

# Second COVID-19 vaccine authorised by medicines regulator

- Vaccine to be made available across the UK to priority groups from Monday
- The UK has pre-ordered 100 million doses of the vaccine
- The NHS will prioritise giving the first dose of the vaccine to those most in need following advice from the Joint Committee on Vaccination and Immunisation (JCVI) and the UK's Chief Medical Officers

The second COVID-19 vaccine has been authorised for use in the UK, allowing a significant expansion of the immunisation programme with hundreds more vaccination sites opening in the coming weeks and months to protect those most at risk from the virus.

The UK regulator has accepted the recommendation of the Commission on Human Medicines and authorised the Oxford University/AstraZeneca COVID-19 vaccine. This follows months of rigorous clinical trials involving tens of thousands of people and an extensive analysis of the vaccine's safety, quality and effectiveness by the Medicines and Healthcare products Regulatory Agency (MHRA).

The vaccine is highly effective in preventing disease, including in the elderly, and vaccinations will begin from next week.

The UK was the first in the world to sign an agreement with Oxford University/AstraZeneca, securing access to 100 million doses of the vaccine on behalf of the whole of the UK, crown dependencies and overseas territories. Hundreds of thousands of doses are available from Monday 4 January with more to be delivered over the coming weeks and months so that, alongside the existing Pfizer/BioNTech vaccine, the UK's vaccination programme can continue its steady expansion over the first part of next year.

The vaccine, which was backed by significant government funding, 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.

Health and Social Care Secretary Matt Hancock said:

The approval of the Oxford vaccine is a massive step forward in our fight against coronavirus. It is a tribute to the incredible UK scientists at Oxford University and AstraZeneca, whose breakthrough will help to save lives around the world. The light at the end of the tunnel just got brighter.

Vaccines are the exit route from the pandemic. We have already vaccinated hundreds of thousands of vulnerable people and the new Oxford jab will allow us to accelerate our vaccination plan, allowing us to return to normality in the future.

This is a moment to celebrate British innovation – not only are we responsible for discovering the first treatment to reduce mortality for COVID-19, this vaccine will be made available to some of the poorest regions of the world at a low cost, helping protect countless people from this awful disease.

I want to thank every single person who has been part of this British success story. While it is a time to be hopeful, it is so vital everyone continues to play their part to drive down infections.

In line with the [recommendations of the 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 can be stored at fridge temperatures, between 2 and 8 degrees, making it easier to distribute to care homes and other locations across the UK.

The NHS has decades of experience in rolling out successful widespread vaccination programmes and will now begin to implement extensive preparations for the roll-out of the Oxford/AstraZeneca vaccine.

Business Secretary Alok Sharma said:

The Oxford University/AstraZeneca vaccine is a great British success story, involving our very best minds at every stage across every part of the UK. As a result of significant government investment, not only has the vaccine been developed on home turf, but we have built a robust supply chain across the country to ensure the UK will be the first in the world to receive this vaccine.

Thanks to the determination and sheer ingenuity of our incredible scientists, this vaccine will save very many lives at home and protect those in some of the world's poorest nations, helping to bring this global pandemic to an end.

From our researchers and manufacturers, to the thousands of trial volunteers and NHS staff who'll administer this life-saving vaccine to those most in need, your country owes you an enormous debt of gratitude. Your unwavering spirit will go down in history.

The MHRA started the rolling review of Oxford/AstraZeneca's data in September 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.

The vaccine will be deployed through similar methods as the Pfizer/BioNTech vaccine, including:

- 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

In 2016, the UK Vaccine Network provided funding to support Oxford University to develop a vaccine for MERS. This vaccine technology was rapidly repurposed to develop a COVID-19 vaccine using initial funding from a National Institute for Health Research (NIHR) and UK Research and Innovation (UKRI) research call launched in February.

In April the government announced £20 million of further funding so that the Oxford clinical trials could commence immediately. Since then the government has bought 100 million doses of the final vaccine product via further investment.

The UK government is making every effort to increase the UK's vaccine manufacturing capability to ensure vaccines are widely available to the public. As a result, the vaccine is being made in Oxfordshire and Staffordshire, with filling into vials at sites in North Wales. From the end of 2021, the UK will have 2 new permanent manufacturing sites each with the capability to manufacture tens of millions of doses within 6 months.

Professor Chris Whitty, Chief Medical Officer for England and co-lead of the National Institute for Health Research, said:

It is very good news that the independent regulator has now authorised for use the Oxford/AstraZeneca vaccine.

There has been a considerable collective effort that has brought us to this point. The dedication and hard work of scientists, regulators and those who funded the research, such as the NIHR, UKRI and United Kingdom Vaccine Network (UKVN), and the willingness and selflessness of so many volunteers who took part in the vaccine trials were essential in delivering this safe and effective vaccine. They deserve our recognition and thanks.

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

This is another remarkable achievement for science in the global effort to tackle COVID-19. The hard work of the researchers and scientists and the selflessness of clinical trial volunteers will soon begin to save lives.

This vaccine is easier to transport and deploy, and will benefit UK

citizens as well as many vulnerable people around the world.

The UK has secured phased access to very large amounts and so this is fantastic news for NHS vaccine roll-out. The vaccine will protect those who have it, but as we roll this out over the next few months it's crucial we continue to follow the rules to protect each other until enough people have received it.

