# Cambridgeshire Pharmaceutical Needs Assessment: Monitoring Protocol

A protocol for the monitoring, assessment and response to changes in pharmaceutical needs in Cambridgeshire (2017 – 2020)

## Summary

To facilitate commissioning of pharmaceutical services responsive to population needs, the Health and Wellbeing Board (HWB) will, in accordance with regulations, update the Pharmaceutical Needs Assessment (PNA) every three years. Regulation 6 of the *National Health Service* (*Pharmaceutical and Local Pharmaceutical Services*) Regulations 2013 describes the requirements of the HWB to respond to any significant changes to pharmaceutical provision or need within the three years before a revised assessment is next published.

The Cambridgeshire PNA Steering Group will, on behalf of the HWB, continue to identify changes to the need for pharmaceutical services within the area and assess the significance of any such changes. These changes may be due to population growth or the closure or merger of pharmaceutical sites. The HWB will publish supplementary statements or a revised PNA, where deemed appropriate in consideration of the national regulations.

This protocol describes the process that will be taken to monitor, assess and respond to any changes in the need for pharmaceutical services. It applies to the period from the publication of the Cambridgeshire PNA 2017 Final Report (July 2017) until a revised PNA is published, which is currently planned for July 2020. All members of the steering group have agreed to the delivery of this protocol.

## 1. Background:

#### 1.1 Pharmaceutical needs assessments

Since 1 April 2013, every Health and Wellbeing Board (HWB) in England has had a statutory responsibility to publish and keep up-to-date a statement of the needs for pharmaceutical services for the population in its area, referred to as a 'pharmaceutical needs assessment' (PNA). The 2014 PNA is currently being updated and is due for publication in July 2017. It will describe the pharmaceutical needs for the population of Cambridgeshire, which includes Cambridge City, East Cambridgeshire, Fenland, Huntingdonshire and South Cambridgeshire, but not Peterborough. A separate PNA is produced by the Peterborough Health and Wellbeing Board.

The PNA will be used by NHS England when making decisions on applications to open new pharmacies and dispensing appliance contractor premises; or applications from current pharmaceutical providers to change their existing regulatory requirements. Of note, before a new pharmacy can dispense prescriptions issued under the National Health Service, it must be included in the pharmaceutical list relating to a Health and Wellbeing Board Area, and applications are made to NHS England, not by the HWB. As these decisions may be appealed and challenged via the courts, it is important that PNAs comply with regulations and that mechanisms are established to keep the PNA up-to-date.

The PNA will also inform decisions by local commissioning bodies, including local authorities (public health services from community pharmacies), NHS England and Clinical Commissioning Groups (CCGs), on which NHS funded services are provided

locally and where pharmacies may be able to deliver commissioned services (such as Stop Smoking and Sexual Health Services).

#### 1.2 Legal requirements to keep the PNA up-to-date

HWBs are required to publish a revised PNA within three years of publication of their first assessment<sup>i</sup>. A revised Cambridgeshire PNA will therefore be due for publication in July 2020.

If, during the next three years (2017 – 2020), the HWB identifies relevant changes to the need for pharmaceutical services, it is responsible for either making a revised assessment or publishing a supplementary statement as soon as is reasonably practicable. Regulation 6 of the *National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013*<sup>i</sup> states that:

- "(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."

Amendments were made to the pharmacy *National Health Service (Pharmaceutical Services, Charges and Prescribing) Regulations* in December 2016<sup>i</sup>. One key change was a new regulation which describes the potential consolidation of two or more

pharmacies onto one existing site. A new pharmacy would be prevented from stepping in straight away if a chain closes a branch or two pharmacy businesses merge and one closes which would protect two pharmacies that choose to consolidate on a single existing site – where this does not create a gap in provision.

"Applications to consolidate will be dealt with as "excepted applications" under the 2013 Regulations, which means in general terms they will not be assessed against ... the pharmaceutical needs assessment ("PNA") produced by the HWB. Instead, they will follow a simpler procedure, the key to which is whether or not a gap in pharmaceutical service provision would be created by the consolidation..... If the NHSCB is satisfied that the consolidation would create a gap in pharmaceutical services provision, it must refuse the application. The opinion of the HWB on this issue must be given when the application is notified locally and representations are sought (regulations 12 and 13). If the application is granted and pharmacy premises are removed from the relevant pharmaceutical list, if the HWB does not consider that a gap in service provision is created as a consequence, it must publish a supplementary statement published alongside its pharmaceutical needs assessment recording its view (regulation 3)."

