Pfizer/BioNTech bivalent COVID-19 booster approved by UK medicines regulator

Press release

The adapted COVID-19 vaccine targets both the original virus and the Omicron variant



A second, "bivalent" vaccine has today been approved as a booster by the Medicines and Healthcare products Regulatory Agency (MHRA) after it was found to meet the UK regulator's standards of safety, quality and effectiveness.

The updated booster vaccine made by Pfizer/BioNTech, targeting two coronavirus variants, has been approved for use in individuals aged 12 years and above. This decision has been endorsed by the Commission on Human Medicines, after a careful review of the evidence.

In each dose of the booster vaccine, 'Comirnaty bivalent Original/Omicron', half of the vaccine (15 micrograms) targets the original virus strain and the other half (15 micrograms) targets Omicron (BA.1).

The MHRA's decision is based on data from a clinical trial which showed that a booster dose with the bivalent Pfizer/BioNTech vaccine triggers a strong immune response against both Omicron and the original strain. Safety monitoring showed that the side effects observed were the same as those seen for the original Pfizer/BioNTech booster dose and were typically mild and self-resolving, and no new serious safety concerns were identified.

Dr June Raine, MHRA Chief Executive said:

I am pleased to announce that we now have a second approved vaccine for the UK Autumn booster programme. The clinical trial of the Pfizer/BioNTech bivalent vaccine showed a strong immune response against the Omicron BA.1 variant as well as the original strain. Bivalent vaccines are helping us to meet the challenge of an everevolving virus, to help protect people against COVID-19 variants.

We have in place a comprehensive safety surveillance strategy for all UK-approved COVID-19 vaccines, and this will include the updated booster we approved today.

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

Following an independent review of the safety, quality and effectiveness of the vaccine, the Commission on Human Medicines and its COVID-19 Vaccines Expert Working Group supports the MHRA's decision.

As with any medicinal product, including vaccines, it is important to continually monitor effectiveness and safety when it is deployed, and we have the relevant processes and expertise in this country to do that.

The Joint Committee on Vaccination and Immunisation (JCVI) will advise on how this vaccine should be offered as part of the deployment programme.

Notes to Editors

- The <u>Commission on Human Medicines (CHM)</u> advises ministers 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.
- This new authorisation to the Conditional Marketing Authorisation (CMA) granted by the MHRA is valid in Great Britain only and was approved via the <u>European Commission (EC) Decision Reliance Route</u>. 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). In such cases, the MHRA considers the application together with due consideration of the EC decision, before making an independent decision on the quality, safety, and effectiveness of the vaccine.
- More information can be found in <u>product information for the</u> <u>Pfizer/BioNTech bivalent vaccine</u>.
- A recent paper in a Lancet journal suggested that COVID-19 vaccines have prevented up to 20 million deaths in the first year of use.

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<u>£110m fund to level up rural</u> <u>communities unveiled</u>

Rural businesses such as farms, wedding venues and pubs will benefit from up to £110 million of funding being allocated today to support countryside communities across England.

The funding will be invested in projects which will boost productivity and create rural job opportunities. These could include farm businesses looking to diversify by opening a farm shop, wedding venue or tourism facilities or improvements to village halls, pubs and other rural hubs for community uses.

Investment will be based on local priorities and support investment in projects such as grants for:

- converting farm buildings to other business uses
- rural tourism, such as investments in visitor accommodation
- capital grants for provision of gigabit-capable digital infrastructure at hubs such as village halls, pubs and post offices for community use
- capital grants to develop, restore or refurbish local natural, cultural and heritage assets and sites
- creation of new footpaths and cycle paths, particularly in areas of health need, or capital grants to enable people to develop volunteering and social action projects locally

The Rural England Prosperity Fund worth up to £110 million will be delivered by eligible local authorities and give local leaders a greater say in investment than they previously had under EU schemes. It will be in addition to the £2.6 billion allocated via the UK Shared Prosperity Fund (UKSPF) to support levelling up across the UK. The fund will be part of the UKSPF and is a rural top-up for eligible local authorities.

Secretary of State for Levelling Up, Greg Clark MP said:

This major investment in rural businesses will help us boost the countryside economy and close the rural productivity gap.

It's our mission to spread opportunity across the whole of the UK and this funding will help us do just that.

Lord Benyon, Minister for Rural Affairs, said:

We are addressing the rural productivity gap, levelling-up opportunities and outcomes, and looking after the rural areas and countryside that so many of us are proud to call home.

The Rural England Prosperity Fund worth up to £110 million

recognises the unique strengths and challenges of rural communities, and will support them to invest and grow their economies in line with local priorities.

