Community pharmacy COVID-19 vaccine rollout from Phase 2A (May 2021 onwards)

This document provides a background to the use of community pharmacies in Australia for the COVID-19 Vaccination Program, details how section 90 approved community pharmacies may express their interest in being a provider under the program and the minimum requirements to participate.

The Australian Government will facilitate the supply of doses to community pharmacies selected to participate in the rollout and provide payment per vaccination delivered, as well as providing vaccine-specific training and access to the National Booking System.

The community pharmacies will have responsibility for operations on its own premises, including:

- on-site storage and administration of the vaccine;
- ensuring availability of an adequately skilled workforce; and
- taking all reasonable steps to ensure compliance with the minimum site requirements.

This EOI is solely intended to identify individual community pharmacies capable of participating from Phase 2 of the rollout to commence from May 2021. An EOI should be completed for each individual pharmacy location.

Community pharmacies who do not participate in Phase 2 may still be involved in later phases of the vaccine rollout. All community pharmacies who meet requirements may have the opportunity to participate in the vaccine rollout as more vaccines become available.

health.gov.au/covid19-vaccines
Background

Providing access to safe and effective COVID-19 vaccines to everyone living in Australia seeking to be vaccinated is a key priority of the Australian COVID-19 Vaccination Policy. Community pharmacies are a critical partner in achieving this goal and in providing comprehensive primary health care for people in Australia.

All approved section 90 community pharmacies are invited to submit an expression of interest (EOI) to participate in the delivery of the COVID-19 vaccine to priority populations from Phase 2A onwards of the national rollout strategy, planned to commence from May 2021. The EOI process will be managed by the Pharmacy Programs Administrator (PPA) on behalf of the Department of Health.

The focus of this EOI is to identify community pharmacies who are willing and able to deliver the AstraZeneca COVID-19 vaccine, initially to priority populations (outlined below). This includes capacity to vaccinate patients over and above the pharmacy’s usual population. Community pharmacies will be funded by the Australian Government Department of Health per vaccination delivered (details provided below) via the PPA. The second vaccination payment will be higher than the first vaccination payment, only where a patient receives both doses of the vaccine at the same community pharmacy. Community pharmacies are not permitted to charge patient co-payments.

The Australian Government is supporting community pharmacies to vaccinate people with the AstraZeneca COVID-19 vaccine. States and territories have legislative responsibility for who can vaccinate and with what vaccines, and may need to amend their legislation to enable pharmacists to deliver the COVID-19 vaccine.

Community pharmacies will not be involved in delivering the Pfizer-BioNTech COVID-19 vaccine.

Final locations in the rollout from Phase 2A will be approved and determined by the Australian Government Department of Health, in liaison with states and territories, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia. Community pharmacies will be selected with consideration to suitability, amenity, ability to reach the priority populations, geographical coverage and sustainability. As the vaccine rollout progresses, all section 90 approved community pharmacies willing and able to administer the vaccinations will be invited to participate in the program.

The COVID-19 vaccine will be administered in the community pharmacy setting by appropriately COVID-19 vaccine trained health professionals, in accordance with state/territory regulations.

The following settings are specifically excluded under this program: outreach programs; outstation premises; the patient’s place of residence; aged care facilities; any other clinics or settings which are not inside the pharmacy’s approved premises.

This EOI is specific to community pharmacies. Separate EOIs have been issued for COVID-19 vaccine delivery in other health care settings and for higher risk populations.

Only Phase 2 and 3 are within the remit of this community pharmacy program. More detail on the priority populations can be found within the Australian COVID-19 Vaccine National Roll-out Strategy.
Populations for Phase 2 and 3

In Phase 2, doses of the COVID-19 vaccine will be provided in multiple locations, including community pharmacy.

The Phase 2 priority population includes:

- Adults aged 60-69 years;
- Adults aged 50-59 years;
- Aboriginal and Torres Strait Islander people aged 18-54 years;
- Other critical and high risk workers;
- Balance of adult population;
- Catch up any unvaccinated Australians from previous phases.

In Phase 3, doses of the COVID-19 vaccine will be provided in multiple locations, including community pharmacy.

The Phase 3 priority population includes:

- < 18 years if recommended.

