Report to:	Health and Wellbeing Board	Date of Meeting:	Wednesday 6 March 2024					
Subject:		For information and approval: Pharmaceutical Needs Assessment 2025-28 development process and scope report						
Report of:	Director of Public Health	Wards Affected:	(All Wards);					
Portfolio:	Health and Wellbein	Health and Wellbeing						
Is this a Key Decision:	No	Included in Forward Plan:	No					
Exempt / Confidential Report:	No							

Summary:

The purpose of this report is to outline the resources and processes required to deliver a fully revised three-year Sefton Pharmaceutical Needs Assessment (PNA) for 1 October 2025

Recommendations:

That the Board

- (1) Note the large breadth and depth of information required by the year-long PNA development process and final document, as set out in the 'Pharmaceutical Needs Assessment Information Pack for Local Authority Health and Wellbeing Boards' (DHSC, October 2021).
- (2) Note the opportunity cost in terms of public health analyst and consultant time and endorse proposals for organisations and partners with the most relevant knowledge and expertise to produce content for specified parts of the assessment.

Reasons for the Recommendation(s):

The Board is a Committee of the Council and has responsibility for producing and updating the Pharmaceutical Needs Assessment under the Health and Social Care Act 2012, in accordance with the 2013 regulations.

Alternative Options Considered and Rejected: (including any Risk Implications)

No alternative options have been considered as the Health and Wellbeing Board is legally required to publish a fully revised Pharmaceutical Needs Assessment by 1st October 2025 (or sooner under certain circumstances). Information aimed at helping Health and Wellbeing Boards to fulfil their duties in relation to the PNA¹ advises that

¹ Pharmaceutical needs assessments: Information pack for local authority health and (publishing.service.gov.uk) (page 9)

there is a risk of judicial review if the PNA falls short of minimum requirements in terms of content, does not adhere to the process for developing the PNA as set out in law, or does not meet the statutory deadline for publication.

What will it cost and how will it be financed?

(A) Revenue Costs

There are no additional costs resulting directly from the content of this report. If in the future a decision is made to procure additional external resource to support aspects of PNA development, this will be enacted in accordance with Contract Procurement rules and funded from within the public health budget.

(B) Capital Costs

Not applicable.

Implications of the Proposals:

Resource Implications (Financial, IT, Staffing and Assets):

Based on experience, resource implications of the PNA development process are a key point in this report, which includes proposals to help lessen the burden on Sefton Council staff.

Legal Implications:

The relevant law is:

- Section 128A of the National Health Service Act 2006 amended by the Health and Social Care Act 2012 requires each health and wellbeing board to assess the need for pharmaceutical services in its area and to publish a statement of its assessment.
- The NHS (Pharmaceutical Services and Local Pharmaceutical Services)
 Regulations 2013 set out the minimum information that must be contained within a pharmaceutical needs assessment and outline the process that must be followed in its development.

There is no right of appeal against the findings or conclusions within a pharmaceutical needs assessment. Health and wellbeing boards (the local authority) therefore face the risk of a judicial review should they fail to develop a pharmaceutical needs assessment that complies with the minimum requirements for such documents as set out in the 2013 regulations, or should they fail to follow due process in developing their pharmaceutical needs assessment, e.g. by failing to consult properly or take into consideration the results of the consultation exercise undertaken, or fail to publish by the required deadlines.

Equality Implications:

There are no equality implications arising directly from this report. The pharmaceutical needs assessment must identify the different needs of those who share a protected

characteristic according to the Equality Act 2010, and PNAs are also advised to collate information about relevant needs of other groups for example, university students, offenders, people who are homeless, refugees and asylum seekers, military veterans, and visitors to the area. An equality impact assessment is developed alongside the PNA.

Impact on Children and Young People: Yes

There is an impact on children insofar as provision of enough pharmaceutical services premises and the appropriate range of pharmaceutical services makes an important contribution to the health and wellbeing of children in the population, as it does for other population groups. Range and accessibility of such services is of particular importance for the parents and carers of children because they need to interact with pharmacies on behalf of children.

Climate Emergency Implications:

The recommendations within this report will

Have a positive impact	No
Have a neutral impact	Yes
Have a negative impact	No
The Author has undertaken the Climate Emergency training for	Yes
report authors	

The PNA process is not expected to have a direct effect on climate sensitive emissions.

