



**Urgent preparing for
community pharmacy to
contribute to a potential
COVID-19 vaccination
programme:
Annex B: Community
pharmacy site
designation process**

COVID-19 vaccination programme 2020/21

27 November 2020

Community Pharmacy Site Designation Process

COVID-19 vaccination programme

Publishing approval number: PAR C0912

Version number: 1

First published: 27 November 2020

Prepared by NHS England and NHS Improvement

Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities."

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If you have any queries about the designation process, please send these to your local NHS England & NHS Improvement regional team. Contact details can be found at <https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-contract-teams/>.

1. Introduction

- 1.1. Several potential vaccines for COVID-19 are in the later stages of phase III trials. If one or more are authorised for use, the NHS needs to be ready to start immediate vaccination. Community pharmacy will have an important role in a potential COVID-19 vaccination programme, alongside other providers.
- 1.2. NHS England and NHS Improvement regional teams will commission selected community pharmacy contractors who are able to meet the requirements to provide a COVID-19 vaccination service from pharmacy-led designated sites. Due to the likelihood of complex logistics in this new supply chain, there will be a limited number of sites commissioned to deliver high volumes of vaccines mostly at a separate site, for twelve-hour days, seven days a week.
- 1.3. We expect to commission fewer community pharmacy sites than GP PCN led centres. We do not expect the majority of contractors will be able to meet these requirements and expect them to continue their very important role in flu vaccination, particularly of the new 50-64 year-old cohort, and provision of other pharmaceutical services
- 1.4. Aspects of a potential COVID-19 vaccination programme can only be finalised when final trial results and licensing of vaccines has occurred. A final local enhanced service (LES) agreement will be issued as soon as details are clear.
- 1.5. A key requirement of pharmacies wishing to lead a pharmacy designated vaccination site under the LES is that the contractor can meet the core site and workforce requirements.
- 1.6. A designation process has been established to provide assurance to the commissioner that all pharmacy-led sites administering COVID-19 vaccination under the LES meet the required criteria.
- 1.7. This document sets out the designation process and is aimed at:
 - **NHS England and NHS Improvement regional teams** (as commissioner of the service) who have reviewed existing vaccination centre coverage and have established that additional designated vaccination sites are required to maximise system capacity and/or provide equitable access for its local population and wish to commissioned a LES from pharmacy contractors.
 - **Pharmacy contractors** who believe that they can meet the need established by NHS England and NHS Improvement that additional sites

are required to maximise system capacity and wish to nominate a site to be designated for delivering COVID-19 vaccinations under the LES.

- 1.8. NHS England and NHS Improvement regional teams will formally consult the Local Pharmaceutical Committee (LPC) on commissioning a Local Enhanced Service (LES). They may also communicate with contractors who have expressed an interest in providing the service. Regional teams are strongly encouraged where possible to engage a lay member or patient representative in the process, to reflect patient involvement duties. When considering criteria relating to accessibility and equality of access, the regional team should take account of the needs of the local population including specific health inclusion groups, and availability of alternate pharmaceutical services.
- 1.9. During the designation process, NHS England and NHS Improvement regional teams will review the nominations and supporting evidence submitted by contractors in response to the identified need, considering whether the total number and geographical distribution of sites supports fair and equitable access for patients and can be supported by local COVID-19 vaccination supply chains. Where the number of recommended sites exceeds the number that can be accommodated, NHS England and NHS Improvement regional teams will prioritise the list of sites according to need. They will then, working with the local system, take a decision as to whether a nominated site should be approved.
- 1.10. Due to the likelihood of complex logistics in this new supply chain, only providers who can meet the designation requirements will be commissioned to provide this service. We are also commissioning an [enhanced service from general practice](#). Community pharmacy contractors may alternatively wish to discuss collaboration with their local Primary Care Network by entering into a sub-contracting agreement, for example, to increase capacity or target certain populations such as care homes.
- 1.11. As new vaccines or further vaccine supplies become available, or if there are changes in requirements, NHS England and NHS Improvement may choose to commission this service from additional sites or with amended requirements. If this becomes the case, then further communication will follow.
- 1.12. Once designated, all sites must continue to meet the designation criteria for so long as required in the LES agreement. The commissioner should be informed immediately if for any reason, a designated site ceases to meet the criteria.