Vaccine details

Phase 2 onwards of the vaccine rollout will deliver the AstraZeneca COVID-19 two dose vaccine which is stored at 2-8 degrees Celsius and packaged in multi dose vials. A single 5 mL vial contains 10 doses (each dose 0.5 mL). Further details related to the vaccine, including administration, observation periods, timeframe between doses etc. will be available following Therapeutic Goods Administration (TGA) evaluation/registration.

Models of care

Community pharmacies who are selected to administer COVID-19 vaccines from Phase 2 onwards will need to provide a vaccination model of care including:

- Ensuring vaccinators undertake mandatory training designed and provided by the Commonwealth, this is in addition to any training requirements of the jurisdiction.
- Provision of the vaccine to people in the Phase 2 priority population, initially, continuing onto further priority groups sequentially in accordance with Australia’s COVID-19 vaccine national rollout strategy, within the TGA approved product information for the dose frequency.
- Using an appropriately qualified and authorised workforce in accordance with jurisdictional requirements to administer the vaccine, which may include registered: pharmacists, nurse practitioners, nurses and Aboriginal Health Workers, if applicable.
- Use of the National Booking System which is being established to provide a single point of entry to people who require vaccination. The role of the National Booking System and the relationship with other Pharmacy Systems will be finalised in coming weeks, with the intention of avoiding duplication.
- Within practical limits, and in consultation with the Commonwealth Department of Health, have the willingness and scope to scale-up vaccination workforce and site with potentially short lead times.
- Meeting the requirements for COVID-19 vaccination sites, outlined in Attachment A.
- Facilitating support and care in cases of potential adverse events and provide real-time reporting of any adverse events to the TGA/relevant state/territory government department in line with relevant state or territory requirements.
• Providing clear and accessible information at the community pharmacy for patients before, during, and after vaccination. This includes use of Commonwealth Department of Health communications.
• Supporting mechanisms to facilitate proof of COVID-19 vaccination, including entering all vaccinations into the Australian Immunisation Register within an appropriate timeframe, ideally within 24 hours of administration;
• Being responsible for all on-premises clinical governance.

Differences in physical infrastructure (including vaccine storage capacity), workforce, patient population and usual service commitments mean there will be substantial variation in vaccine delivery capacity between community pharmacies. Community pharmacies will need to account for their local context and develop models of vaccine delivery which are most suitable to their setting; for example, some pharmacies may choose to utilise currently unused rooms, others may choose to dedicate specific sessions to vaccine delivery with or without expansion of total pharmacy hours. Models will need to take into account the anticipated increased clinical load. As the AstraZeneca COVID-19 vaccine is still under evaluation by the TGA, many of the specifics of vaccine storage and delivery have not yet been confirmed in the Australian setting, including storage duration, usable window of multi-dose vials and delivery schedules. Each of these influence potential vaccine throughput and risks of product wastage.

Community pharmacies approved through this EOI to administer the COVID-19 vaccine from Phase 2 may be triaged based on throughput and readiness to administer the vaccine. Rollout may be staggered over a number of tranches based on pharmacy preparedness, vaccine availability, geographical reach/spread and other logistical considerations. As the rollout progresses and more vaccines become available, it is intended that all section 90 approved community pharmacies who are willing and able to administer the COVID-19 vaccine will have the opportunity to participate.

References
The Pharmaceutical Society of Australia (PSA) Professional Practice Standards, Standard 11: Vaccination Service and the PSA Practice Guidelines for pharmacists providing immunisation services:
Funding

COVID-19 vaccines will be made available for free for everyone living in Australia, including all Australian citizens, permanent residents, and most visa-holders, including those not Medicare eligible. Patients who are not eligible for Medicare will be encouraged to attend a General Practice Respiratory Clinic or state or territory vaccination clinic to receive their vaccine.

Community pharmacies delivering the COVID-19 vaccine will be eligible for up to $42.00 in metropolitan areas and up to $48.00 in non-metropolitan areas for each person who completes the full (two dose) vaccination program at the same community pharmacy.

Funding for community pharmacies to administer vaccines will be provided on a fee for service basis, via the PPA. The second vaccination payment* will be higher than the first vaccination payment only where a patient receives both doses of the vaccine (within the TGA approved product information for dose frequency) at the same community pharmacy.