Rural areas contribute hugely to the life of our nation economically, socially and culturally. 85% of England's land mass is rural, rural areas are home to 9.6 million people (17% of England's population) and the rural economy is worth £260 billion to the economy (15% of England's output).

Published today, the 'Delivering for Rural England' report describes how rural interests will be at the heart of the government's approach to levelling up to ensure the 12 levelling-up missions deliver for these communities.

The report summarises the considerable progress that has been made in supporting rural areas, for example in improving connectivity with 30% of rural premises now having access to gigabit-capable connections compared with 19% in January 2021.

As well as the ongoing work to recruit 20,000 more police officers across the whole country and make our streets safer, the government has also taken steps through the Police, Crime, Sentencing and Courts Act to tackle crimes prevalent in rural communities such as illegal hare coursing. The new measures came into force on 1 August and strengthen penalties for those caught hare coursing who will now face an unlimited fine and up to six months in prison.

The report sets out how the government is working to close the productivity gap for rural areas, which has fallen from 90% of the England average in 2001 to 83% in 2019. Funding announced today through the Rural England Prosperity Fund, together with the government's UK Shared Prosperity Fund (UKSPF), Food Strategy and the Agricultural Transition Plan, is set to unlock billions of investment in rural communities over the coming years.

Rural proofing — the process by which government ensures the needs of rural communities are met in government policy-making — has also been supported with the development of new guidance and training for civil servants. Work will also continue in developing the role that the Levelling Up Advisory Council can play in offering specific insights into the design and delivery of levelling up in rural areas.

- The second rural proofing report 'Delivering for Rural England' can be found on GOV.UK.
- Further details on the Rural England Prosperity Fund can be found in the England Prosperity Fund: prospectus on GOV.UK.
- The Rural England Prosperity Fund is integrated into the UK Shared Prosperity Fund (UKSPF), which supports productivity and prosperity in places that need it most. Rural England Prosperity Fund funding is available from April 2023 to March 2025.
- For eligible local authorities, the Rural England Prosperity Fund is a rural top-up to UKSPF allocations. It supports activities that

specifically address the challenges rural communities face. It is complementary to funding used to support rural areas under the UKSPF.

- The REPF succeeds EU funding from LEADER and the Growth Programme which were part of the Rural Development Programme for England.
- Funding has already been provided to devolved governments to support rural communities in Scotland, Wales and Northern Ireland as part of the agreed replacement to the Common Agricultural Policy. UK Government is incorporating England's share of funding to support rural economies into the UKSPF to better streamline and simplify the spending landscape.

Rough sleepers helped to rebuild their lives with new strategy backed by £2bn government support

- Government publishes landmark Rough Sleeping Strategy to drive forward manifesto commitment to end rough sleeping for good
- 14,000 beds and 3,000 support staff this year will help individuals find work and access mental health services
- Extra 2,400 long-term supported homes will be created for those with most complex needs
- To break the cycle of addiction and rough sleeping, drug and alcohol treatment services will be expanded

Thousands of people living on the streets will be given a roof over their heads and tailored support to rebuild their lives under landmark government plans set out today (3 September 2022) to end rough sleeping.

The cross-government <u>Rough Sleeping Strategy</u> is backed by £2 billion and builds on the significant action already taken by the government, which has driven a 43% drop in rough sleeping since 2019 and rough sleeping has fallen to an 8-year low. As a result, England now one of the lowest rough sleeping rates in the world.

In this year's Spending Review we announced we are spending £2 billion over the course of this parliament to end rough sleeping and tackle homelessness – today's strategy sets the key funding allocations, totalling £764 million.

This includes up to £500 million over 3 years for the Rough Sleeping Initiative, which this year will help provide 14,000 beds for rough sleepers and 3,000 staff to provide tailored support across England. This includes helping individuals find work, manage their finances and access mental and physical health services.

An extra 2,400 long-term supported homes for those with the most complex needs, including young people, will also be provided, through our new £200

million Single Homelessness Accommodation Programme. This is on top of 3,200 homes that have already been delivered.

To break the cycle of addiction and rough sleeping, the government is also expanding its Rough Sleeping Drug and Alcohol Treatment Grant programme to an additional 20 areas in England, bringing the total to 83. The scheme provides funding for substance misuse treatment services for people sleeping rough or at risk of sleeping rough.

The government has a manifesto commitment to end rough sleeping in this parliament. This means rough sleeping is prevented wherever possible and, where it cannot be prevented, it is a rare, brief and non-recurring experience.

