



Circular 016/2021

7th July 2021

Dear Pharmacist,

Please find enclosed from Pat Healy, National Director, Clinical Programme Implementation & Professional Development, a communication outlining the COVID-19 Vaccine Janssen® Service Update for people aged 18 - 34.

FAQs have been developed and are attached to assist Pharmacists at this time.

Clinical Guidelines and Information for Healthcare Professionals are available at:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/>

The Operational Guidance has been updated to reflect the updated HSE Implementation Plan. It will be available at <https://www.hse.ie/eng/about/who/gmscontracts/pharmacist-contracts/> and will also include a Guide to Managing Multiple COVID-19 vaccines in a Community Pharmacy.

Yours faithfully,

A handwritten signature in blue ink, appearing to read 'Shaun Flanagan'.

Shaun Flanagan
Primary Care Eligibility & Reimbursement



Office of National Director, Clinical Programme
Implementation & Professional Development
HSE, Dr Steevens Hospital, Dublin 8. D08 W 2A8

Date: 2nd of July 2021

Circular 016 / 2021

Re: COVID-19 Vaccine Janssen® Service Update

Dear Pharmacist

You will be aware that the Minister has announced that from Monday July 5th, people aged 18 - 34 can choose to get vaccinated with the single shot COVID-19 Vaccine Janssen® from their local pharmacy. This revision of the HSE implementation plan is possible following the updated advice from the National Immunisation Advisory Committee (NIAC) regarding the possible use of adenoviral vector vaccine for those aged under 50 years of age.

- The Opt-In model will run in parallel with the current age-based cohort plan
- The Opt-In model will provide 18 -34 year olds with an opportunity to receive a Janssen vaccine in participating pharmacies a number of weeks in advance of when they would receive an mRNA vaccine (as part of the current age-based cohort model)

HSE Pharmacy Working Group

The HSE has in place a working group representative of stakeholders including the IPU and the PSI, which meets weekly and through which the overall plan, operating guidance and other arrangements have been developed on a partnership basis, as part of the overall national vaccination programme. The working group will continue to monitor progress and adjust plans as necessary as the programme progresses.

Operational Guidance

The Operational Guidance has been updated to reflect the updated HSE Vaccine Implementation Plan. It will be available at <https://www.hse.ie/eng/about/who/gmscontracts/pharmacist-contracts/> and will also include a Guide to Managing Multiple COVID-19 vaccines in a Community Pharmacy. This Opt-In model will commence in line with the operational guidance from Monday next, 5th July 2021, which should provide sufficient time for pharmacists to become familiar with the updated guidance and the specific issues relating to informed consent.

Informed Consent

It is important that individuals requesting a single dose Janssen® vaccine are enabled to provide informed consent. This is to ensure that anyone under 35 years of age wishing to avail of earlier access to vaccination is appropriately informed of the rare side-effects associated with the adenoviral vector vaccines.

The pharmacist, who has specific expertise in medicines and their use, is well placed to explain the risks and benefits to be considered for and with the individual. The COVID-19 Vaccine Janssen® Vaccination Consent Form to be used is published through the links below. It must be completed and retained at the pharmacy for every individual in the younger cohort who elects to have a Janssen vaccine. Please find below links for all the developed materials for pharmacists to support the programme:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/janssen-consent-form.pdf>

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/covid-19-vaccines-for-18-34-yr-olds.pdf>

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/rates-per-100k-of-deaths-and-icu-from-covid-19-and-spontaneous-reports-of-all-clotting-events.pdf>

The National Immunisation Office (NIO) is arranging in the normal way for the printing of hard copy leaflets, which will be distributed to pharmacies over the coming week, in the meantime, the links above will provide you with the capacity to print copies.

Distribution of vaccine to pharmacies

You will be aware that over 750 pharmacies are already participating in the Janssen vaccine over 50s programme with approximately 60,000 already allocated to and with approximately 10,000 doses already administered. In line with the updated operating guidance, the programme will commence on Monday next utilising the existing volume of vaccine already distributed to pharmacies.