Consistent with the Australian Government’s commitment that the vaccine will be free, community pharmacies will not be permitted to charge patient co-payments for vaccine administration.

Where any part of a service is delivered through any other Federal, state or territory, or private program, the service cannot be claimed through this program.

<table>
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<th>Payment metropolitan (MM 1)</th>
<th>Amount</th>
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<tbody>
<tr>
<td>Dose 1</td>
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<tr>
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<th>Payment non-metropolitan (MM 2-7)</th>
<th>Amount</th>
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<tbody>
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<tr>
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*The second vaccination payment will be higher than the first vaccination payment only where a patient receives both doses of the vaccine (within the TGA approved product information for dose frequency) at the same community pharmacy. Otherwise, payment for a single dose administered through a community pharmacy will be in accordance with the Dose 1 rate outlined above.
Training requirements

Training requirements for people administering vaccines are being developed in line with guidance from vaccine manufacturers, jurisdictional legislation and reporting requirements for COVID-19 vaccines. All providers administering a COVID-19 vaccine will need to have undertaken routine immunisation training specific to their health profession, as well as COVID-19 vaccine specific training which the Commonwealth Department of Health will make available. This training will be available online and is planned to be available by the end of January 2021. Every person administering vaccines must have evidence that they have appropriate qualifications in line with jurisdictional requirements and have completed the COVID-19 specific training.

Physical infrastructure

See Attachment A for specifications.

What the Australian Government will provide

Participating community pharmacies will receive vaccine stock and access to a National Booking System.

Assistance with provision of personal protective equipment (PPE) where indicated, vaccination related consumables (including needles, syringes, alcohol wipes, labels etc) will be considered on a case by case basis.

Information for patients about the COVID-19 vaccination, including to support the informed consent process, potential adverse events following vaccination, and the need to return for a second vaccine dose.

Selection criteria, processes and outcomes

The PPA will receive and review all EOs according to the following criteria:

1. **Capability**: Section 90 approved pharmacies that can provide safe vaccination services according to the specifications in Attachment A and willingness to undertake COVID-19 vaccination specific training.

2. **Capacity and volume**: Ability to administer, track, record, store, maintain and manage vaccination services with equitable access to all eligible people on a large scale, as per the site specifications outlined in Attachment A.

3. **Lead Time**: Ability to accelerate administration of vaccination services to meet nominated timeframes.

4. **Population coverage and access**: Additional consideration may be placed on pharmacies servicing populations in low-access geographic areas or with specific access needs.

Requests for clarification

Potential applicants can seek clarification on the EOI process from the PPA Support Centre via support@ppaonline.com.au. Common questions and their responses will be made available via a webpage to be established on the PPA’s website. The webpage, which is currently being established, will be at www.ppaonline.com.au/covidvaccine-eoi.

This documentation outlines all the information currently available. Whilst we appreciate that the more information you can receive on logistics (delivery cycles, vaccine vial volumes, the national booking system etc) will inform your EOI, we are unlikely to be able to provide further detail at this stage. We will continue to provide information as it becomes available.
Lodgement of EOI

As indicated previously, the Department of Health has engaged the PPA to coordinate the EOI process.

The PPA is currently developing an online response form for completion by interested community pharmacies. A link to the online response form will be emailed to community pharmacies with an account on the PPA Portal on Friday 5 February 2021. The online response form will require pharmacies to:

- Provide information regarding their capability, including a response as to whether they meet, or will meet, the site readiness requirements provided at Attachment A
- Submit information regarding their capacity, including information such as opening hours, staffing levels and estimated number of vaccines able to be administered daily
- Provide a declaration in relation to the responses included in the EOI.

The PPA will work collaboratively with the Department to consider each EOI and approve community pharmacies to participate in the delivery of COVID-19 vaccines. A notification regarding approval will be emailed to each community pharmacy that submits an EOI. Timing for this notification is to be confirmed.