Through the Vaccines Taskforce, the UK has secured early access to 357 million doses of 7 of the most promising vaccines 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:

Our brilliant NHS teams across the UK have been working tirelessly to vaccinate hundreds of thousands of people with the Pfizer/BioNTech vaccine, despite the significant logistical hurdles.

The Oxford/AstraZeneca vaccine will significantly boost our efforts to protect those most at risk from COVID-19 as it can be transported easier and, once extensive quality checks have taken place, the vaccine will be sent to vaccination sites across the UK and carefully unpacked ready for vaccinations to begin next week.

The UK's 4 Chief Medical Officers agree with the JCVI advice that at this stage of the pandemic the priority should be to deliver first vaccine doses to as many people on the JCVI phase 1 priority list in the shortest possible timeframe. This will allow the administration of second doses to be completed over the longer timeframes in line with conditions set out by the independent regulator, the MHRA, and advice from the JCVI. The evidence shows one dose of either vaccine provides a high level of protection from COVID-19.

From today the NHS across the UK will prioritise giving the first dose of the vaccine to those in the most high-risk groups, with the second dose due to be administered within 12 weeks after the first. The second dose completes the course and is important for longer-term protection.

The JCVI's independent advice is that this approach will maximise the benefits of both vaccines allowing the NHS to help the greatest number of people in the shortest possible time. It will ensure that more at-risk people are able to get meaningful protection from a vaccine in the coming weeks and months, reducing deaths and starting to ease pressure on our NHS.

With the exception of those who have appointments for their second dose booked this week (week commencing 28 December), the NHS will contact those who have already received their first dose to reschedule their appointment in

line with this new advice.

Interim Chair of the government's Vaccines Taskforce Clive Dix said

Today is a huge moment for the scientists and researchers involved in this vaccine and is a result of many years of hard work and late nights – I thank them all for their grit and determination.

We recognised the significance of the Oxford University/AstraZeneca vaccine right from the start, which is why it was the first vaccine in our diverse portfolio, with the UK being the first country to sign an agreement for 100 million doses and why we fully backed their clinical trials.

The Oxford University/AstraZeneca vaccine stands out on the global stage because it is being made on a not-for-profit basis and will be available to some of the world's most vulnerable populations. This is an ethos the Vaccines Taskforce shares and we are determined to ensure the fair and equitable access to vaccines across the globe regardless of status and influence.

The JCVI has also amended its previous highly precautionary advice on COVID-19 vaccines for pregnancy or breastfeeding. Vaccination with either vaccine in pregnancy should be considered where the risk of infection is high and cannot be avoided, or where the woman has underlying conditions that place her at very high risk of serious complications of COVID-19, and the risks and benefits of vaccination should be discussed.

Those who are trying to become pregnant do not need to avoid pregnancy after vaccination, and breastfeeding women may be offered vaccination with either vaccine following consideration of the woman's clinical need for immunisation against COVID-19. The UK Chief Medical Officers agree with this advice.

The MHRA has also updated its advice on administering the Pfizer/BioNTech vaccine to people with allergies, recommending that anyone with a previous history of allergic reactions to the ingredients of the vaccine should not receive it, but those with any other allergies such as a food allergy can now have the vaccine.

The full prioritisation list is (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

Vaccination will be managed by the health services in each nation:

- NHS England and NHS Improvement
- NHS Wales
- NHS Scotland
- 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 Vaccines 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

## **UK vaccine manufacturing**

The UK government invested £100 million to fund a state-of-the-art manufacturing innovation centre in Braintree, Essex, in collaboration with the Cell and Gene Therapy Catapult, to accelerate the mass production of a successful COVID-19 vaccine in the UK. Due to open in December 2021, the Centre will have the capacity to produce millions of doses of vaccines each month, ensuring the UK has the capabilities to manufacture both vaccines and advanced medicines, including for emerging diseases, far into the future.

The government has also provided £4.7 million funding to the Catapult to ensure that the UK has the best skills and expertise in vaccine manufacturing and advanced therapies

The government has created the UK's first dedicated Vaccine Manufacturing and Innovation Centre (VMIC) and accelerated its development with £93 million of investment. This investment will rapidly accelerate the construction of the facility, enabling us to bring it online sooner. It will also have expanded capability for advanced vaccine process development, fill and finish and bulk

manufacture. In addition, the facility's capacity will be significantly increased to be able to respond to this pandemic. Once open, it will be able to manufacture 70 million vaccines doses in just 6 months – enough for the UK population. Located in Oxfordshire the centre will be the UK's first not-for-profit organisation established to develop and advance the mass production of vaccines. This will boost the UK's long-term capacity against future viruses.

While VMIC is being built, the government established a Rapid Deployment Facility with £8.75 million investment to manufacture at scale

The government has made a multi-million-pound investment in a manufacturing facility in Scotland, creating a major UK vaccine facility and to support rapid scale-up if its candidate is successful. This unique facility will establish a permanent UK capability to manufacture inactivated viral vaccines – one of the most proven, widely used vaccine formats. It is one of few Biosafety Level 3 (BSL3) containment facilities in Europe and has the capacity to produce up to 200 million doses annually of COVID-19 viral vaccines in 2021.