Secretary of State for Levelling Up, Housing and Communities Greg Clark said:

Ending rough sleeping in this parliament is an important manifesto commitment.

We've made great strides towards that goal in the last few years, and today's strategy backed by £2 billion of support will give some of the most vulnerable people in our society a roof over their heads and targeted support so they can rebuild their lives.

The full weight of government is behind this very necessary pledge and this landmark strategy will give us the right tools to identify people at risk of rough sleeping earlier and provide the help they need.

Minister for Rough Sleeping Eddie Hughes said:

No one should have to sleep on our streets and our strategy will help make that a reality.

We will pull every lever at our disposal so councils, working hand in hand with the voluntary, faith and community sectors, can intervene swiftly when someone is sleeping rough.

When I worked at YMCA Birmingham, I saw first-hand how the right support can help people turn their life around. We're making great progress and this strategy is hugely important step towards ending rough sleeping for good.

The government is also extending the Housing First Pilots in the West Midlands, Manchester and Liverpool, which give homeless people with multiple and complex needs access to independent long-term housing as a secure and stable platform from which other issues can be addressed.

Thousands of prison leavers at risk of homelessness will also be helped into

rental accommodation as part of an expanded government scheme designed to reduce reoffending and tackle rough sleeping.

The second phase of the Accommodation for Ex-Offenders programme – to be launched later this year as part of this strategy – will help councils provide rental deposits, landlord incentives and dedicated support staff.

It builds on the 2021/22 scheme, which helped 145 councils across England and Wales provide the much-needed support. With prison leavers without a stable home around 50% more likely to reoffend, the scheme will help cut crime by reducing the number of prison leavers ending up homeless so that they have the foundation to get a job and access treatment for addictions.

And the government is helping to put night shelters on a more secure and stable footing by increasing the variety and quality of services so they can be relied on for the long term.

To improve transparency and accountability for the mission to end rough sleeping, the government will publish quarterly data showing progress.

Finally, as part of our support we are repealing the outdated Vagrancy Act as no-one should be criminalised simply for having nowhere to live. However, to ensure we don't weaken the ability of police to protect the public and communities from crime and anti-social behaviour we are considering bringing forward new legislation, while also embedding rehabilitation and support at the heart of our approach.

Interim CEO at St Mungo's homeless charity Rebecca Sycamore said:

As a leading homelessness charity we know first-hand how important it is to focus on the root causes of rough sleeping in order to help break that cycle. We deliver a huge range of services to support people out of homelessness and into rebuilding their lives and so welcome this new strategy.

Currently there is a significant gap in supported accommodation for people with complex needs and the announcement of an extra 2,400 homes in particular, is a step forward to helping people sustain a life away from the streets.

Actions introduced today include:

Rough Sleeping Initiative

The <u>Rough Sleeping Initiative</u> is the government's flagship programme to drive the manifesto commitment to end rough sleeping. Up to £500 million will help provide emergency beds, off-the-street accommodation and wrap-around support.

Rough Sleeping Accommodation Programme

The <u>Rough Sleeping Accommodation Programme</u>, announced in 2020, is backed by up to £433 million over the lifetime of this parliament. This funding will provide up to 6,000 homes for rough sleepers. Once in their new home, rough sleepers will be supported by specialist staff to access the help they need, such as support for mental health and substance abuse problems, moving towards training and work.

From the total budget of the programme, £39.4 million will continue the work of providing a roof over people's heads and the support they need to sustain it.

Single Homelessness Accommodation Programme

Many areas need more accommodation with suitable support for adults experiencing multiple disadvantage, both long-term and good quality hostel accommodation, as well as specialist accommodation for young people (under 25) who are already experiencing rough sleeping or are at risk.

This is why the government is introducing the Single Homelessness Accommodation Programme (SHAP), a new £200 million fund, which will deliver up to 2,400 homes by March 2025, including supported housing and Housing First accommodation, and accommodation for young people at risk of homelessness, including rough sleeping.

Rough Sleeping Drug and Alcohol Treatment Grant

Since 2020/21 the Rough Sleeping Drug and Alcohol Treatment Grant has provided £50 million for substance misuse treatment services for people sleeping rough or at risk of sleeping rough. This includes evidence-based drug and alcohol treatment and wraparound support to improve access to treatment, including for people with additional mental health needs.

The government will provide extra investment of up to £186.5 million over the spending review period, expanding these vital services to 20 more areas, bringing the total to 83 areas and 5 pan-London projects. This includes an investment of £15 million announced as part of the cross-government Drug Strategy.