As such, in the event of a consolidation in future, in accordance with Paragraph 19 of schedule 2 of the regulations the Cambridgeshire HWB must publish a supplementary statement which will become part of the PNA, explaining whether, in its view, the proposed removal of premises from its pharmaceutical list would or would not create a gap in pharmaceutical services provision that could be met by a routine application:

- (a) to meet a current or future need for pharmaceutical services; or
- (b) to secure improvements, or better access, to pharmaceutical services.

#### 2. Current context

There are a number of factors which may affect the likelihood of changes to the need for pharmaceutical services. These include the impact of the new national pharmacy contract and the future population changes and housing growth in Cambridgeshire.

## 2.1 Local impact of the new national pharmacy contract (2016)

On 20th October 2016 the Government imposed a two-year funding package on community pharmacy, with a £113 million reduction in funding in 2016/17<sup>ii</sup>. This is a reduction of 4% compared with 2015/16, and will be followed by a further 3.4% reduction in 2017/18. Key changes were also made to the national pharmacy contract with the aim of creating a more efficient service which is better "*integrated with the wider health and social care system*".

Full details of the final Community Pharmacy proposals can be found in the Department of Health (DoH) report "Community pharmacy in 2016/2017 and beyond: final package". Appendix 5 of the PNA 2017 provides a summary of the proposed changes to the

pharmacy contracts and the potential impact of these as assessed by the DoH and the national Pharmaceutical Services Negotiating Committee (PSNC) who represent all community pharmacies providing NHS services in England.

As described in the DoH health impact assessment, it is complex to assess the impact of these changes on Cambridgeshire residents at this stage. There is no reliable way of estimating the number of pharmacies that may close or the services which may be reduced or changed as a result of the policy and this may depend on a variety of complex factors, individual to each community pharmacy and their model of business.

## 2.2 Future population changes and housing growth

Over the coming years the population in Cambridgeshire is expected to both age and grow substantially in numbers. An increase in population size is likely to generate an increased need for pharmaceutical services, but on a local level changes in population size may not necessarily be directly proportionate to changes in the number of pharmaceutical service providers required, due to the range of other factors influencing local pharmaceutical needs. Several large-scale housing developments are in progress and considerations when assessing needs for local pharmaceutical service providers should be based on a range of local factors specific to each development site. These are further described in Section 6 of the PNA report.

#### 3. Process

The following process has been agreed to by all members of the steering group and applies to the period from publication of the Cambridgeshire PNA 2017 Final Report (July 2017) until a revised PNA is published, which is currently planned for July 2020. Membership of the steering group is listed in the 2017 PNA Final Report.

#### 3.1 Convening of the steering group:

The Cambridgeshire PNA Steering Group will meet every six months (actually or virtually) to assess any identified potential changes to the need for pharmaceutical provision.

The group will be provided with:

- a) a summary report of the latest population growth data and potential implication for pharmaceutical provision (more details in section 3.2);
- b) a summary of any closures or mergers of pharmacy sites, and the potential implications of these (section 3.3);
- c) a summary of any applications for new pharmacy sites that have been considered by NHS England in the last six months (section 3.4);
- d) a summary of any other changes to pharmaceutical provision, such as relocations or changes to opening hours (section 3.5); and
- e) updated maps of pharmaceutical provision (section 3.6).

The group will use the available information to decide whether:

- A supplementary statement of fact should be published to explain any changes;
- A revised assessment is required if changes of a significant extent have been identified; or,
- No further action is required before July 2020.

The steering group will be guided by the legal requirements of the relevant regulations (see section 1.2) and the *Department of Health Information Pack on Pharmaceutical Needs Assessments for local authority Health and Wellbeing Boards*<sup>iii</sup>. The group will also identify and consider best practice from other areas where appropriate and available.

## 3.2 Monitoring of population growth:

Given the significant planned growth of new developments across Cambridgeshire, the Senior Public Health Manager for Environment and Planning will continue to monitor and assess pharmaceutical need in these areas. They will produce a report in advance of each steering group meeting using the information sources described in section 6 of the PNA, to update the steering group on the latest data on housing development sites and population projections, and the potential implications for pharmaceutical provision. Section 6 of the PNA also describes the factors that will be considered in relation to needs for pharmaceutical services.