- 1.13. Upon publication of the final LES agreement, commissioners will invite pharmacy contractors who have a designated site to sign up to deliver the COVID-19 Vaccination Programme Local Enhanced Service.
- 1.14. Decisions on the supply of vaccine to designated sites will be taken by the national COVID-19 vaccination programme, to maximise access to priority groups set by government on the basis of the Joint Committee on Vaccination and Immunisation's (JCVI) advice. Designation of a site does not guarantee any specific vaccine delivery schedule.

2. Timescales

2.1. The designation process for the initial nominated sites will be undertaken according to the following timescales:

Date	
End November	Designation process and criteria published
6 December	Deadline for contractors to advise NHS England and NHS Improvement regional teams of nominated site for designation. <i>(Note that where pharmacies submit nominations earlier the designation process can commence).</i>
11 December	Deadline for further supporting information requested by regional teams to be submitted by contractors (where the nominated site can be matched to an NHS England and NHS Improvement established need).
w/c 14 December	NHS England and NHS Improvement consideration of assessment and decision on which sites will be designated.
18 December	NHS England and NHS Improvement decision communicated to pharmacies.
As soon as possible after a vaccine becomes available.	Final local enhanced service agreement published

3. Designation process

- 3.1. NHS England and NHS Improvement must review existing vaccination centre coverage and establish whether additional designated vaccination sites are required to maximise system capacity and/or provide equitable access for its local population. Regional teams are strongly encouraged where possible to engage a lay member or patient representative in the process, to reflect patient involvement duties. When considering criteria relating to accessibility and equality of access, the regional team should take account of the needs of the local population including specific health inclusion groups, and availability of alternate pharmaceutical services
- 3.2. Where a need is established, NHS England and NHS Improvement regional teams will formally consult the Local Pharmaceutical Committee on commissioning a Local Enhanced Service. They may also communicate with contractors who have expressed an interest in providing the service.
- 3.3. Pharmacy contractors should read this document carefully before completing Section 1 of the Community Pharmacy Site Designation Process Form (Annex B). This section requires the details of the site being nominated for designation and the name and contact details of the contractor. The form also requires a contact with whom the NHS England and NHS Improvement regional team can liaise throughout the designation process.
- 3.4. Pharmacy contractors may use existing premises where they can accommodate the expected throughput of patients and maintain access to pharmaceutical services. Where contractors can demonstrate a clear plan to maintain pharmaceutical services, eg where two premises in a locality have agreed to work collaboratively, they may wish to apply to NHS England and NHS Improvement to change their hours or to limit the provision of pharmaceutical services from their premises for the purposes of administering COVID-19 vaccines.¹ Otherwise the pharmacy contractor will be expected to nominate alternative premises that can meet General Pharmaceutical Council standards.
- 3.5. The completed form (Section 1) should be submitted to the local NHS England and NHS Improvement regional team no later than 4pm on **Sunday 6**

¹ <https://www.legislation.gov.uk/ukxi/2020/1126/made>

December. Note that where pharmacy contractors submit nominations earlier, the designation process can progress.

- 3.6. An NHS England and NHS Improvement regional team representative will then undertake a process to assess the extent to which the nominated site meets the need for additional designated vaccination sites to maximise system capacity and/or provide equitable access for its local population. Where the need is met, the representative will invite the pharmacy contractor to complete Section 2 of the Community Pharmacy Site Designation Process Form (Annex B), submitting supporting evidence that they meet the requirements.
- 3.7. The completed form (Sections 1 and 2) should be submitted to the local NHS England and NHS Improvement regional team no later than 4pm on **Friday 11 December.** Note that where pharmacy contractors submit supporting evidence earlier, for example with their Section 1 submission, the designation process can commence.
- 3.8. In collaboration with the pharmacy contractor's nominated contact, an NHS England and NHS Improvement regional team representative will then undertake a process to assess the extent to which the nominated site meets each of the specified criteria set out in Section 2 of the Form. This may be done remotely by an NHS England and NHS Improvement representative familiar with the nominated site. The regional team representative will record on the form their view as to whether each of the specified criteria has been met.
- 3.9. **Nominated sites that do not meet all of the designation criteria cannot be recommended for designation. Pharmacy contractors should note that even if a site is assessed by the regional team as having met all of the designation criteria, this does not automatically mean that it will be designated as further factors such as equity of access, geographical coverage and total number of sites that can be accommodated within the COVID-19 vaccine supply chain need to be considered.**
- 3.10. Once all site assessments are complete, the regional team should consider the total number of sites in its geographical area that have been assessed as meeting the designation criteria, and consider which sites it wishes to commission, factoring in:
 - equity of patient access
 - achieving good geographical coverage

- whether there is unmet need in a local geography.

