Policy for applications for inclusion in the pharmaceutical list received by primary care trusts before 1 April 2013
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Standard operating policies and procedures for primary care

Issue Date: April 2013

Document Number: OPS-1008

Prepared by: Primary Care Commissioning (PCC)
**Information Reader Box**

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<tr>
<td>Author</td>
<td>Primary Care Commissioning 1N04, Quarry House LEEDS E-mail: <a href="mailto:england.primarycareops@nhs.net">england.primarycareops@nhs.net</a></td>
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Policy for applications for inclusion in the pharmaceutical list received by primary care trusts before 1 April 2013

Document Status

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Purpose of policy

1 NHS England is responsible for direct commissioning of services beyond the remit of clinical commissioning groups, namely primary care, offender health, military health and specialised services.

2 This document forms part of a suite of policies and procedures to support commissioning of primary care. They have been produced by Primary Care Commissioning (PCC) for use by NHS England’s area teams (ATs).

3 The policies and procedures underpin NHS England’s commitment to a single operating model for primary care – a “do once” approach intended to ensure consistency and eliminate duplication of effort in the management of the four primary care contractor groups from 1 April 2013.

4 All policies and procedures have been designed to support the principle of proportionality. By applying these policies and procedures, Area Teams are responding to local issues within a national framework, and our way of working across the NHS England is to be proportionate in our actions.

5 The development process for the document reflects the principles set out in *Securing excellence in commissioning primary care*[^1], including the intention to build on the established good practice of predecessor organisations.

6 Primary care professional bodies, representatives of patients and the public and other stakeholders were involved in the production of these documents. NHS England is grateful to all those who gave up their time to read and comment on the drafts.

7 The authors and reviewers of these documents were asked to keep the following principles in mind:

- Wherever possible to enable improvement of primary care
- To balance consistency and local flexibility
- Alignment with policy and compliance with legislation
- Compliance with the Equality Act 2010
- A realistic balance between attention to detail and practical application
- A reasonable, proportionate and consistent approach across the four primary care contractor groups.

This suite of documents will be refined in light of feedback from users

This document should be read in conjunction with:

- The NHS (Pharmaceutical Services) Regulations 2005, as amended
- The 2012 Regulations – the NHS (Pharmaceutical Services) Regulations 2012, as amended
- The 2013 Regulations – NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
- Regulations under the Health Act 2009: Market entry by means of Pharmaceutical Needs Assessments. Information for Primary Care Trusts. Transitional provisions (Gateway reference 17812)

**Policy aims and objectives**

The objective of this policy is to ensure that NHS England deals with applications received by primary care trusts (PCTs) prior to 1 April 2013 in line with the respective regulations.

**Background**

Before 1 April 2013 where a person wished to provide pharmaceutical services from premises in England they were required to apply to the PCT in whose area the proposed premises were to be located. From 1 April 2013 they will apply to the AT in whose area the proposed premises are to be located. There will, however, be applications received up to and including 31 March 2013 that although submitted to PCTs will be dealt with by the NHS CB.

Applications may have been submitted to PCTs under:

- the NHS (Pharmaceutical Services) Regulations 2005, as amended (the 2005 regulations); or

The 2012 regulations came into force on 1 September 2012 and schedule 7 contained the transitional provisions for applications received up to and including 31 August 2012. While most applications submitted under the 2005 regulations should have been dealt with by PCTs by 31 March 2013,
there may be some that have not been dealt with or there may be residual matters that need to be dealt with by the NHS England.

14 The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the 2013 regulations) came into force on 1 April 2013 and schedule 9 contains the transitional provisions for applications received up to and including 31 March 2013. This includes applications received under the 2012 regulations and also those that remain to be dealt with under the 2005 regulations by virtue of the transitional provisions contained within the 2012 regulations.

Scope of the policy

15 This policy covers applications submitted to PCTs on or before 31 March 2013 for inclusion in a pharmaceutical list that fall to be determined on or after 1 April 2013. Where there is any doubt as to the action that should be taken, ATs must refer to the relevant transitional provisions and regulations.

16 For the purposes of this policy ‘person’ includes a sole trader, partnership or body corporate that has applied for inclusion in either a PCT’s pharmaceutical list or one of NHS England’s pharmaceutical lists.

Applications submitted under the 2005 regulations

Applications yet to be determined

17 It is expected that PCTs will have dealt with all applications submitted under the 2005 regulations and which fell to be determined in line with those regulations by virtue of the transitional provisions in schedule 7 of the 2012 regulations. There may, however, be some applications that were deferred under the 2005 regulations and have not yet been determined. For example, an application was received and the PCT decided that it first needed to make a controlled locality determination.

