5. Summary:

The Health and Social Care Act 2012 confers responsibility for developing and updating of the Pharmaceutical Needs Assessment (PNA) to Health and Wellbeing Boards (HWBs).

The Board is required to issue a PNA for its area by April 2015.

The PNA is designed to inform commissioners about what services are or can be provided by community pharmacies to meet local need. It contributes to the overall JSNA.

NHS England (NHS E) will rely on the PNA when making decisions on market entry for applications to open new pharmacy and dispensing appliance contractor premises. Such decisions are appealable and decisions made on appeal can be challenged through the courts.

6. Recommendations:

That the Board note the requirement for publication of the PNA by 1 April 2015 and the proposed timetable for delivery.
7. Proposals and Details:

A pharmaceutical needs assessment must meet the requirements of the NHS Pharmaceutical and Local Pharmaceutical Services Regulations 2013 as amended by statutory instrument No 349.

- The regulations place a statutory duty on HWBs to develop and publish their first PNA by 1 April 2015.
- HWBs are required to publish a revised assessment as soon as is reasonably practical after identifying significant changes to the availability of pharmaceutical services since the publication of its PNA unless it is satisfied that making a revised assessment would be a disproportionate response to those changes. NHS England have been requested to supply the relevant information to allow the development of the Rotherham PNA.
- Part 2 of the regulations sets out matters each HWB must have regard to under this duty. These include the demography of its area, current provision of pharmaceutical services relating to choice and sufficiency, whether further provision of pharmaceutical services would secure improvements, or better access, to services. The PNA will also consider the likely future needs for services.
- HWBs are required to publish a revised assessment within three years of publication of their first assessment.
- The development of the PNA will be overseen by the Director of Public Health and involve a range of stakeholders including the Local Pharmaceutical Committee (LPC) and NHS England.
- Rotherham will work with neighbouring HWBs to consider cross-border commissioning of services and impact within the PNA.
- Key milestones are summarised below:

<table>
<thead>
<tr>
<th>Key Steps</th>
<th>Timescale</th>
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<tr>
<td>PNA Regulations come into force</td>
<td>1 April 2013</td>
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<tr>
<td>Engagement of Stakeholders</td>
<td>May 2013 – April 2014</td>
</tr>
<tr>
<td>First draft of PNA and copy to Board</td>
<td>January 2014</td>
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<tr>
<td>Formal Consultation (60 days)</td>
<td>February 2014</td>
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<tr>
<td>Analysis of Consultation</td>
<td>May 2014</td>
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<td>Amend PNA in light of Consultation</td>
<td>May 2014</td>
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<tr>
<td>Final Report to Trust Board including Consultation</td>
<td>June 2014</td>
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<tr>
<td>PNA published</td>
<td>1 April 2014</td>
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8. Risks and Uncertainties:

Decisions on applications to open new premises may be appealed to the NHS Litigation Authority’s Family Health Services Appeal Unit (FHSAU), and may also be challenged via 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 by NHS E will be appealed and that eventually there will be judicial reviews of decisions made by the FHSAU. 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.

Where a party believes that the HWB has not complied with the requirements of the regulations and that they have been unfairly disadvantaged as a result their only recourse will be via the courts.

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 the NHS CB of their application to open new premises. The risk of challenge is significant and HWBs should add the PNA to the risk register.

9. Background Papers and Consultation:

http://www.dh.gov.uk/health/2013/02/pharmaceutical-services-regulations/.

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