS ASSESSMENT

### SUMMARY

This briefing is provided to update the Board on statutory duties, responsibilities and actions regarding the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations<sup>1</sup> 2013 SI 2013/349 and Pharmaceutical Needs Assessments (PNA).

### RECOMMENDATIONS

1. The Stockton Health and Wellbeing Board is asked to acknowledge the content of the Report including the outline plan and timetable towards publication of the first PNA of the Hartlepool HWB, commencing immediately.

2. It is further recommended that

- a Statement (or a link to a Statement) reporting this will thereafter be available on the HWB website as follows:

*“Stockton on Tees Health and Wellbeing Board understands its statutory duties in relation to Pharmaceutical Needs Assessment and intends to publish its own first PNA within the required timeframe. The HWB acknowledges that the PNA inherited from their respective PCT was, according to the Regulations in place at the time, intended to ‘expire’ in Feb 2014. Notwithstanding any changes to pharmaceutical services and related NHS services that have taken place since first publication, and without prejudice to the assessment of need described in the existing PNA, the HWB for Hartlepool formally reports that the Pharmaceutical Needs Assessment of NHS Hartlepool (2011) is under review. Hartlepool HWB has commenced the process leading to publication of a revised assessment, its own first PNA; with a planned publication date in March 2015.”*

- TVPHSS continue to facilitate and advise on all issues related to the Regulations and the PNA on behalf of the HWB as noted above
- agenda items related to consultation, review, maintenance (including Supplementary Statements) and future publication of the Stockton on Tees PNA be received as required at future Board meetings.

### DETAIL

#### Background

1. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 SI 2013/349 which came into force on 1st April 2013 are the

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<sup>1</sup> Hereafter referred to as the Regulations

current legislative regime which governs the arrangements for the provision of these services in England.

2. Each Health and Wellbeing Board (HWB) has key duties and risks in relation to these Regulations, including the requirement that the HWB *must publish its first PNA by 1 April 2015*. Experience suggests that development and publication of the new PNA for Stockton on Tees will take a minimum of 12 months.
3. The 2013 Regulations set out the minimum requirements for the first Stockton on Tees HWB PNA produced under this duty, and these include such things as data on the health needs of the population, current provision of pharmaceutical services, and gaps in current provision. The PNA will also consider the future provision of pharmaceutical services. HWBs will be required to undertake a consultation on their first PNA for a minimum of 60 days and the Regulations list those persons and organisations that must be consulted.
4. It is equally important to recognise that publication of a new PNA is not the only duty, nor is publication by 1<sup>st</sup> April 2015 the conclusion of responsibility, but part of on-going duties / risks which may require action more regularly than 3-yearly publication.
5. In accordance with the 2013 Regulations, the Stockton on Tees HWB is now responsible for the latest PNA published by the former PCT (NHS Stockton on Tees). This inherited PNA<sup>2</sup> is now in use by NHS England (Durham, Darlington Tees Area Team), directing decision-making on the commissioning of pharmaceutical services in our HWB area (such as applications to open new pharmacies).
6. It is therefore important that each PNA is robust and up date. Consequently, the HWB also have a (statutory) duty to publish a revised PNA if there are significant changes to pharmaceutical services in their area. The only exception to this is where the HWB is satisfied that making a revised assessment would be a disproportionate response. A process for assessing change in need and proportionality of response is therefore essential to avoid a potential failure to act.
7. The HWB are required to put systems in place that allow them to:
  - make the PNA (and any Supplementary Statements) publically available
  - be properly informed about any and all changes to pharmaceutical services in their area by (a) establishing and maintaining formal communication pathways with both the DDT AT <sup>3</sup> and the local CCGs<sup>4</sup> and (b) keeping good records of any changes notified
  - identify changes to the need for pharmaceutical services within their area and additionally
    - assess whether the changes are significant and
    - decide whether producing a new PNA is a disproportionate response
    - decide whether to publish a supplementary statement explaining changes to the availability of pharmaceutical services since the publication of it's or a Primary Care Trust's pharmaceutical needs assessment.