Housing First Pilots

Housing First supports homeless people with multiple and complex needs to access and maintain independent housing. Unlike traditional 'staircase' or 'treatment first' approaches, it places people directly in independent long-term settled housing, with personalised, flexible and non-time-limited support. This gives people choice and control over both their housing and the support they receive — secure housing offers a stable platform from which other issues can addressed, rather than setting preconditions such as being 'housing ready' or participating in treatment.

We are extending our <u>Housing First Pilots</u> in the West Midlands, Manchester, and Liverpool, providing a further £13.9 million over 2 years on top of the £28 million already invested.

Voluntary, Community and Frontline Sector programme

Up to £7.3 million will ensure <u>local rough sleeping services have the tools</u> <u>they need to end rough sleeping</u> and develop prevention services to stop people arriving on the streets in the first place.

Streetlink

We will revitalise this initiative, which enables people to connect local services with somebody they see sleeping rough, with new investment to improve the website and make it more user friendly.

Transparency and data-led Framework

We are committed to ending rough sleeping — this means rough sleeping will be prevented wherever possible or, where it cannot be prevented, be a rare, brief and non-recurring experience. In practice this approach, developed in consultation with experts at the Centre for Homelessness Impact, means more effective support to prevent rough sleeping from happening in the first place, and a tailored offer of support where it does, so people can build an independent life off the streets.

To hold the government and local leaders to account and measure progress, we will <u>publish quarterly data</u> to set out how the government and its partners are delivering on this mission.

Night Shelter Transformation Fund

Help for faith and community groups to develop night shelter services, to expand high-quality single-room accommodation and move-on support for rough sleepers. DLUHC will work with Homeless Link and Housing Justice to help organisations, with up to £10 million of funding across 2022-2025.

This fund aims to transform the sector for the long term, with a wider range of services, partner organisations on a firmer footing and less reliance on government funding to meet core costs.

<u>£2 bus fare cap across England to save</u>

passengers money

- people could save more than £3 per single bus ticket to help with cost of living pressures
- £2 bus fare cap on almost every single journey across England, saving people 30% on the average fare, helping millions with travel costs for work and essential journeys
- government providing up to £60 million over 3 months to subsidise operator costs and incentivise greener travel for commuters

Millions across England will save money through a new $\pounds 2$ cap on single bus journeys from January to March 2023, backed by up to $\pounds 60$ million to ensure affordable transport across the country.

The Transport Secretary has today (3 September 2022) announced the government will provide up to £60 million from January to March next year, to help bus operators to cap single adult fares at £2 per journey.

The move will help passengers with travel costs for work, education, shopping and medical treatments over the winter months while they are facing pressures from the rising cost of living.

Bus fares vary across different parts of the country and between bus operators, and can even reach almost £6 for a single journey in rural areas. The new cap means passengers in those areas could save more than £60 a month if they took 4 single trips a week.

The average single fare for a 3-mile journey is estimated at over £2.80, meaning that the new fare will save passengers almost 30% of the price every time they travel.

The funding to keep fares down follows the government's announcement of $\underline{f130}$ million last month to protect vital bus routes and services across the country, which those on lower incomes in particular rely on.

Transport Secretary Grant Shapps said:

Buses are by far and away the most used form of public transport, so ensuring that almost all bus journeys are no more than £2 will assist passengers over the winter months and provide direct help to thousands of households across the country.

This £60 million boost will mean everyone can affordably get to work, education, the shops and doctor's appointments.

We know people will be feeling the pressure of rising costs this winter, and so we have been working hard this summer to provide practical concrete help that will lower daily expenditure. The new initiative follows the allocation of more than £2 billion to support bus services in England through the pandemic and a commitment to fund improved services, new bus priority measures and new electric or hydrogen buses as part of <u>Bus Back Better</u>, the ambitious national bus strategy, published last year.

During the pandemic bus passenger numbers declined significantly, along with other public transport users, and figures show usage has not returned to prepandemic levels.

However, ensuring the public can access affordable bus fares will encourage more people to choose buses for local journeys, which helps to reduce carbon emissions as the country moves towards <u>Net Zero targets</u>. The scheme is estimated to take at least 2 million car journeys off the roads, cutting congestion and pollution for everyone.

Introducing the fare cap by January enables the government to work with operators and local authorities to implement a scheme that most effectively delivers real savings for passengers. Operators representing around 90% of the bus market have expressed support for the scheme and we hope that all bus operators will participate.

The fare cap builds on lots of offers around the country in areas with high bus demand, which include daily, weekly and monthly ticket options and promotional offers. Single fares which are already lower than £2 will not be affected by the cap.