18 Such applications will be dealt with by the relevant AT in line with the provisions of the 2005 regulations.

Applications that have been determined

19 There may also remain some applications that have been approved – either by the relevant PCT or, on appeal, by the NHS Litigation Authority’s Family Health Services Appeal Unit (FHSAU) – but for which the premises
have not yet opened. For example, where a preliminary consent application was submitted and the applicant now wishes to submit their full application.

20 Such applications will be dealt with by the relevant AT in line with the provisions of the 2005 regulations. The following paragraphs identify the most likely situations that ATs will need to deal with.

**Conversion of preliminary to full consent**

21 Where an application for preliminary consent made under the 2005 regulations has been approved in line with those regulations, the applicant may submit their full application in line with those regulations. ATs will ensure that such applications are valid, i.e. they are submitted within six months of grant of the preliminary application, and where they are will determine them in line with the provisions of the 2005 regulations. This includes notifying decisions, giving rights of appeal and responding to any subsequent appeals.

**Request for an extension to the timescale within which to open**

22 Under the 2005 regulations, persons whose full applications for inclusion in the pharmaceutical list had been approved could request an extension or extensions to the six-month period within which to open. The PCT had to be satisfied that there was good cause to allow an extension or extensions and, where it was so satisfied, could grant a further period of time not exceeding nine months from the date the application was granted.

23 Where ATs receive such a request they will establish that it has been submitted in time, and the basis for the need for an extension. An extension to the period within which to open will only be given where it is established that there is good cause.

**Notifications of change of address prior to inclusion in the relevant pharmaceutical list**

24 There may be occasion where an AT is notified of a change of address by a person whose application to open premises was approved under the 2005 regulations. On receipt of such a request the AT will ensure that it is received in time and where it is satisfied that the change is a minor relocation it will amend the premises named in the original application. It will notify such a decision and give appeal rights in line with the 2005 regulations. Any appeals against such a decision will be dealt with by the FHSAU.
Receipt of notice of commencement

25 On receipt of a notice of commencement from a person whose application was approved under the 2005 regulations, the AT will ensure that it has been received within the required timescale. Where it has, the person will be included in the relevant pharmaceutical list with effect from the date in the notice.

Applications submitted under the 2012 regulations

26 Applications that have been submitted to a PCT on or before 31 March 2013 under the 2012 regulations and which have not been determined will be dealt with in line with the transitional provisions set out in schedule 9 of the 2013 regulations.

Routine applications

27 Routine applications will be dealt with as follows:

- Applications offering to meet a current or future need included in a pharmaceutical needs assessment (PNA) will be dealt with in accordance with the 2012 regulations and the National Health Service Act 2006.
- Applications offering to secure current or future improvements or better access included in a PNA, which have not been notified before 1 April 2013, will be dealt with in accordance with the 2013 regulations.
- Applications offering to secure current or future improvements or better access included in a PNA, which have been notified before 1 April 2013, will be dealt with in accordance with the 2012 regulations and the National Health Service Act 2006.
Excepted applications

28 Excepted applications will be dealt with as follows:

- Excepted applications which are not notifiable applications\(^2\) and which have not been determined by the PCT before 1 April 2013 will be dealt with in accordance with the 2013 regulations.
- Excepted applications which are notifiable applications\(^3\) and which have not been notified before 1 April 2013 will be dealt with in accordance with the 2013 regulations.
- Excepted applications which are notifiable applications and which have been notified before 1 April 2013 will be dealt with in accordance with the 2012 Regulations and the National Health Service Act 2006.

Monitoring and review of policy

29 This procedure will be reviewed regularly, with frequency determined by NHS England. There are robust arrangements for the maintenance and storage of all records, minutes, and reports associated with the procedure to ensure a clear audit route through the procedure for each contractor. NHS England may instigate an internal audit, or be required to submit information to an external body for scrutiny.

\(^2\) Applications regarding providing directed services, changes of ownership, temporary listings arising out of a suspension, right of return applications and applications for temporary arrangements during emergencies or because of circumstances beyond the control of a contractor.

