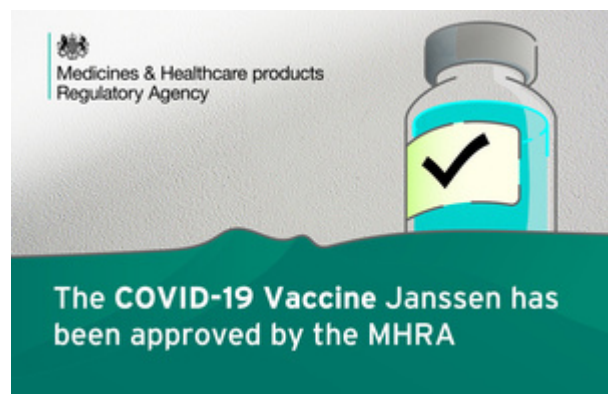


One-dose Janssen COVID-19 vaccine approved by the MHRA

Press release

The vaccine has been approved after meeting the required safety, quality and effectiveness standards.



The COVID-19 Vaccine Janssen has today been given regulatory approval by the Medicines and Healthcare products Regulatory Agency (MHRA).

This is the fourth COVID-19 vaccine to be authorised by the UK's independent regulator and is the first to be approved for protection against COVID-19 with a single dose.

Dr June Raine, MHRA Chief Executive, said:

We have undertaken a thorough review of the conditional marketing authorisation application submitted by Janssen, including the information on quality, safety and effectiveness. I am pleased to confirm today that this authorisation has been granted.

This is encouraging news for the public and the healthcare sector. We now have four safe and effective vaccines approved to help protect us from COVID-19.

Our work does not end here. We are continually monitoring all COVID-19 vaccines in use once they have been approved to ensure that the benefits in protecting people against the disease continue to outweigh any risks.

The safety of the public will always come first – you can be

absolutely sure of our commitment to this.

The MHRA also obtained independent scientific advice from the Commission on Human Medicines (CHM) and its COVID-19 Expert Working Group.

Professor Sir Munir Pirmohamed, Chair of the independent Commission on Human Medicines, said:

The independent Commission on Human Medicines and its COVID-19 Expert Working Group have carefully considered the MHRA's evaluation of the application submitted by Janssen and are pleased to say that we have given the vaccine a positive recommendation.

This is yet another win for the vaccination programme, which has saved thousands of lives so far.

[The National Institute for Biological Standards and Control](#), part of the Agency, is carrying out independent batch release on all of the approved COVID-19 vaccines to ensure that every batch meets the expected quality standards, and will do so for the COVID-19 Vaccine Janssen.

Who can receive the COVID-19 Vaccine Janssen

The MHRA approval authorises the use of the vaccine in people aged 18 and over. The decision on whether to use the vaccine in pregnant or breast-feeding women should be made in consultation with a healthcare professional after considering the benefits and risks. People who have an allergy to one of the components of the vaccine listed in [section 6.1 of the Patient Information Leaflet](#) should not receive the vaccine.

See [the Summary of Product Characteristics and Patient Information Leaflet for COVID-19 Vaccine Janssen](#).

Notes to Editor

1. The Conditional Marketing Authorisation (CMA) granted by the MHRA is valid in Great Britain only and was approved via the [European Commission \(EC\) Decision Reliance Route](#). This is when the marketing authorisation application made by the company references the decision made by the EMA's Committee for Medicinal Products for Human Use (CHMP). The MHRA reviews this application, together with due consideration of the EC decision, before making an independent decision on the quality, safety, and effectiveness of the vaccine. COVID-19 Vaccine Janssen is authorised in Northern Ireland under the CMA granted by the European Medicines Agency on 11 March. This CMA has similar requirements to that granted by the MHRA.
2. [The Medicines and Healthcare products Regulatory Agency](#) is responsible for regulating all medicines and medical devices in the UK. All work is

underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

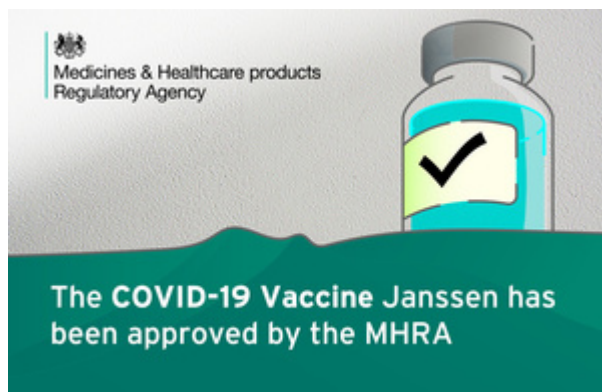
3. The Medicines and Healthcare products Regulatory Agency ('the agency') has three centres. The MHRA, the [National Institute for Biological Standards and Control \(NIBSC\)](#) and the [Clinical Practice Research Datalink \(CPRD\)](#). The agency is an executive agency of the Department of Health and Social Care.
4. [The Commission on Human Medicines \(CHM\)](#) advises ministers and the MHRA on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the [Department of Health and Social Care](#).