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<sup>2</sup> Reference to the 'inherited PNA' means the NHS Stockton on Tees PNA dated 1.2.2011 and any associated Refresh documents incorporating Supplementary Statements

<sup>3</sup> E.g., requesting DDT AT report the outcome of any decisions or changes to pharmaceutical services to the TVPHSS on behalf of the HWB

<sup>4</sup> Reminding CCGs that decisions related to commissioning/ de-commissioning of enhanced services or other pharmaceutical services take PNA into account and inform or consult with HWB via the TVPHSS

8. Additionally, in the course of their administration of applications to provide or amend pharmaceutical services, Schedule 2 to the Regulations requires NHS England to give notice to the “relevant HWB and any other HWB any part of whose area is within 2 kilometres of the premises or location to which the application relates.” This notice gives the HWB the right to make representations in relation to the application (within 42 days). This is an important element of the HWB involvement.
9. HWBs need to ensure that they have good relationships with NHS England to allow the flow of information with regards the provision of pharmaceutical services by pharmacies, dispensing appliance contractors and dispensing doctors. HWBs also need to ensure they are aware of any changes to the commissioning of public health services by the local authority and the commissioning of services by clinical commissioning groups as these may affect the need for pharmaceutical services.
10. Council members and officers, and HWB members should also understand their new ‘relationship’ to the current and future PNAs as a consequence of the transfer of responsibility to the HWB. In the past, members were often approached by potential applicants of new pharmacies to seek endorsement of the ‘need’ for a new pharmacy in a given area. Now this document is owned by the HWB, members and officers should be aware of the implications of supporting views which may conflict with those contained within the PNA.
11. The Tees Valley Public Health Shared Service (TVPHSS) provides the expertise of a team which includes highly specialist Pharmacist Advisers and Public Health Intelligence Specialists offering Stockton on Tees HWB assurance of their capacity to deliver on these statutory duties.

## **Proposals**

12. In assessing the PNA and associated Refresh documents inherited from the PCT against the 2013 Regulations, it must be acknowledged that this Assessment was, according to the Regulations in place at the time, intended to ‘expire’ in Feb 2014.
13. Consequently, notwithstanding any changes to pharmaceutical services and related NHS services that have taken place since first publication in 2011, and without prejudice to the assessment of need described in the existing PNA, the Board is advised to formally report that the Pharmaceutical Needs Assessment of NHS Hartlepool 2011 is under review. The Board is similarly advised to formally commence the process leading to publication of a revised assessment, its own first PNA; with a planned publication date in March 2015. Tees Valley Public Health Shared Service will co-ordinate the development of a suitable action plan towards development of the first PNA.
14. The new PNA 2015 must reflect the priorities and needs of the HWB. For economy of scale and efficient use of resources, TVPHSS will establish and lead a Joint PNA Project Steering Group that provides clear direction and project plans, specialist pharmaceutical and PH intelligence, and other clinical advice, resource and action towards development of the PNA. TVPHSS will facilitate suitable learning events as required throughout the development process.
15. The Director of Public Health has identified Sarah Bowman, Consultant in Public Health, as PNA Champion from within the Public Health team. Sarah will work within the context of this shared resource and lead the PNA development process for Stockton on Tees to ensure suitable engagement with local teams, partners,

processes and population from the start. This is vital to the successful production of a high quality and valuable PNA.

16. A draft PNA will be presented to the HWB for approval mid-late summer 2014 prior to formal 60-day consultation to include those stakeholders identified in Part 2, Regulation 8 (1) of the 2013 Regulations i.e.,
  - (a) any Local Pharmaceutical Committee for its area (including any Local Pharmaceutical Committee for part of its area or for its area and that of all or part of the area of one or more other HWBs);
  - (b) any Local Medical Committee for its area (including any Local Medical Committee for part of its area or for its area and that of all or part of the area of one or more other HWBs);
  - (c) any persons on the pharmaceutical lists and any dispensing doctors list for its area;
  - (d) any LPS chemist in its area with whom the NHSCB has made arrangements for the provision of any local pharmaceutical services;
  - (e) any Local Healthwatch organisation for its area, and any other patient, consumer or community group in its area which in the opinion of HWB1 has an interest in the provision of pharmaceutical services in its area; and
  - (f) any NHS trust or NHS foundation trust in its area;
  - (g) the NHSCB (NHS England); and
  - (h) any neighbouring HWB.

