COVID-19 vaccine authorised by medicines regulator

- UK medicines regulator authorises first COVID-19 vaccine
- Pfizer/BioNTech vaccine meets regulator's strict standards of safety, efficacy and quality
- Vaccine to be made available across the UK to priority groups from next week

Tens of thousands of people will receive an effective and high-quality COVID-19 vaccine from next week, as the UK becomes the first country in the western world to authorise a vaccine.

Following rigorous clinical trials involving thousands of people and extensive analysis of the vaccine's safety, quality and effectiveness by experts from the Medicines and Healthcare products Regulatory Agency (MHRA), Pfizer/BioNTech's vaccine has been authorised for use in the UK.

Now authorisation has been granted, Pfizer will deliver the vaccine to the UK. In making the recommendation to authorise supply, the MHRA will decide what additional quality assurance checks may be required before a vaccine can be made available. Pfizer will then deliver the vaccines to the UK as soon as possible.

The NHS has decades of experience in rolling out successful widespread vaccination programmes and has put in place extensive deployment plans.

In line with the recommendations of the independent Joint Committee for Vaccination and Immunisation (JCVI), the vaccine will be rolled out to the priority groups including care home residents and staff, people over 80 and health and care workers, then to the rest of the population in order of age and risk, including those who are clinically extremely vulnerable.

The vaccine is given in 2 doses – 3 weeks apart – and data from clinical trials showed the vaccine is 94% effective in protecting people over the age of 65 from coronavirus, with trials suggesting it works equally well in people of all ages, races and ethnicities. There were also no serious safety concerns reported in the trials.

The UK was the first country to pre-order supplies of the vaccine from Pfizer/BioNTech, with 800,000 doses being made available next week and 40 million doses ordered overall – enough to vaccinate up to a third of the population, and the majority of doses anticipated in the first half of next year.

Health and Social Care Secretary Matt Hancock said:

> This is a momentous occasion and provides fresh hope that we can beat this pandemic, with the UK at the forefront of this

> revolutionary breakthrough.
>
> I can’t thank enough every single person who has contributed to this triumph – from the thousands of volunteers who took part in clinical trials, to the teams of expert scientists and clinicians at the MHRA who carefully analysed reams of data.
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> This vaccine, when combined with effective treatments, will form a vital part in making COVID-19 a manageable disease, hopefully allowing us to return to normality in the future.
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> This work will take time so for now we must all play our part and abide by the local restrictions to suppress the virus and protect the NHS as they start this vital work.

Business Secretary Alok Sharma said:

> Since the start of the pandemic, every single person has made an immense sacrifice to protect themselves, their loved ones and the health of our nation. Through it all, we have remained united to defeat a virus that has taken too many before their time.
>
> As a nation we owe every scientist, clinician and trial volunteer an enormous debt of gratitude for their victory won against odds that at times seemed impossible. It is thanks to their efforts, and of our Vaccine Taskforce, that the UK was the first country to sign a deal with Pfizer/BioNTech and will now be the first to deploy their vaccine.
>
> While today’s breakthrough is a positive one, we will not end the pandemic overnight. But in years to come, we will look back and remember this moment as the day the United Kingdom led humanity’s charge against this terrible disease.

The MHRA started the rolling review of Pfizer/BioNTech’s data in October and the government asked the regulator to assess the vaccine for its suitability for authorisation under Regulation 174 of the Human Medicines Regulations, enabling the temporary supply of medicines to be authorised in response to a public health need, which the regulator has recommended.

NHS England will outline further details on deployment shortly, but the plans will include:

- hospital hubs for NHS and care staff and older patients to get vaccinated
- local community services with local teams and GPs already signing up to take part in the programme
- vaccination centres across the country, ensuring people can access a vaccine regardless of where they live

The global deployment of the Pfizer/BioNTech vaccine will require a huge logistical exercise over land, air and sea.

Pfizer has years of proven experience in cold supply chain management and delivering temperature-controlled vaccines to locations across the world. It has developed packaging and storage innovations for the vaccine, including specifically designed, temperature-controlled thermal shippers to maintain conditions of ultra-low temperatures.

Deputy Chief Medical Officer for England Professor Jonathan Van-Tam said:

> This is a remarkable day – congratulations to Pfizer/BioNTech and their researchers, and to all my colleagues in the Vaccine Taskforce for their tremendous work to get us to this point, and I want to thank the MHRA experts, including the experts at the Commission on Human Medicines, who have tirelessly and rigorously assessed the safety, effectiveness and quality of the vaccine.
>
> This vaccine has now passed all of the extensive checks needed for authorisation to supply and will soon be ready to be delivered to the NHS.
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> To all those who are eligible – this is the start of vaccine supply for the UK. In time, you will be invited to book your appointments to get your vaccinations. I urge you to be ready, and to help make the process as smooth as possible. For now, stay patient, and keep yourselves safe by continuing to follow the rules and maintaining social distancing.