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Published 28 May 2021

[Janssen coronavirus \(COVID-19\) vaccine authorised by UK medicines regulator](#)

- Government has secured 20 million doses for all of UK
- Doses expected to be available from later this year

The Medicines and Healthcare products Regulatory Agency (MHRA) has today announced that the COVID-19 Vaccine Janssen meets the expected standards of safety, quality and effectiveness. The independent Commission on Human Medicines (CHM) has reviewed the MHRA's decision and endorsed it.

Earlier this year, the single-dose vaccine was shown to be 67% effective overall in preventing COVID-19 infection and 85% effective in preventing

severe disease or hospitalisation.

The vaccine can be stored at fridge temperatures, between 2 and 8 degrees, making it ideal for distribution to care homes and other locations across the UK.

Through the UK's Vaccine Taskforce, 20 million doses of the vaccine have been secured for all 4 nations of the UK and first deliveries are expected to arrive from later this year.

The vaccination programme continues at pace and remains on track to offer a jab to all adults by the end of July.

Health and Social Care Secretary Matt Hancock said:

This is a further boost to the UK's hugely successful vaccination programme, which has already saved over 13,000 lives, and means that we now have 4 safe and effective vaccines approved to help protect people from this awful virus.

As Janssen is a single-dose vaccine, it will play an important role in the months to come as we redouble our efforts to encourage everyone to get their jabs and potentially begin a booster programme later this year.

As with all vaccines, the government is in regular contact with the manufacturers, including exploring how best to optimise supply across the current programme and preparing for a potential booster programme from later this year. Janssen's COVID-19 vaccine is part of the Cov-Boost study to assess its safety and effectiveness as the third dose of a potential booster programme.

Alongside this, the government is working with the devolved administrations to ensure the vaccine is deployed fairly across the UK.

The Vaccine Taskforce originally secured 30 million doses of the Janssen vaccine last year, based on the predicted clinical need at the time. With the UK's COVID-19 vaccination programme continuing at an unprecedented scale and pace, the government has decided to amend its original order to 20 million.

The Joint Committee on Vaccination and Immunisation (JCVI) will submit updated advice for the Janssen vaccine before doses become available.

The company continues to explore a 2-dose regimen of their vaccine. The single-dose regimen has also been authorised by the European Medicines Agency (EMA), the Food and Drug Administration (FDA) and the World Health Organization (WHO).

The government is preparing for a booster programme based on clinical need and will publish further details in due course. The final policy will be informed by advice from the JCVI and take into account the results of

clinical trials.

Vaccine Deployment Minister Nadhim Zahawi said:

The Janssen vaccine will be another weapon in our arsenal to beat this pandemic.

We are doing everything we can to vaccinate all adults as quickly as possible and I encourage everybody to come forward for a jab as soon as they are eligible.

Vaccinated people are far less likely to get COVID-19 symptoms. Vaccinated people are even more unlikely to get serious COVID-19, to be admitted to hospital, or to die from it, and there is growing evidence that vaccinated people are less likely to pass the virus to others.

Through the government's Vaccine Taskforce, the UK has secured early access to over 500 million doses of 8 of the most promising vaccine candidates, including: BioNTech/Pfizer, Oxford/AstraZeneca, Moderna, Janssen, Novavax, GSK/Sanofi, Valneva and CureVac.

The [latest data from PHE's real-world study](#) shows the vaccines are already having a significant impact in the UK, reducing hospitalisations and deaths, saving more than 13,200 lives and preventing more than 39,700 hospitalisations in England up to 13 May.

PHE analysis also shows that individuals who receive a single dose of the Oxford/AstraZeneca vaccine have approximately 80% lower risk of death against the B.1.1.7 coronavirus variant originating in Kent and a second dose of the vaccine can provide 85% to 90% protection against symptomatic disease. Protection against death from the Pfizer/BioNTech vaccine rises from approximately 80% after one dose to 97% after 2 doses against the Kent variant.

[Ministers across government urge women to shape women's health strategy](#)

- Government ministers are touring the country to encourage women to have their say on the Women's Health Strategy ahead of 13 June deadline
- Completing the call for evidence takes just 10 minutes and it is easily accessible from a phone, tablet or laptop

To mark the International Day of Action for Women's Health, ministers across government are touring the country to urge women to make their voices heard and help shape the first ever government-led Women's Health Strategy.

The Women's Health Strategy is designed to increase the health and well-being outcomes of women in England, and ministers and the government are determined that women get to shape the policies that will drive up equality in our health system.