The distribution approach, as agreed through the working group, will be a push model distributing available vaccine on a fair and equitable basis among the pharmacists participating in the programme. Vaccines will be distributed in pack sizes of 100 doses and/or 50 doses with allocations of vaccine at all times determined by the availability of supply. While allocations of vaccine are at all times limited by the supply, the HSE will, in line with current policy, ensure early distribution of all available vaccines, with a view to maximising uptake across the target population. Additional consumables will also be made available aligned to vaccine delivery volumes.

The intention is that next week c.80,000, vaccines will be distributed commencing over Wednesday, Thursday, Friday and into the following week. It is essential that the vaccine is administered in a timely fashion and that the returns through PharmaVax are completed on a real time basis as this information will inform decisions on further supply, to ensure that distribution of vaccine is targeted reflecting geographic uptake.

You will be aware that a team has been established as agreed through the working group to support the pharmacists in the implementation of the programme and to deal with pharmacist issues and concerns as they arise. The Chief Pharmacist and her team in PCRS have also continued to provide a dedicated support to this overall programme. Relationship managers will be in contact with pharmacies and there is no need to place an additional order.

We are aware that some pharmacies who did not accept delivery of their original allocation wish to re-join the campaign. Where a pharmacy wishes to re-join the campaign, they should forward their details to include their GMS Number and Cold Chain account number to pharmacy.response@hse.ie. There are a number of elements to be organised in such a 're-join' to include 'on boarding' to the PharmaVax system which will take some time to complete.

The HSE thanks the IPU as well as community pharmacists and pharmacy teams for their continued support to ensure we can roll out the vaccine in as safe and timely a manner as possible.

Yours sincerely,



**Pat Healy,
National Director,
Clinical Programme Implementation
& Professional Development**



COVID-19 vaccination service in Community Pharmacy FAQs

To assist and support community pharmacy contractors in running a COVID-19 vaccination campaign, the following FAQs have been developed.

GENERAL VACCINE QUERIES

Q1. *Which COVID-19 vaccine will I be administering from my pharmacy?*

A. COVID-19 Vaccine Janssen® and Comirnaty® (Pfizer BioNtech) Vaccine are the Vaccines that are being delivered to selected community pharmacies.

Q2. *Where can I access HSEland vaccine training?*

- A.** This is the link that is operational currently: <https://t.co/FLsEe3RHfl>
https://twitter.com/hse_hseland/status/1401850438668914688?s=27
- B.** Pharmacists vaccinating 18-34 - NIO has developed a consent form, decision aid and created a dedicated page for pharmacists which will be of assistance.
them. <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/phvacc1834/>

Q3. *What are the delivery arrangements for the vaccines?*

A. Deliveries of Vaccine product to participating pharmacies have started. You will be contacted by 'Vision', the support service to Coldchain to validate key information. 'Vision' will also be contacting pharmacies in due course to inform them of the anticipated day of delivery on an ongoing basis.

Consumables will be automatically delivered to match your allocated supply. Further information will be provided in advance of subsequent phases of the programme.

HSE leaflets, patient information leaflet (PIL) from the manufacturer, aftercare leaflets and record cards will also be delivered to participating community pharmacies.

Q4. *Can I amend the size of the vaccine delivery?*

A. There is not an opportunity to amend the size of the delivery due to product pack sizes and FMD considerations. As it is a cold chain product, it is not possible to return the Vaccine to Coldchain.

Q5. *If a situation arises whereby individuals from the contingency list fail to show up where there are unused doses in a vial, what is the advice?*

A. Contingency planning is a focus in all the published documentation. Frequency of occurrence will be a consideration for the HSE in their overview at the end of this campaign. It is important that appropriate Vaccine clinics are scheduled for each vial to reduce the risk of this occurring. In the context of the *Comirnaty*[®] (Pfizer BioNtech) Vaccine, your contingency list could encompass the next patient cohort (i.e. 30 – 35 age group).