Timeline

<table>
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<tr>
<th>Date</th>
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<tr>
<td>1 February 2021</td>
<td>EOI document released</td>
</tr>
<tr>
<td>5 February 2021</td>
<td>Link to EOI response form sent</td>
</tr>
<tr>
<td>19 February 2021</td>
<td>EOI close date / Last date for submitting EOI responses</td>
</tr>
<tr>
<td>19 March 2021 (TBC)</td>
<td>Respondents notified of outcome</td>
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Attachment A: ATAGI site requirements for COVID-19 vaccination in community pharmacies

The following site readiness requirements for COVID-19 vaccination in community pharmacies have been developed by the Australian Government in consultation with expert advice from the Australian Technical Advisory Group on Immunisation (ATAGI) and standards outlined in the Australian Immunisation Handbook. Identified/participating community pharmacies must confirm compliance with the minimum requirements outlined in the below requirements prior to delivery of vaccine doses.

1.0 Physical environment

1.1 Have adequate space for patients waiting to be vaccinated that observes physical distancing requirements, and is sheltered from weather elements

1.2 Have a private and quiet space for consultation with patients and vaccinator (including obtaining informed consent, answering patient questions and assessment of any conditions that may preclude vaccination or require further assessment and administration of vaccine)

1.3 Have a dedicated area (e.g. clean, and away from direct patient contact and distraction), separate from areas that provide other clinical services at the same time, where vaccines from multi-dose vials may be drawn up, labelled, and prepared for administration

1.4 Have a dedicated, clean, well-lit space for administration of the vaccine to patients, including a desk and chairs for patients, carers/parents and vaccinator(s)

1.5 Have adequate space for patients to be seated to wait and be observed post-vaccination that observes physical distancing requirements (note this may be the same as the waiting area) and is in accordance with jurisdictional requirements and guidance

1.6 Have safe and directed access in pharmacy areas to allow movement of staff between areas while minimising the risk of workplace incidents (e.g. moving doses from preparation area to patient administration area, accessing refrigerators or cool boxes, etc.)

1.7 Adequate handwashing facilities for staff, and antimicrobial hand sanitisers available. Have visual reminders and cues in place to reduce the risk of errors

1.8 Have a process in place to safely dispose of unused vaccines, in accordance with TGA and other regulatory requirements

1.9 Have adequate sharps disposal bins, appropriate for the volume of patients, and securely placed and spaced to mitigate the risk of needle stick injuries

1.10 Appropriate security provisions to ensure no unauthorised access to vaccine doses

1.11 Have ready access to appropriate emergency equipment for managing anaphylaxis

1.12 Other useful information - Advise if you have access to other emergency equipment, such as oxygen or defibrillator
### 2.0 Workforce requirements

2.1 Adequate number of appropriately trained staff to ensure clinical safety including:

2.1.1 Vaccinators (COVID-19 trained health worker under the supervision of an Approved Pharmacist and in accordance with state and territory regulations) to prepare and administer vaccines

2.1.2 Team leader (to direct clinic flow)

2.1.3 Clerical staff

2.1.4 First aid staff, additional to vaccinating staff as per jurisdictional requirements

2.1.5 Staff to manage staff/patient/stock safety (if/when required)

2.2 Acknowledge that everyone administering vaccines must have appropriate training and/or qualifications in line with jurisdictional requirements, and have received adequate specific training in COVID-19 vaccination, including regarding the use of multi dose vials

2.3 Have documented procedure for managing and recording training of staff handling vaccine doses

### 3.0 Cold chain management

3.1 Have adequate number and capacity of refrigerators to store vaccines (in addition to usual pharmacy stock requiring refrigeration), with refrigerators to be maintained and monitored at 2 – 8 degrees Celsius

3.2 Have appropriate refrigerators and opaque containers to store vaccine syringes that have been prepared for administration under appropriate temperature conditions and protected from light from the time they are prepared till the time they are administered

3.3 Have specific procedures associated with receipt of vaccine doses including packaging acceptance, temperature checks

3.4 Sites [community pharmacy] must be able to adhere to the Strive for 5 guidelines\(^1\) and will need to have or be able to develop policies for cold chain management including:

3.4.1 Able to monitor the temperatures of the refrigerator(s) where vaccines are stored

3.4.2 Have an appropriate policy and protocol in place to respond to temperature breaches, including relocating vials to another refrigerator (or freezer, where relevant) and responding at times where clinic [community pharmacy] may not have any staff present