Contribution to the Council's Core Purpose:

Protect the most vulnerable:

Assesses health needs that can be met by pharmaceutical services, with consideration of needs of people with protected characteristics under the Equality Act 2010, and other 'inclusion groups'. The PNA is part of ensuring equity of access to pharmacy services for all population groups.

Facilitate confident and resilient communities:

Community resilience is influenced by the health of its population. This relationship has been highlighted through the unequal impacts of the COVID-19 pandemic.

Pharmaceutical services play an important part in meeting health needs across our different communities.

Commission, broker and provide core services:

Provides a basis for understanding health needs and pharmaceutical service needs in Sefton for service commissioners in NHS England and NHS Improvement (to be delegated to Cheshire and Merseyside in Integrated Care Board from April 2023), and in organisations working together within Sefton Partnership.

Place - leadership and influencer:

Takes a place-based approach to assessment of need and influences decisions on applications to provide services within Sefton borough.

Drivers of change and reform:

PNA includes specific statements on needs in Sefton and sets out processes used to determine when a revised assessment must be prepared or supplementary statement on need issued.

Facilitate sustainable economic prosperity:

Provision of information to those with responsibility for making decisions on market

entry and consolidation applications for pharmacies.

Greater income for social investment:

None

Cleaner Greener:

The PNA process is a means to identify and address gaps in the sufficiency of pharmaceutical premises in terms of their spatial distribution and the range and type of services on offer. The use of transport time analysis and assessment of accessibility by means other than car stand should maintain or lessen dependence on cars, which contribute to environmental pollution, and especially air pollution, which can harm health.

What consultations have taken place on the proposals and when?

(A) Internal Consultations

The Executive Director of Corporate Resources and Customer Services (FD.7554/24....) and the Chief Legal and Democratic Officer (LD.5654/24....) have been consulted and any comments have been incorporated into the report.

(B) External Consultations

An initial meeting was held to discuss the task of revising the Sefton PNA with the Chief Executive of Sefton Community Pharmacy (Local Pharmaceutical Committee). Development of PNAs for the next three-year period has also been an agenda item at meetings of Cheshire and Merseyside Directors of Public Health.

Implementation Date for the Decision

Immediately following the Committee / Council meeting.

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Appendices:

There are no appendices to this report.

Background Papers:

There are no background papers available for inspection.

1. Introduction

The purpose of this report is to outline the resources and processes required to deliver a fully revised three-year Sefton Pharmaceutical Needs Assessment (PNA) for 1 October

2025. In so doing, this report provides the Health and Wellbeing Board with relevant information about:

- Legal context
- Uses of the PNA
- The range of information required
- Required and recommended steps and process
- Timescales
- Resource implications and collaboration.

2. Background

2.1 The responsibility for producing and updating the Pharmaceutical Needs Assessment (PNA), transferred to Health and Wellbeing Boards (HWB) on 1st April 2013. At the same time responsibility for using pharmaceutical needs assessments as the basis for determining market entry to a pharmaceutical list transferred from primary care trusts to NHS England and NHS Improvement.

The PNA is used as the framework for commissioning pharmacy services in a defined area and is a statutory document, by virtue of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which set out requirements for PNAs, as follows.

- When a new assessment needs to be published (within three years of the previous publication date, in this case 1st October 2022, but earlier reassessment can be required when there are 'significant' changes in need).
- When a supplementary statement to the PNA must or may be published
- Information which must be included
- Matters which the HWB must have regard to. These include five key statements which capture specific conclusions resulting from the needs assessment process:
 - The pharmaceutical services that the health and wellbeing board has identified as services that are necessary to meet the need for pharmaceutical services.
 - 2. The pharmaceutical services that have been identified as services that are not provided but which the health and wellbeing board is satisfied need to be provided to meet a current or future need for a range of pharmaceutical services or a specific pharmaceutical service.
 - 3. The pharmaceutical services that the health and wellbeing board has identified as not being necessary to meet the need for pharmaceutical services but have secured improvements or better access.
 - 4. The pharmaceutical services that have been identified as services that would secure improvements or better access to a range of pharmaceutical services or a specific pharmaceutical service, either now or in the future; and
 - 5. Other NHS services that affect the need for pharmaceutical services or a specific pharmaceutical service.