Q6. *The portal is currently open for the 35-40 age group. Are there many individuals in the over 50 category who have not yet been vaccinated?*

A. The HSE does not have a central list of unvaccinated over 50s. The Central Statistics Office records suggest that there remains a significant number of people over 50 who have not been vaccinated. The figures suggest 140,000 and even taking into account the last census was 2016 - that would suggest more than 100,000 remain to be vaccinated.

Q7. *Some staff members in this pharmacy have yet to receive their second dose of the Vaccine. How can I ensure that all staff members will be fully vaccinated in advance of Vaccine rollout from my pharmacy?*

A. The Vaccine Leads are progressing people for their second dose in line with availability of vaccine in sequential order. The PCRS is not in a position to influence scheduling of recalls.

Q8. *Can I access PharmaVax currently?*

A. When selected to provide a HSE Vaccine service, notification to Healthmail to progress 'on boarding' with PharmaVax occurs. If pharmacies opted out of the 'Over 50s' campaign, they are a little later in the onboarding process.

Q9. *How do I submit a vaccination claim for reimbursement?*

- A.** The Pharmavax systems feeds the information into the National COVAX system which then transfers the information to the PCRS so that payments are made for vaccinations administered.

Q10. *Can I see if a patient has previously received a COVID-19 vaccine in PharmaVax?*

- A.** The second phase of PharmaVax (just delivered) will enable vaccination history lookup in order to have visibility of vaccination records on COVAX.

Q11. *How do I submit a claim for reimbursement for Anapen®?*

- A.** The HSE will issue a circular in July with the precise details for claims at the end of July. It will most likely be a manual claim format on a pharmacy specific stock order form. Any IT solution has necessarily been deferred due to the cyber-attack.

Q12. *Can I vaccinate someone who does not have a PPSN? Should I administer the vaccine as a chargeable service in this instance?*

- A.** No - the service is free of charge to all. You cannot charge the individuals. It is recognised that there may be people who genuinely do not have a PPSN – Roma / Immigrants / people in direct provision / homeless individuals etc. The Operational Guidance sets out that there will be an exceptional process for reimbursement of such claims. In these circumstances, please ensure, that at a minimum, you retain a record in the pharmacy of the Name / Address/ Date of Birth / Place of Birth / Mobile number for each person you vaccinate where they genuinely do not hold a PPSN. It would be prudent to retain a copy of photographic evidence of identification / GNIB / passport etc.

Q13 *Is it possible to delete a patient who I have already registered on Pharmavax? (The patient changed their mind and was not vaccinated in the pharmacy)*

- A.** There is currently no edit facility on the Pharmavax system. Make a record on the PMR of the patient for your own records. It is possible that the 'data lake' team may make further enquiries.

Q14. *I have been approved to administer the COVID-19 Vaccine Janssen® vaccine, however I would also like to partake in the Comirnaty® (Pfizer BioNtech) Vaccine. Why wasn't I contacted about this?*

A. The invites went out through the Pharmaceutical Society of Ireland as the HSE was in the initial throes of the cyberattack. A separate process was used to determine suitability of pharmacies to provide the Comirnaty® (Pfizer BioNtech) Vaccine. Pharmacies near to HSE Vaccination Centres were not selected.

COVID-19 Vaccine Janssen®

Q1. *Can I offer the Vaccine to the under 50s?*

A. As you are aware, the Minister has announced that from Monday July 5th, people aged 18 – 34 can choose to be vaccinated with the single shot COVID-19 Vaccine Janssen®. This revision of the HSE implementation plan is possible following the updated advice from the National Immunisation Advisory Committee (NIAC) regarding the possible use of adenoviral vector vaccine for those aged under 50 years.

Q2. *When will I receive my next allocation of COVID-19 Vaccine Janssen® Vaccine?*

A. All pharmacies who received vaccine already will receive a further allocation starting on Wednesday, 7th July. Those who did not accept their original allocation will be rejoined in the coming days and confirmed for the next schedule of deliveries to start from the 14th July.

Q3. *How can I secure additional stocks of COVID-19 Vaccine Janssen® Vaccine to satisfy demand locally?*

A. Provision of the Vaccine to pharmacies is limited by national supplies and allocation is subject to distribution constraints.