*More guidance regarding cold chain management will be provided by the Commonwealth.*

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4.0 Multi-dose vial administration

4.1 Have a process in place to vaccinate multiple patients per vial/dose (minimum number of patients to be specified by the Australian Government)

5.0 Technology and Record Keeping

5.1 Access to community pharmacy service management system (e.g., MedAdvisor or Guild Care etc) or other patient management system and Australian Immunisation Register via Provider Digital Access (PRODA)

5.2 There will be a requirement for the ability to connect with and use a National Booking System, as necessary.

5.3 Ability to meet mandatory requirements regarding reporting of all vaccine administration into AIR within an appropriate timeframe, ideally within 24 hours

5.4 Have a process of obtaining and recording informed consent

Be able to identify individuals where immunisation should take place in a specialist facility (e.g., history of anaphylaxis), or where further consultation may be required (e.g., pregnancy)

5.5 Be able to develop policies and procedures for:

5.5.1 Identifying individual vaccine recipients, checking to confirm any record of previous receipt of any COVID-19 vaccine doses (including date and brand of product received), and recording immunisation encounters (electronic records are preferable)

5.5.2 Labelling syringes when they are drawn up from multi-dose vials, including date and time of preparation and of expiry

5.5.3 Recording and reporting of vaccines used and stock on hand and those discarded, including reasons for discarding, and vaccine wastage

5.6 Ability to monitor, manage and report adverse events (including complying with relevant state/territory requirements) following immunisation, including anaphylaxis and emergency management (e.g., calling for an ambulance).

6.0 Waste disposal

6.1 Facilities to dispose of all waste, including sharps and unused vaccine appropriately in accordance with standard precautions (TGA, OGTR (if appropriate) and other regulatory requirements for vaccines)

7.0 Personal protective and other equipment

7.1 Appropriate PPE, as per requirements in the Australian Immunisation Handbook and jurisdictional requirements

7.2 Labels for syringes (if filling in advance)

7.3 Antimicrobial/disinfectant wipes to clean stations between patients

7.4 Sanitation equipment for administration site
### 8.0 Accreditation and other regulatory requirements

#### 8.1 Approved Section 90 Pharmacy

#### 8.2 All immunisers to be authorised under the relevant state or territory Public Health Act/ Medicines and Poisons Act to provide vaccines

#### 8.3 Have AIR registration required for the relevant community pharmacy, as advised by the Commonwealth

#### 8.4 Compliance with compulsory COVID-19 training

### 9.0 Accessibility and cultural safety

#### 9.1 Will need to be able to develop [or have existing] policies and procedures for ensuring services are culturally safe for Aboriginal and Torres Strait Islander peoples

#### 9.2 Will need to have arrangements for identification of and assistance for those with additional or specific needs, including:
- Ensuring culturally appropriate policies and procedures for multicultural communities
- Qualified interpreters available when needed such as through the Australian Government Translating and Interpreting Service (TIS)
- Translations to languages other than English

#### 9.3 Will need to have arrangements to provide accessibility to those with Disability (including intellectual disability and those with other mobility issues)

### 10.0 Management of the community pharmacy

#### 10.1 Standardised screening process to exclude patients who display symptoms of COVID-19, and refer for appropriate assessment for COVID-19 or other conditions (as per guidance provided in the ATAGI Guiding Principles for Maintaining Immunisation Services During the COVID-19 Pandemic)

#### 10.2 Standardised screening process for contraindications, receipt of previous doses of COVID-19 vaccines and/or receipt of other vaccines (observing any interval requirements)

#### 10.3 Clear assignment of duties and responsibilities of all staff and clear plan of workflow, particularly regarding drawing up from a multi dose vial and administering individual vaccine doses drawn from a particular vial for each clinic [community pharmacy vaccination] session

#### 10.4 Incident management in place, with staff knowledgeable about relevant procedures and able to report any clinical incident (e.g. injury in workplace) to the appropriate health authorities

#### 10.5 Has process in place to manage injuries to workforce (e.g. needle stick injury)

#### 10.6 Process in place to prevent and manage violence or aggression in the clinic
11.0 Vaccine administration equipment requirements for each patient vaccination - *the Commonwealth will provide majority of consumables required for the vaccine*