This is a critical part of the development process that the Director of Public Health, and the HWB, acknowledge the necessity to resource.

17. Final draft of the PNA will then be presented to the HWB in late 2014/early 2015 to ensure approval and readiness for final formal publication in March.

18. In the intervening time, the HWB (facilitated by TVPHSS) is still required to

- (a) respond, as appropriate, to any invitation from NHS England to submit representation consultation in respect of pharmacy applications
- (b) undertake the decision-making required in relation to the publishing of any associated Supplementary Statement and
- (c) maintain and publish an up to date map as required
- (d) respond, 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.

19. It is therefore also advised that the HWB acknowledge the need for systems to be maintained via the TVPHSS that allow them to receive such notifications and, in response, determine whether or not to make representations in response to a particular application and as required

- prepare and deliver a response to the DDT AT within the required time-frame

- maintain records of these representations with the outcome of any decision subsequently reported to the HWB.
20. The Director of Public Health provides the link to the Health and Wellbeing Board in this respect as advised by the TVPHSS.

## **FINANCIAL IMPLICATIONS**

21. Notwithstanding the requirement to acknowledge the need to resource the formal consultation process, existing resources will be employed to support development and publication of the PNA, including the economy of scale achieved by the use of the expertise of the TVPHSS.

## **LEGAL IMPLICATIONS**

22. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations<sup>5</sup> 2013 SI 2013/349 describe statutory duties and responsibilities of the HWB in relation to the PNA.
23. The inherited PNA is used by NHS England in their decision-making. Such decisions are appealable and decisions made on appeal can be challenged through the courts. The use of PNAs for the purpose of determining applications for new premises is relatively new. It is therefore expected that many decisions made will be appealed and that eventually there will be judicial reviews of decisions made by the NHS Litigation Authority's Family Health Services Appeal Unit. It is therefore vitally important that PNAs comply with the requirements of the regulations, due process is followed in their development and that they are kept up-to-date.
24. Failure to comply with the regulatory duties may lead to a legal challenge, for example where a party believes that they have been disadvantaged following the refusal by NHS England of their application to open new premises. Due to the high level of risk associated with these duties, it may be recommended that the development of the PNA is added to a suitable risk register.

## **RISK ASSESSMENT**

25. See legal implications above. In addition to the Regulatory requirement for NHS England to use the PNA in their decision-making regarding commissioned pharmaceutical services, the PNA should also be referenced when others in the local commissioning economy (e.g., the Stockton and Hartlepool CCG, perhaps via NECs, and even the Borough Council themselves) consider commissioning (or decommissioning) pharmaceutical services. The HWB may wish to be assured that all potential commissioners are fully aware of the existence and content of the PNA.
26. The Tees Valley Public Health Shared Service (TVPHSS) provides the expertise of a team which includes highly specialist Pharmacist Advisers and Public Health Intelligence Specialists offering Stockton on Tees HWB assurance of their capacity to deliver on these statutory duties.

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<sup>5</sup> Hereafter referred to as the Regulations

## **SUSTAINABLE COMMUNITY STRATEGY IMPLICATIONS**

27. The Pharmaceutical Needs Assessment will take account of and should have a positive impact on both the Sustainable Community Strategy and Joint Health and Wellbeing Strategy themes.

## **CONSULTATION**

28. See above, consultation is an integral part of the proscribed process for development and publication of a PNA.

**Name of Contact Officer:** Sarah Bowman  
**Post Title:** Consultant in Public Health  
**Telephone No:** 01642 526828  
**Email address:** [sarah.bowman2@Stockton.gov.uk](mailto:sarah.bowman2@Stockton.gov.uk)

**Name of Contact Officer:** Philippa Walters  
**Post Title:** Pharmaceutical Adviser  
Tees Valley Public Health Shared Service  
**Telephone No:** 01642 746873  
**Email address:** [philippa.walters@nhs.net](mailto:philippa.walters@nhs.net)