Comirnaty® (Pfizer BioNtech)

Q1. *What patient cohort can I offer the Comirnaty® (Pfizer BioNtech) Vaccine to?*

A. As the HSE calls for younger age groups to register on the Portal, you may align with this age cohort in administering the Comirnaty® (Pfizer BioNtech) Vaccine in community pharmacy settings. For information, the Portal will open for the 30 – 34 age group from Thursday, 8th July.

Q2. *When is delivery scheduled to take place?*

A. Delivery will be across two weeks starting at the end of June. Deliveries are scheduled every two weeks thereafter with no requirement to transmit an order.

Q3. *What quantity of the Comirnaty® (Pfizer BioNtech) vaccine will be delivered to my pharmacy?*

A. Initial quantities have been distributed. The logic of providing Pfizer vaccine to pharmacies was to enable geographical spread but supplies will be modest.

Q4. *Can I provide a second vaccine dose to someone who availed of their first Comirnaty® (Pfizer BioNtech) dose elsewhere (e.g. in a mass vaccination clinic)?*

A. No – Patients should return to their original location of vaccine service – otherwise there is a risk that the ‘data lake’ may not link records such that a digital certificate can be seamlessly generated.

MISCELLANEOUS QUERIES

- **Mixing of vaccines – see advice below from the National Immunisation Office (NIO)**

The National Immunisation Advisory Committee (NIAC) Expert Committee of the Royal College of Physicians in Ireland makes recommendations on vaccination policy.

The National Immunisation Office provides the guidance from the National Immunisation Advisory Committee recommendations only.

Both the National Immunisation Advisory Committee and the World Health Organization have to date always advised the Covid vaccines are not interchangeable as there is inadequate data available to show mixing Covid vaccines is effective. The vaccines are also not licensed to be given in a mixed schedule.

- **Issues with Healthmail and access to PharmaVax**

Healthmail wrote to Pharmacies earlier this year with a view to streamlining the process of onboarding. Where you have formally updated and notified Healthmail of a new address, the updated address is needed for purposes of access to PharmaVax. The HSE prioritised 'onboarding' those pharmacies who confirmed deliveries to Healthmail. Each addition is subject to the same checks and balances as was required for the initial data load. This means that there may be a time lag in adding a pharmacy that had previously opted out, back into the roll out programme.

- **My pharmacy was approved to administer the Vaccine, however I opted out. How can I opt back in?**

Pharmacies wishing to rejoin the campaign may do so by emailing pharmacy.response@hse.ie in order to be added to the schedule of Vaccine deliveries from 14th July. Please include your pharmacy GMS number and Coldchain account number.

- **My pharmacy did not submit an Expression of Interest (EOI) to deliver a COVID-19 vaccination service as outlined in Circular 010/21, however I now wish to be considered for inclusion in the vaccination campaign. How may I proceed?**

Pharmacies that did not formally complete an EOI and now wish to, should send a completed EOI to pharmacy.response@hse.ie.

VACCINE SUPPORT

Issue	Contact details	
Supply of consumables	JMC Logistics - Vision make the arrangements	
Vaccine allocation and delivery dates	PharmacyVaccines@vision.com	
Vaccine clinical queries	Immunisation@hse.ie	
Additional patient information leaflets, vaccine cards etc. required	immunisation@hse.ie	
Delivery discrepancies / damage in transit	vaccines@udd.ie	
EOI submission	Pharmacy.response@hse.ie	
PharmaVax – Healthmail password issues	ictsupport@three.ie	1800 800 002 (option 2)
PharmaVax – Verification code issues	ictsupport@three.ie	1800 800 002 (option 2)
PharmaVax – PSI details update	ictsupport@three.ie	1800 800 002 (option 2)
PharmaVax – Usability queries	a2ihids.support@healthmail.ie	087 1056654 087 2941377
Pharmavax – System issues	a2ihids.support@healthmail.ie	087 1056654 087 2941377

Please note that pharmacy.response@hse.ie should only be used for queries which cannot be directed to any of the resources outlined above.

In all email correspondence, please include the Pharmacy GMS number and Coldchain account number.