To ensure the strategy works for women, the government issued a [call for evidence](#), which closes on 13 June. There has already been a staggering response with over 80,000 women, organisations, clinicians and carers responding so far.

With just over 2 weeks until the call for evidence closes, the government is calling on women of all ages and backgrounds to share their experiences, insights and priorities.

Health and Social Care Secretary Matt Hancock said:

The public have a right to expect a health and care system that truly works for everyone in society, regardless of background or gender.

There is unmistakable evidence, in the data and in people's health outcomes, that there is a gender gap in our health system and it is this gap that we want to eradicate with the first ever government-led Women's Health Strategy.

This strategy has to be one that reflects the views and experiences of women across the country, from Hartlepool to Cornwall, and the response so far has been overwhelming. Whether you work in the health and care profession or are somebody who uses it, we want to hear from you.

To further raise awareness, this week ministers across government are visiting women's health-related charities, projects and healthcare settings across the country to make sure women are making their voices heard, including:

- Health and Social Care Secretary Matt Hancock at the Royal Cornwall Hospitals NHS Trust, site of Women and Children's Hospital
- Minister for Women's Health Nadine Dorries at St Thomas' maternity unit with Jacqueline Dunkley Bent
- Minister of State for Health Ed Argar will visit the Royal Marsden Hospital
- Minister for Innovation Lord Bethell will visit UKHSA Collindale lab
- Minister for Care Helen Whately will visit Kent Medical school
- Parliamentary Under-Secretary of State for Housing and Rough Sleeping Eddie Hughes will visit the Green Lane Hostel in Walsall, which provides support to vulnerable young people aged 16 to 25
- Minister of State for Digital and Culture Caroline Dinenage will undertake an endometriosis-focused visit on the south coast
- Prisons and Probations Minister Alex Chalk will visit a Gloucester rape and sexual abuse centre

- Environment Minister Rebecca Pow will visit a local hospital in Taunton
- Minister of State for Universities Michelle Donelan will host a roundtable with women in her constituency to discuss women's health
- Parliamentary Under Secretary of State at the Department for Digital, Culture, Media and Sport Baroness Barran will virtually visit Ovarian Cancer Action
- Chairman of the Party Amanda Milling will visit a women's gym in Pudsey

Minister for Women's Health, Nadine Dorries, said:

For generations, women's issues have often been marginalised, and seldom given the attention they deserve. At the same time, we have consistently been underrepresented in research and clinical trials.

It is high time we change that. We need to make sure ours is a healthcare system that is really meeting women's needs. I urge all women, from all walks of life, to tell us their experiences and thoughts in our call for evidence so we can put your voices at the heart of our Women's Health Strategy and make sure our future policy works for you.

It really is the final countdown – there are only 16 days left for you to make sure your voice is heard.

Other ministers, including the Prime Minister, Secretary of State for International Trade and Minister for Women and Equalities Liz Truss, Secretary of State for Justice Robert Buckland, Children's Minister Vicky Ford, Parliamentary Under Secretary of State at the Department for Digital, Culture, Media and Sport Baroness Barran and Paymaster General Penny Mordaunt are expected to support activity on social media.

Charities, Royal Colleges, patient groups and other stakeholders are also lending their support today. Mencap, the Eve Appeal, the Royal College of Midwives, Endometriosis UK and the British Heart Foundation will share content, including videos and case studies, urging their members and supporters to respond to the call for evidence.

As well as health issues specific to women, the strategy will look at the different ways in which women experience health issues that affect both women and men. Women with health conditions such as diabetes, heart conditions and osteoarthritis are also being urged to share how their condition has affected them.

The call for evidence has been designed to be user friendly, quick to fill in and easily accessible from people's mobiles. People who live with and care for women, organisations with experience of providing services for women and those with an expertise in women's health are also encouraged to share their views.

Read the [Women's Health Strategy: Call for Evidence](#).

The 6 core-themes included in the call for evidence are:

- placing women's voices at the centre of their health and care – how the health and care system engages with and listens to women at the individual level as well as at the system level
- improving the quality and accessibility of information and education on women's health – women having access to high-quality information when they need to make a decision, increasing health literacy, as well as increasing awareness and understanding of women's health conditions among clinicians
- ensuring the health and care system understands and is responsive to women's health and care needs across the life course – supporting women to maximise their health across their lives, and ensuring services are designed to maximise benefits for women
- maximising women's health in the workplace – deepening our understanding of how women's health issues can affect their workforce participation and outcomes, both with regards to female-specific issues such as the menopause, but also conditions that are more prevalent in women such as musculoskeletal conditions, depression or anxiety
- ensuring that research, evidence and data support improvements in women's health – inclusion of women and women's health in research and data collection and how that information is used, and driving participation in clinical trials to support improvements in women's health
- understanding and responding to the impacts of COVID-19 on women's health – supporting women through the unique challenges they've faced during the pandemic.