As the JCVI has made clear, there will need to be flexibility in terms of operational challenges around delivery of the vaccine to those in care homes. In line with the advice, every effort will be made to supply vaccine and offer vaccinations to care home residents and we will deliver the vaccine according to clinical prioritisation and operational necessity.

The vaccine will be available for free across the UK and the government is working with the devolved administrations to ensure it is deployed fairly across the UK under the Barnett formula.

Through the Vaccine Taskforce, the UK has secured early access to 357 million doses of 7 of the most promising vaccine candidates so far. To date, the government has invested over £230 million into manufacturing a successful vaccine. In the Chancellor's Spending Review, published on 25 November, it was announced that the government has made more than £6 billion available to develop and procure successful vaccines.

Vaccine Deployment Minister Nadhim Zahawi said:

> The NHS has decades of experience in delivering highly successful vaccination programmes and has put in an enormous amount of work to

> get ready to roll out a COVID-19 vaccine to those most in need as quickly as possible.
>
> Once extensive quality checks have taken place, it can be transported to vaccination sites across the UK and carefully unpacked ready for vaccinations to begin this month, with large-scale vaccination happening in the new year.

Chair of the government's Vaccine Taskforce Kate Bingham said:

> Today is a momentous occasion and the UK will go down in history as the country that led the world in one of the biggest scientific breakthroughs of our time.
>
> I am incredibly proud of my team in the government's Vaccine Taskforce who have worked tirelessly over the last six months to negotiate agreements with vaccine developers around the world and step up the UK's vaccine manufacturing and logistics capabilities, so any potential candidate can be rolled out as soon as possible.
>
> The work does not stop here. The taskforce will continue to monitor vaccines being developed around the world so that we have a diverse mix available, as well as ensure the UK is able to respond quickly to any future health crises.

Background information

The full prioritisation list is on GOV.UK and is as follows (in order of priority):

1. Residents in a care home for older adults and their carers
2. All those 80 years of age and over and frontline health and social care workers
3. All those 75 years of age and over
4. All those 70 years of age and over and clinically extremely vulnerable individuals
5. All those 65 years of age and over.
6. All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
7. All those 60 years of age and over
8. All those 55 years of age and over
9. All those 50 years of age and over

Deployment plans

Despite the huge complexities, staff have been working to ensure that when it is approved and ready for use, the NHS is able to vaccinate from day one. The time between approval and deployment of a vaccine like this might typically

be expected to take around a week, due to travel and extensive safety and quality control checks.

The steps include:

- Pfizer dispatches the vaccine from Belgium and it will arrive in the UK. This is followed by a post-delivery quality assurance process to ensure the vaccine's quality and integrity has been maintained.
- Once all checks are complete the vaccine will be made available to order by authorised sites in the NHS.
- Orders will be packed and shipped as appropriate for the required storage temperature of each vaccine. Generally vaccines will be delivered on a next day delivery schedule except for more remote parts of the UK where delivery may take 48 hours.
- Delivering the Pfizer/BioNTech COVID-19 vaccine is complex as it needs to be stored at very cold temperatures and moved carefully, so at first we will only be able to deliver it from 'hospital hubs'. Defrosting the vaccine takes a few hours and then additional time is required to prepare the vaccine for administering.
- Stage one of the phased roll-out of the vaccine will begin when it has been distributed.

Further information

Vaccination will be managed by the health services in each nation: NHS England and NHS Improvement, NHS Wales, NHS Scotland, and Health and Social Care Northern Ireland.

Until the end of December, and as part of the transition period, vaccines must be authorised via the European Medicines Agency and that authorisation will automatically be valid in the UK.

However, if a suitable COVID-19 vaccine candidate, with strong supporting evidence of safety, quality and effectiveness from clinical trials becomes available before the end of the transition period, EU legislation which we have implemented – Regulation 174 – allows the MHRA to temporarily authorise the supply of a medicine or vaccine, based on public health need.

Through the government's Vaccine Taskforce, the UK has secured early access to 357 million doses of 7 of the most promising vaccine candidates, including:

- BioNTech/Pfizer for 40 million doses
- Oxford/AstraZeneca for 100 million doses
- Moderna for 7 million doses
- GlaxoSmithKline and Sanofi Pasteur for 60 million doses
- Novavax for 60 million doses
- Janssen for 30 million doses
- Valneva for 60 million doses