The Senior Public Health Manager will link with any ongoing work that is happening in partnership with the Cambridgeshire and Peterborough Clinical Commissioning Group (CCG) and NHS England (East) in relation to forecasting the impact of population growth on health services in general to ensure that pharmaceutical provision is considered alongside other health services.

#### 3.3 Closures and mergers of pharmaceutical provision:

The relevant Contract Manager in NHS England (East) will inform and consult with the Lead Consultant in Public Health on any closures or mergers of pharmaceutical service providers, who will convene a steering group meeting (actually or virtually) to assess the potential impact of the closure or merger and produce a supplementary statement to the PNA.

#### 3.4 Applications for new pharmaceutical provision:

The relevant Contract Manager in NHS England (East) will inform and consult with the Lead Consultant in Public Health on any application for new pharmaceutical provision. This will enable public health to share any relevant knowledge, including current information about population growth and its impact on pharmaceutical services. If an

application is approved, the Health and Wellbeing Board will issue a supplementary statement to update the current PNA.

## 3.5 Other changes to pharmaceutical provision:

The relevant Contract Manager in NHS England (East) will inform and consult with the Lead Consultant in Public Health, on behalf of the steering group, on any other changes to pharmaceutical provision in Cambridgeshire which may have an impact on local access to pharmaceutical services. This may include relocation of community pharmacies and changes to opening hours, such as significant changes to the opening hours of one pharmacy that plays a key role in providing pharmaceutical services out of hours, or smaller changes to a number of pharmacies in a local area.

## 3.6 Maps of pharmaceutical provision:

The Public Health Intelligence (PHI) team will be responsible for updating the maps of pharmaceutical provision as soon as possible following notification from NHS England of any closures, mergers or new pharmaceutical providers. The PHI team will review the maps in advance of the steering group meetings and provide the steering group with the latest version.

## 3.7 Role of the Cambridgeshire Health and Wellbeing Board:

The steering group will assess any changes in the need for pharmaceutical provision and produce supplementary statements or a revised assessment on behalf of the Cambridgeshire HWB. The steering group will write to the HWB to inform them of the identified change and the action the group has taken in advance of publishing any supplementary statements. It is proposed that the HWB delegates authority to the Director of Public Health, in discussion with the Chair or Vice-Chair of the HWB to note the information and approve any supplementary statements for publication. If a revised assessment is required, the steering group will inform the HWB and start the process for producing a revised PNA (as outlined in section 2 of the 2017 PNA report).

#### 3.8 Publication:

Following endorsement by the HWB, any supplementary statements or revised assessments will be published on the Cambridgeshire Insight website <a href="https://www.cambridgeshireinsight.org.uk">www.cambridgeshireinsight.org.uk</a>, alongside the original 2017 PNA report. The steering group will write to all key stakeholders, who were involved in the development of the PNA, to inform them of the publication of any supplementary statements. Publication will be communicated to the public via the Cambridgeshire County Council website and social media accounts. Other members of the steering group will publicise the information via their websites and/or social media as they deem appropriate.

## 3.9 Review of protocol:

This protocol will be reviewed at each steering group meeting, at least every six months, to ensure it continues to be fit for purpose.

<sup>&</sup>lt;sup>i</sup> National Health Service England. 'The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2016' (2016 No.1077). Available at: <a href="http://www.legislation.gov.uk/uksi/2016/1077/contents/made">http://www.legislation.gov.uk/uksi/2016/1077/contents/made</a>

ii Department of Health. 'Community pharmacy in 2016/2017 and beyond: final package'. (Oct 2016) Available at: <a href="https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/561495/Community\_pharmacy\_package\_A.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/561495/Community\_pharmacy\_package\_A.pdf</a>
iii Department of Health. 'Pharmaceutical needs assessments – information pack for local authority Health and Wellbeing Boards. (May 2013). Available at: <a href="https://www.gov.uk/government/publications/pharmaceutical-needs-assessments-information-pack">https://www.gov.uk/government/publications/pharmaceutical-needs-assessments-information-pack">https://www.gov.uk/government/publications/pharmaceutical-needs-assessments-information-pack</a>