\(^3\) Relocations that do not result in significant change within and between health and wellbeing board areas, distance selling premises, combined change of ownership and relocation that does not result in significant change within and between health and wellbeing board areas.
Annex 1: abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>A&amp;E</td>
<td>accident and emergency</td>
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<td>APHO</td>
<td>Association of Public Health Observatories (now known as the Network of Public Health Observatories)</td>
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<td>APMS</td>
<td>Alternative Provider Medical Services</td>
</tr>
<tr>
<td>AT</td>
<td>area team (of NHS England)</td>
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<td>AUR</td>
<td>appliance use reviews</td>
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<td>BDA</td>
<td>British Dental Association</td>
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<tr>
<td>BMA</td>
<td>British Medical Association</td>
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<td>CCG</td>
<td>clinical commissioning group</td>
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<td>CD</td>
<td>controlled drug</td>
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<td>controlled drug accountable officer</td>
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<td>CGST</td>
<td>NHS Clinical Governance Support Team</td>
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<td>CIC</td>
<td>community interest company</td>
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<td>CMO</td>
<td>chief medical officer</td>
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<td>COT</td>
<td>course of treatment</td>
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<td>CPAF</td>
<td>community pharmacy assurance framework</td>
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<td>CQC</td>
<td>Care Quality Commission</td>
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<td>CQRS</td>
<td>Calculating Quality Reporting Service (replacement for QMAS)</td>
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<td>DAC</td>
<td>dispensing appliance contractor</td>
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<td>Days</td>
<td>calendar days unless working days is specifically stated</td>
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<td>DBS</td>
<td>Disclosure and Barring Service</td>
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<td>DDA</td>
<td>Disability Discrimination Act</td>
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<td>DES</td>
<td>directed enhanced service</td>
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<td>DH</td>
<td>Department of Health</td>
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<td>EEA</td>
<td>European Economic Area</td>
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<td>ePACT</td>
<td>electronic prescribing analysis and costs</td>
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<td>ESPLPS</td>
<td>essential small pharmacy local pharmaceutical services</td>
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<td>EU</td>
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<td>family health services appeals unit</td>
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<td>family health shared services</td>
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<td>FTA</td>
<td>failed to attend</td>
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<td>first-tier tribunal</td>
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<td>GDP</td>
<td>general dental practitioner</td>
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<td>GDS</td>
<td>General Dental Services</td>
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GMC  General Medical Council
GMS  General Medical Services
GP  general practitioner
GPES  GP Extraction Service
GPhC  General Pharmaceutical Council
GSMP  global sum monthly payment
HR  human resources
HSE  Health and Safety Executive
HWB  health and wellbeing board
IC  NHS Information Centre
IELTS  International English Language Testing System
KPIs  key performance indicators
LA  local authority
LDC  local dental committee
LETB  local education and training board
LIN  local intelligence network
LLP  limited liability partnership
LMC  local medical committee
LOC  local optical committee
LPC  local pharmaceutical committee
LPN  local professional network
LPS  local pharmaceutical services
LRC  local representative committee
MDO  medical defence organisation
MHRA  Medicines and Healthcare Products Regulatory Agency
MIS  management information system
MPIG  minimum practice income guarantee
MUR  medicines use review and prescription intervention services
NACV  negotiated annual contract value
NCAS  National Clinical Assessment Service
NDRI  National Duplicate Registration Initiative
NHAIS  National Health Authority Information System (also known as Exeter)
NHS Act  National Health Service Act 2006
NHS BSA  NHS Business Services Authority
NHS CB  NHS Commissioning Board (NHS England)
NHS CfH  NHS Connecting for Health
NHS DS  NHS Dental Services
NHS LA  NHS Litigation Authority
NMS  new medicine service
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NPE  net pensionable earnings
NPSA  National Patient Safety Agency
OJEU  Official Journal of the European Union
OMP  ophthalmic medical practitioner
ONS  Office of National Statistics
OOH  out of hours
PAF  postcode address file
PALS  patient advice and liaison service
PAM  professions allied to medicine
PCC  Primary Care Commissioning
PCT  primary care trust
PDS  personal dental services
PDS NBO  Personal Demographic Service National Back Office
PGD  patient group direction
PHE  Public Health England
PLDP  performers’ list decision panel
PMC  primary medical contract
PMS  Personal Medical Services
PNA  pharmaceutical needs assessment
POL  payments online
PPD  prescription pricing division (part of NHS BSA)
PSG  performance screening group
PSNC  Pharmaceutical Services Negotiating Committee
QOF  quality and outcomes framework
RCGP  Royal College of General Practitioners
RO  responsible officer
SEO  social enterprise organisation
SFE  statement of financial entitlements
SI  statutory instrument
SMART  specific, measurable, achievable, realistic, timely
SOA  super output area
SOP  standard operating procedure
SPMS  Specialist Personal Medical Services
SUI  serious untoward incident
UDA  unit of dental activity
UOA  unit of orthodontic activity
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Version control tracker

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<td>01.01</td>
<td>June 2013</td>
<td>Primary Care Commissioning</td>
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