There is strong evidence of the need for greater focus on women's health:

Although female life expectancy is higher than men in the UK, women on average spend less of their life in good health compared with men. Female life expectancy in this country has been improving more slowly than male life expectancy since the 1980s.

Less is known about conditions that only affect women, including common gynaecological conditions which can have severe impacts on health and well-being, but for which there is currently little treatment. A key example of this is endometriosis with the average time for a woman to receive a diagnosis being 7 to 8 years, and with 40% of women needing 10 or more GP appointments before being referred to a specialist.

There is also evidence that the impact of female-specific health conditions such as heavy menstrual bleeding, endometriosis, pregnancy-related issues and the menopause on women's lives is overlooked. This includes the effect they can have on women's workforce participation, productivity, and outcomes.

High-quality research and evidence is essential to delivering improvements in women's health, yet studies suggest gender biases in clinical trials and research are contributing to worse health outcomes for women. Although women make up 51% of the population, there is less evidence and data on how conditions affect women differently. A University of Leeds study showed women

with a total blockage of a coronary artery were 59% more likely to be misdiagnosed than men, and found that UK women had more than double the rate of death in the 30 days following heart attack compared with men.

[Volunteers clear floating pennywort from 10km of the River Cam](#)

Thanks to the determination of volunteers the 10 kilometres stretch between Byrons Pool and Jesus Green lock is now clear of floating pennywort.

The invasive non-native aquatic plant had formed thick mats along the river and was growing at a rate of 20 centimetre a day. This meant back channels were lost, navigation for boaters and canoers was difficult and repercussions for wildlife and plants was more likely.

The Environment Agency and the Cam Conservators undertook the initial surveys and worked together to remove large masses of the invasive plant with weed boats.

The Floating Pennywort on the river Cam before the volunteers helped to remove it.

Mike Foley, a retired volunteer at Cam Valley Forum, continued the work and has spent years tackling the invasion on the River Cam. Mike has worked relentlessly to clear the invasive plant. Over the last year he worked extra hard to ensure the momentum carried on when meeting in groups has been difficult to coordinate.

Anne Miller, a volunteer who worked closely with Mike, helped raise funds so they were able to prune 3 kilometres of overhanging branches. This allowed them to remove pennywort which was trapped, this was critical in the elimination of the invasive plant.

The same stretch of the river Cam as above but with the Floating Pennywort removed.

Anne Miller, a volunteer from the Cam Valley Forum, said:

I was saddened to see the river above Cambridge getting clogged with this invasive weed and was inspired by Mike to start tackling it. There was hundreds of tonnes of material to remove and the pennywort was tangled in tree branches, so I thought we needed

help.

Thanks to funding from the Environment Agency and others, I engaged some contractors who did a brilliant job in removing drooping tree branches on a 3 kilometre stretch above Cambridge. This sort of partnership working is very satisfying.

Mike Foley, a volunteer from the Cam Valley Forum, said:

It is great to see this stretch of the River Cam free from pennywort. Once you start to remove this invasive plant it is impossible to stop as you just want to see the job done. I would like to thank everyone who got involved and helped us along the way. This project is evidence that hard work pays off and we are better working together.

James Brokenshire- Dyke, a project engineer at the Environment Agency, said:

Mike has gone above and beyond to clear the pennywort. He digs and handpicks the plant, he conducts numerous walks to check it hasn't grown back, and talks with various people to raise awareness and so much more.

Without him the pennywort would have spread further and we would not be aware of new outbreaks. Mike's work is invaluable to us, as is all the volunteers who have contributed.

Tom Larnach, river manager at Cam Conservators, said:

Working with Mike and the volunteers has been great, we are only a small team so we really appreciate all their help. This project has been a good example of partnership working. Normally this time of year we start to see pennywort mats forming but I haven't seen 1 bit.

Mike Foley, a volunteer from Cam Valley Forum, standing on the riverbank.

Pennywort can change the availability of oxygen in the water which threatens fish and invertebrates. It can also choke drainage systems and crowd native water plants.

Members of the public can stop the spread of this invasive species by recording any sightings on the [iRecord App](#).

Boaters and other users can also help by following the Check, Clean and Dry

procedures.

- Check: Check your equipment and clothes for live organisms – in particular areas that are damp or hard to inspect.
- Clean: Clean and wash all your equipment, footwear and clothes thoroughly. Use hot water if possible. If you find one of these organisms leave them at the water body where you found them.
- Dry: Dry all equipment and clothing – some species can live for many days in moist conditions. Make sure you don't transfer them somewhere else.