

Contents

1	INTRODUCTION	2
	<i>Key messages.....</i>	<i>2</i>
1.1	What is a pharmaceutical needs assessment?	2
1.2	What is the purpose of the PNA?	2
1.3	Legislative background	3
1.4	What are NHS pharmaceutical services?	4
1.5	Local pharmacy services.....	5
	1.5.1 <i>Public health services</i>	<i>5</i>
	1.5.2 <i>NHS England</i>	<i>5</i>
	1.5.3 <i>Clinical commissioning groups.....</i>	<i>5</i>
1.6	What are pharmaceutical lists?	6
1.7	What information will this PNA contain?	6
	References	7

1 Introduction

Key messages

From 1 April 2013, every health and wellbeing board (HWB) in England has 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 PNA will help in the commissioning of pharmaceutical services in the context of local priorities, and will be used by NHS England when making decisions on applications to open new pharmacies. 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. In accordance with these regulations, the pan-Lancashire PNA will be updated every three years.

This PNA describes current provision and what may be needed for the population of Blackburn with Darwen Council, Blackpool Council and Lancashire County Council, and includes information on

- pharmacies in the region and the services they currently provide, including dispensing, providing advice on health, medicines reviews and local public health services such as stop smoking, sexual health and support for drug users
- relevant maps of the pan-Lancashire area and providers of pharmaceutical services in the area
- pharmaceutical contractors in neighbouring HWB areas that might affect the need for services in pan-Lancashire
- potential gaps in provision and likely future needs for the population of the pan-Lancashire area
- potential opportunities relating to needs of the population

1.1 What is a pharmaceutical needs assessment?

The PNA is a structured approach to identifying unmet pharmaceutical need. It can be an effective tool to enable HWBs to identify the current and future commissioning of services required from pharmaceutical service providers. The Department of Health (DH) published an information pack to help HWBs undertake PNAs.ⁱ

1.2 What is the purpose of the PNA?

This PNA will serve several key purposes.ⁱⁱ

- It 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.
- It will help the HWB to work with providers to target services in areas where they are needed and limit duplication of services in areas where provision is adequate.

- It will inform interested parties of the pharmaceutical needs across pan-Lancashire and enable work to plan, develop and deliver pharmaceutical services for the population.
- It will inform commissioning decisions by local commissioning bodies including local authorities (public health services from community pharmacies), NHS England and clinical commissioning groups (CCGs).

1.3 Legislative background

Section 126 of the NHS Act 2006 placed an obligation on NHS England to put arrangements in place so that drugs, medicines and listed appliances ordered via NHS prescriptions can be supplied to persons. This section of the act also described the types of healthcare professionals who are authorised to order drugs, medicines and listed appliances on an NHS prescription.

In 2012, the Health and Social Care Act was produced and superseded the NHS Act 2006. The 2012 act established HWBs and transferred the responsibility to publish and keep up-to-date a statement of the needs for pharmaceutical services of the population in its area, with effect from 1 April 2013. The requirements on how to develop and update PNAs are set out in regulations 3-9 schedule 1 of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013.ⁱⁱⁱ

The 2012 act also amended the Local Government and Public Involvement in Health Act 2007 to introduce duties and powers for HWBs in relation to joint strategic needs assessments (JSNAs). The preparation and consultation on the PNA should take account of the JSNA and other relevant local strategies in order to prevent duplication of work and multiple consultations with health groups, patients and the public. The development of PNAs is a separate duty to that of developing JSNAs. As a separate statutory requirement, PNAs cannot be subsumed as part of these other documents but can be annexed to them.

The PNA must be published by the HWB by April 2018, and will have a maximum lifetime of three years. As part of developing the PNA, HWBs must undertake a consultation for a minimum of 60 days. The 2013 regulations list those persons and organisations that the HWB must consult. This list includes

- any relevant local pharmaceutical committee (LPC) for the HWB area
- any local medical committee (LMC) for the HWB area
- any persons on the pharmaceutical lists and any dispensing GP practices in the HWB area
- any local Healthwatch organisation for the HWB area, and any other patient, consumer and community group that, in the opinion of the HWB, has an interest in the provision of pharmaceutical services in its area
- any NHS trust or NHS foundation trust in the HWB area
- NHS England
- any neighbouring HWB

The Health and Social Care Act 2012 also transferred responsibility for using PNAs as the basis for determining market entry to a pharmaceutical list from primary care trusts (PCTs) to NHS England. 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. Such decisions are appealable to the NHS Litigation Authority's Family Health Services Appeal Unit (FHS AU), and decisions made on appeal can be challenged through the courts. PNAs will also inform the commissioning of enhanced services from pharmacies by NHS England, and the commissioning of services from pharmacies by the local authority and other local commissioners, for example CCGs. It is extremely important that PNAs comply with the requirements of the Regulations and are kept up to date by submitting supplementary statements when deemed necessary.