3.11. The regional team representative should complete Section 3 of the form for the sites they are recommending for approval. This includes a requirement to indicate the priority for approval it has attached to the site. This information will be used to prioritise sites for approval where the number of sites recommended exceeds the numbers that can be accommodated within the supply chain in that region.

3.12. Regional teams will present the outcome of the assessments and list of sites recommended for designation to each other and relevant members of the NHS England and NHS Improvement national primary care and COVID-19 vaccination teams to ensure that a fair and consistent approach has been taken in all areas. The final decision on which sites have been designated will be communicated in writing by regional teams to pharmacy contractors late in December.

3.13. Initial nominated sites must have completed the designation and commissioning process prior to late December or early January with exact date dependent on individual vaccine licensing dates and manufacturers' supply schedules (or prior to vaccine delivery for subsequent sites).

3.14. As vaccine supply generally increases over time, we anticipate expanding the number of sites. Pharmacy contractors may subsequently be invited by the commissioner to nominate additional premises or new contractors may be commissioned. These new sites would also need to go through the designation process outlined in this document. Contractors may wish to indicate the location of these additional sites now so that once the designation process for the initial nominated sites is complete, additional sites can be assessed and brought on stream rapidly (where they have been judged to meet the designation criteria and the supply chain allow). A separate form should be completed for any additional sites that the contractor wishes to nominate, and it should be clearly marked on the form that it relates to a **FUTURE SITE NOMINATION**.

Annex A

Designation Criteria

#	Criteria	Requirements
1	Storage	1.1 Fridge space to store (2-8°C) 1000 vaccine doses at one time or confirmed plans to have fridge capacity in place, and capacity to administer at least 1000 doses per week, ensuring all doses are administered within appropriate shelf life.
		1.2 Space to store personal protective equipment (PPE) and other consumables and equipment (including those for administering the vaccine, storing waste, making a clinical record, providing written information to patients or for treatment of adverse events).
2	Planning and co-ordination	2.1 Ability to coordinate clinical capacity in line with cohort prioritisation and call/recall schedules and in alignment with national communications guidance, whilst maintaining appropriate provision of pharmaceutical services from the premises that appears on the pharmaceutical list.
		2.2 Ability to deliver vaccinations 7 days a week from 8am to 8pm, including potentially on bank holidays, if required.
		2.3 Capacity and capability to coordinate with the regional/Sustainability and Transformation Partnership (STP) operations centre to plan clinics according to expected vaccine supply, coordinate required trained staff, order required vaccine and consumables supply within required timeframes, receive and safely store supply, amend clinic schedule if there is a disruption to supply and undertake timely communication of any changes to patients (via the National Booking Service as appropriate).
		2.4 Ability to coordinate clinics around the different types of vaccine to ensure patients receive the full course of the appropriate vaccine.
		2.5 Ability to accommodate new vaccine types as they become available.
		2.6 Ability to work with Primary Care Networks and other healthcare partners on local delivery plan to ensure best use of local resources and clinic schedules that offer patients flexibility and choice.
3	Site Safety	Ability to ensure smooth entry and exit from the building complying with social distancing and current COVID-19 guidance, with appropriate security and adequate parking arrangements, and providing security guards

		and/or stewards if needed. The impact on the local community should also be considered.
		a registered pharmacy
4	Wastage	
5	Space	5.1 Physical layout that will support administration of the minimum weekly volume, complying with social distancing and with space for any necessary post-vaccination care, including 15 minutes observation if the patient will be driving.
6	Workforce	6.2 If non-registered staff are to be used to administer vaccines, they must have had appropriate training and be working under clinical supervision and the National Protocol (subject to publication).
7	Patient Experience	
8	Vaccine storage and handling	
9	Preparation	
10	Administration	
11	Aftercare	
12	Data collection	
13	Reporting	