Other mandatory elements of the PNA are: a description of the process and rationale by which the HWB has determined the localities in its area; how it has taken into account the different relevant needs in the localities, and the different needs of those with protected and other shared characteristics in the population; information on demography, maps of where pharmaceutical services are provided; identification of where there is sufficient choice in regards to obtaining pharmaceutical services; provision of pharmaceutical services in neighbouring health and wellbeing board areas.

2.2 This very brief overview of the essential components of the PNA document already gives an indication of the scale and complexity of the task of producing a fully revised assessment. Indeed, the concise information pack published by DHSC in 2021 to support HWBs runs to 76 pages, and final PNA documents are generally more than twice as long². A separate timeline for PNA development has also been provided by DHSC, detailing the necessary steps, and spanning 55 weeks.³

3. The PNA in use

3.1 To provide pharmaceutical services in England a person and the premises from which they will provide services must be included in the relevant pharmaceutical list. NHS England is responsible for preparing, maintaining, and publishing pharmaceutical lists in respect of each health and wellbeing board's area. This function is now a delegated responsibility of Integrated Care Boards (ICBs).

The main purpose of the pharmaceutical needs assessment is to inform the submission of applications for inclusion in a pharmaceutical list, and the subsequent determination of such applications, in which process the HWB is a statutory consultee. Four types of applications can be made based on the PNA, (below).

- To meet a current need identified in the relevant pharmaceutical needs assessment.
- To meet a future need identified in the relevant pharmaceutical needs assessment.
- To secure improvements or better access identified in the relevant pharmaceutical needs assessment.
- To secure future improvements or better access identified in the relevant pharmaceutical needs assessment.

Applications that do not rely on the PNA are those seeking to open a distance selling premises, and to secure improvements or better access that were not identified in the PNA ('unforeseen benefits').

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² pharmaceutical-needs-assessment-pna-2022-25.pdf (sefton.gov.uk)

³ Pharmaceutical needs assessments: information pack - GOV.UK (www.gov.uk) (Appendix 1: suggested timeline).

The Health and Social Care Act 2012 further describes the duty of commissioners, to arrange for the adequate provision and commissioning of pharmaceutical services for their population. Besides commissioners in Cheshire and Merseyside ICB, the PNA also informs commissioning decisions amongst partner organisations within the Sefton Partnership, including the local authority, for example some services commissioned by public health. The PNA is therefore an important tool to ensure that commissioning intentions for services that could be delivered via community pharmacies are incorporated into local planning cycles. Local commissioning priorities need to be driven by the Joint Strategic Needs Assessment (JSNA) of which the PNA is an allied but distinct component.

4. Sefton Pharmaceutical Needs Assessment 2025-28: process, inputs, collaborative working

4.1 The basic timeline below is a simplified version of the recommended DHSC 55-week timeline, shown here in white columns. The shaded grey box shows the preparation phase in Cheshire and Merseyside, during which PNA leads and Consultants from each local authority public health intelligence team meet to agree a common timeline, and to review questionnaires for public and contractor surveys and templates to help harmonise the work going on across the nine areas.

	Sept/Oct	Nov/Dec	Jan/Feb	Mar/Apr	May/June	July/Aug	Sept/Oct
Mar- Sept 2024							2025
C&M PNA leads meetings — review surveys, report template etc. Map and commence governance route to sign-off inc. - report to OSC H&SC (Adults) in this period, ahead of active development phase starting in September. - submissions to consultation and engagement panel	Convene steering group. Collate data and information sources, inc. dispensing and activity data	4-week public, 4-week contractor surveys go live Questionnaire analysis Map service provision data Draft overview, health needs, identified patient groups, and public and contractor engagement sections.	Draft pharmaceutical services sections Draft EIA Complete locality assessments	Steering group review Draft statements of need Finalise PNA in first draft for HWB Agree consultation questions and produce consultation plan and resources	HWB signs off PNA draft for 60-day consultation	60-day statutory consultation Draft consultation report and agree response.	Finalise draft and obtain signoff at HWB. Publish by 1 October 2025