Ability to securely store items listed below:

11.1 Sterile 2mL or 3mL syringes (latex free)
11.2 Sterile drawing up needle (19 or 21 gauge recommended to reduce risk of coring)
11.3 Sterile administration needle (22-25 gauge), 25mm for adults, 38mm for very large or obese person
11.4 Alcohol wipe (for vials)
11.5 Cotton wool ball
11.6 Hypoallergenic tape or latex free band aid
11.7 Dish for drawn up vaccine (kidney dish)
11.8 Sharps containers
11.9 Containers for disposal of biohazardous waste
11.10 Saline (as required)
11.11 Adrenaline 1:1000
11.12 1mL ‘single use only’ syringes, with 23 gauge needle
11.13 Paediatric and adult size Guedel airways
Attachment B: online EOI response form

Respondent Information
Please provide all of the following details.

Name of legal entity: [insert]
Section 90 ID number [insert]
Registered to upload to AIR [insert]
Trading/Business name: [insert]
ABN (if applicable): [insert]
Contact person: [insert]
Contact person position title: [insert]
Registered address or address of principal place of business: [insert]
E-mail address: [insert]
Telephone number: [insert]
What size is the Respondents business?
- Less than 10 employees
- Between 10 and 20 employees
- More than 20 employees

Declaration
Do you confirm that you are a duly authorised representative of the named legal entity and acknowledge that this premises meets the requirements for COVID-19 vaccination community pharmacies outlined in this Expression of Interest.

Do you also acknowledge that the data from this Expression of Interest will be held by the Department of Health and the PPA for the purpose of informing the COVID-19 vaccination program rollout. It may be provided to 3rd parties (such as vaccine delivery partners) as relevant. Your data will not be used beyond this purpose without your knowledge.

Signature
Title

Date / / 2021
Current services
- Does your community pharmacy serve the following community groups?
  - Aboriginal and Torres Strait Islander people
  - LGBTQI+ communities
  - Culturally and linguistically diverse communities
  - People with a disability
  - Older Australians

Capability
- Please indicate any pharmacy experience in vaccine delivery:
  - National Immunisation Program
  - Influenza
  - Measles, Mumps, Rubella
  - Pertussis
  - Meningococcal
  - Other (free text)
- Do you meet all the requirements outlined within the site requirements at Attachment A? (tick boxes)
  - Physical environment (Items 1.1 to 1.11)
  - Workforce requirements (Items 2.1 to 2.3)
  - Cold chain management (Items 3.1 to 3.4)
  - Multi dose vial administration (Item 4.1)
  - Technology and record keeping (Items 5.1 to 5.6)
  - Waste disposal (Item 6.1)
  - Personal protective and other equipment (Items 7.1 to 7.4)
  - Accreditation and other regulatory requirements (Items 8.1 to 8.4)
  - Accessibility and cultural safety (Items 9.1 to 9.3)
  - Management of the community pharmacy (Items 10.1 to 10.6)
  - Vaccine administration equipment requirements for each patient (Items 11.1 to 11.13)
- Please indicate if you hold Quality Care Pharmacy Program (QCPP) accreditation or will be in the process of attaining accreditation within six months of lodging the EOI to participate in the COVID-19 Vaccination Program (the Commonwealth may waive the requirement to hold or be seeking accreditation in order to ensure patients can access the program).

If you currently do not meet one or more of the site requirements (and have not ticked the box), please provide further detail, along with your plans to meet the requirements in the future [free text].

Capacity
- Please describe current opening hours (free text) + number of hours per week (number)
- Do you propose to extend opening hours to accommodate COVID-19 vaccine delivery?
  - If so, please describe proposed opening hours (free text) + number of hours per week (number) for administering COVID-19 vaccines
- Number of current staff currently eligible to deliver vaccines (number)
- Please describe any plans to boost this workforce (either through recruitment or accreditation of existing staff) (free text)
- How many COVID-19 vaccines do you anticipate being able to deliver daily? (number)
- Would you be able to commence providing COVID-19 vaccinations from 1 May 2021? (Yes / No)
- If no, when could you commence? (free text)
How long would you be able to continue to provide COVID-19 vaccination services? (<2 months, 2 – 4 months, 4 – 9 months)?