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 refusal by NHS England of their application to open new premises.^{iv}

HWBs will also be required to publish a revised assessment when significant changes to the need for pharmaceutical services are identified, unless this is considered a disproportionate response. HWBs therefore need to establish systems that allow them toⁱⁱ

- identify changes to the need for pharmaceutical services within their area
- assess whether the changes are significant
- decide whether producing a new PNA is a disproportionate response

HWBs need to ensure they are aware of any other changes to the NHS contract, changes to the commissioning of public health services by the local authority and the commissioning of services by CCGs as these may affect the need for pharmaceutical services. HWBs also need to ensure that NHS England and its Area Offices have access to their PNAs.

1.4 What are NHS pharmaceutical services?

Pharmaceutical services as defined in the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 include the following.

- **Essential services** which every community pharmacy providing NHS pharmaceutical services must provide (as described in schedule 4, part 2 of the Regulations) which includes the dispensing of medicines, promotion of healthy lifestyles and support for self-care.
- **Advanced services** which community pharmacy contractors and dispensing appliance contracts can provide subject to accreditation. These are currently
 - medicines use reviews (MUR)
 - appliance use reviews (AUR)
 - new medicines service (NMS)
 - stoma customisation service (SCS)
 - national influenza adult vaccination services (excluding distance selling pharmacies)
 - NHS urgent medicines supply advanced service (NUMSAS) - the service is currently a time-limited pilot until 30 September 2018.
- **Enhanced services** are commissioned directly by NHS England. These services could be commissioned either through national or local schemes.

1.5 Local pharmacy services

Local pharmacy services are services which are commissioned locally and fall outside of the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013. The 2013 regulations set out the enhanced services which may be commissioned from pharmacy contractors. It is important to note that the definition of enhanced services has changed, and the current commissioning arrangements can now be seen as more complex since pharmacy services previously commissioned by one organisation (PCTs) can now be commissioned by at least three different organisations (CCGs, local authorities and NHS England) and the responsibility for commissioning some services continues to evolve or is subject to review. Enhanced services are currently commissioned directly by NHS England and CCGs. These could include seasonal flu vaccination service, minor ailment services and palliative care.

1.5.1 Public health services

Local authorities are responsible for commissioning a wide range of services, including most public health services and social care services. The local authority can commission pharmacies to provide the following public health services

- supervised administration service for specific drugs
- needle and syringe exchange
- NHS Health checks
- emergency hormonal contraception services
- sexual health services such as chlamydia screening, testing and treatment
- stop smoking
- weight management programmes
- alcohol screening and brief interventions

1.5.2 NHS England

NHS England currently commissions the pharmacy core contract (including advanced services). Currently, NHS England does not commission any enhanced services. However, this position may change according to the future role of pharmacy and the needs of local populations.

1.5.3 Clinical commissioning groups

CCGs have a role to commission NHS services locally. These services include planned hospital care, rehabilitative care, urgent and emergency care (including out-of-hours and accident and emergency services), most community health services, maternity services, mental health and learning disability services.

CCGs also commission local pharmacy services. Through thorough engagement, CCGs are able to ensure locally commissioned pharmacy services are responsive to local needs, such as minor ailments services, palliative care schemes, MUR+ and other medicines optimisation services.

Since the introduction of co-commissioning in April 2015, CCGs have the opportunity to take on greater responsibility for general practice commissioning. Co-commissioning was introduced to support the development of integrated out-of-hospital services, based around the needs of local people. It also offers the opportunity to develop more affordable services through efficiencies gained.

1.6 What are pharmaceutical lists?

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 by NHS England. This is commonly known as the NHS 'market entry' system.

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

- Pharmacy contractors: a person or body corporate who provides NHS pharmaceutical services under the direct supervision of a pharmacist registered with the General Pharmaceutical Council.
- Dispensing appliance contractors: appliance suppliers are a subset of NHS pharmaceutical contractors who supply, on prescription, appliances such as stoma and incontinence aids, dressings and bandages. They cannot supply medicines.
- Dispensing doctors: medical practitioners authorised to provide drugs and appliances in designated rural areas known as 'controlled localities'.
- Local pharmaceutical services (LPS) contractors also provide pharmaceutical services in some HWB areas.

1.7 What information will this PNA contain?

The information to be contained in the PNA is set out in schedule 1 of The NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013. This PNA includes information on

- pharmacies across pan-Lancashire and the services they currently provide, including dispensing, providing advice on health, medicines reviews and local public health services, such as stop smoking, sexual health and support for drug users
- relevant maps relating to pan-Lancashire area and providers of pharmaceutical services in the area
- services in neighbouring HWB areas that might affect the need for services in the pan-Lancashire area
- potential gaps in provision and likely future needs for the population across pan-Lancashire
- potential overprovision of services

References

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- ⁱ Department of Health. 'Pharmaceutical needs assessments: Information Pack for local authority Health and Wellbeing Boards.' May 2013. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/197634/Pharmaceutical_Needs_Assessment_Information_Pack.pdf
- ⁱⁱ Primary Care Commissioning. 'Pharmaceutical needs assessments. March 2013'. <http://www.pcc-cic.org.uk/>
- ⁱⁱⁱ The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. <http://www.legislation.gov.uk/uksi/2013/349/made>
- ^{iv} Pharmaceutical Needs Assessments: Right Service in the Right Place. 25 March 2013. <http://www.pcc-cic.org.uk/article/pharmaceutical-needs-assessments-right-service-right-place>