The information in the table provides further indication of the substantial time, technical and topic expertise that is needed to produce the PNA document. As in other local authorities in Cheshire and Merseyside the work of collating, analysing, and drafting the PNA in Sefton has been led by the public health analyst and a consultant in public health. Particularly time-consuming analytical aspects include the analysis and presentation of questionnaire data, including mapping of pharmacy provision. Additionally, technically challenging aspects that most benefit from pharmaceutical services and relevant commissioner expertise are highlighted **bold** in the timeline. During preparation of the current PNA local authority analysts had difficulties obtaining, analysing, and interpreting dispensing and activity data according to requirements set out in the new information pack (DHSC, 2021).

4.2 In discussing the resourcing implications of revising the PNA it is useful to consider the many different types of information that must be collated, analysed, and synthesised. This is now even more the case given the additional emphasis that is now placed on the level of detail expected in regulatory statements, for example⁴.

"Taking into account the above information, the health and wellbeing board is satisfied that there is a current need for the provision of the community pharmacist consultation service on Saturdays and Sundays between the hours of 09.00 and 19.00, in Anytown, to the north of the river."

Or,

"There is a current need for a pharmacy providing the following services, Monday to Saturday:

- all essential services,
- the community pharmacist consultation service,
- the new medicine service, and
- flu vaccinations."

Information that goes towards the final assessment of needs broadly comprises:

- Demographic and health data, describing the population profile, and relevant health status and inequalities of the population, including groups with protected characteristics or additional barriers to access, and differences in specified localities.
- 2. Information about expected changes in local demography, for example new housing developments.
- 3. Information about people's experiences of using pharmacies in Sefton.
- 4. Information about stakeholder views of the draft PNA (statutory consultation report)

⁴ Pharmaceutical needs assessments: Information pack for local authority health and (publishing.service.gov.uk) pp52-53

- Information about the location, accessibility, opening hours, range of essential, advanced, and enhanced services and activity provided by community pharmacies, dispensing appliance contractors, dispensing doctors and other services that influence demand.
- 6. Information about provision of pharmacy services in neighbouring local authority areas
- 7. Determination of what constitutes a 'necessary' pharmaceutical service in the area; determination of services that are not necessary but could secure better service or access; assessment of whether choice of services is sufficient; specification of gaps in provision in line with the 2013 regulations.
- 4.3 It is important that the PNA is developed to a high standard because it is a legal duty of the Health and Wellbeing Board, and because it is a means to determine the variety and distribution of pharmaceutical services that are best suited to different places and different population groups in Sefton. Therefore, it is proposed that overall co-ordination of the process outlined in the table above will be undertaken by the public health team, but that lead responsibility for production of the various parts of the report should take account of relevant expertise in the wider system as far as possible.
 - Broadly speaking, this would see public health staff taking the lead on points 1-4 above, professionals from Sefton Community Pharmacy, NHS England (Cheshire and Merseyside ICB with Sefton Partnership) supporting more with points 5-7, and the wider steering group helping to shape statements of need.

Other options that may be considered to improve the quality of the process and information that feeds into the revised PNA are to:

- Commission support from Health Watch Sefton to enable more face-to-face engagement during the 4-week public survey, which is currently delivered online only to improve feedback from groups with greater or different needs.
- Explore the feasibility of commissioning external project management and professional pharmaceutical expertise.

5.0 Conclusion

It is a statutory duty of the Health and Wellbeing to publish a legally compliant Pharmaceutical Needs Assessment for the following three years on or before 1st October 2025. This requires a wide range of skills and knowledge and places a big demand on the business intelligence and public health staff involved. A good quality PNA is in the interests of Sefton's communities and is best served through sharing the tasks of analysis and drafting by collaborating with stakeholders in the wider system wherever feasible.

6.0 Recommendations

That the Board:

- 1. Note the large breadth and depth of information required by the year-long PNA development process and final document, as set out in the 'Pharmaceutical Needs Assessment Information Pack for Local Authority Health and Wellbeing Boards' (DHSC, October 2021).
- 2. Note the opportunity cost in terms of public health analyst and consultant time and endorse proposals for organisations and partners with the most relevant knowledge and expertise to produce content for specified parts of the assessment.