The government will continue to work closely with bus operators and local authorities and consider future support to help passengers continue accessing reliable and affordable bus services after March.

A flat-rate bus pilot scheme, backed by £23.5 million of government funding, launched in Cornwall this January and has already seen an indicative 10% increase in passenger numbers. The 'Any Ticket Any Bus' scheme, running over 4 years, includes a £3 day ticket within towns or a £9 day ticket across all of Cornwall, which is valid across different bus operators.

Dawn Badminton-Capps, Director for England for charity Bus Users, said:

The cap on fares being announced today will bring welcome, shortterm relief to the millions of people who rely on buses to access education, employment and health services. Buses make a vital contribution to society and government support is critical in protecting services for the future.

Paul Tuohy, Chief Executive of Campaign for Better Transport, said:

This will be very welcome news for the millions of people who rely on the bus to get to work, to the shops, to medical appointments and to connect with friends and family. It will also encourage more people to find their nearest bus stop and give the bus a try... where could YOU go for just £2?

Buses have great potential to cut traffic and carbon emissions, to connect communities and ease loneliness. This ± 2 fare cap – which we have called for – will help set buses on the road to a bright future.

Alison Edwards, Policy Director at the Confederation of Passenger Transport:

Bus fare caps at £2 are an eye-catching initiative which could help attract new passengers onto the bus, particularly at a time when networks are adapting to new travel patterns, and both customers and operators are facing cost of living and business cost challenges.

We look forward to understanding in detail how the proposed fare cap will work in practice to ensure it supports the long-term sustainability of bus networks, which are vital in connecting communities with jobs, education and skills, as well as friends, family and essential public services.

<u>Sailor who restored hundred-year-old</u> <u>steamship recognised with achievement</u> <u>award</u>

- government celebrates Merchant Navy Day by awarding 14 mariners Merchant Navy Medals – the highest medal of honour within the maritime sector
- mariner awarded medal for his services in restoring historic ship for future generations
- women's rights champion awarded for her services to building a diverse maritime sector

A skipper from Liverpool who has put his life's work into restoring a historic steamship and a sailor who has dedicated her work to advocating for women's rights are among <u>those to be awarded Merchant Navy Medals in honour</u> of their achievements today (3 September 2022).

<u>Merchant Navy Medals have been awarded since 2016</u> for significant contributions to the maritime industry. Each year, seafarers are nominated by their colleagues, friends and family for the medals – the highest medal of honour within the maritime sector. This year 14 mariners have been awarded Merchant Navy Medals, including Captain Dan Cross from Liverpool and Master Mariner Ann Pletschke from Hampshire.

Captain Dan Cross has received the prestigious Merchant Navy Medal for his efforts in restoring the iconic SS Daniel Adamson, which first set sail in 1903. Through Dan's restoration efforts, he has supported young people from all backgrounds and abilities to learn, participate and eventually volunteer as part of the ship's crew and go on to lead careers in engineering and across the maritime sector.

Captain Dan Cross with the SS Daniel Adamson.

Master Mariner Ann Pletschke has championed the rights of women and underprivileged individuals in the industry. She has also supported future Commonwealth seafarers, including disadvantaged children, in obtaining a maritime education, even paying the educational fees for the first ever marine engineer officer to hail from Mauritius.

Maritime Minister Robert Courts said:

It is an honour to celebrate British mariners like Ann and Dan, whose efforts have changed maritime for the better.

Every single nominee embodies the values of the maritime sector and has gone above and beyond within their field. We're grateful to all 14 recipients for their efforts to make the industry better, safer and more accessible for all.

Captain Dan Cross said:

I am deeply honoured to be awarded this wonderful medal alongside some prestigious recipients over the years. I played a small part in saving and returning the Daniel Adamson back to operational condition for future generations to enjoy and benefit from. It is often said the ship runs on 2 things, steam and volunteers and this reflects what a magnificent team effort the project is.

Having worked on harbour tugs for nearly 30 years, the work of the harbour tug is often overlooked. As a key part of ensuring goods keep flowing in and out of the ports and harbours in the UK it is great that services to harbour towage is recognised and the work we do can be remembered through vessels like the Daniel Adamson, which also offers great training and education opportunities.

Master Mariner Ann Pletschke said:

With this award I would like to spotlight many others who work tirelessly for the same aims and to inspire others to give back — if we each do a little, we can all make the industry a safer, more diverse and better industry for all.

Master Mariner Ann Pletschke with her marine engineer colleague from Mauritius.

Merchant Navy Medals form part of the UK government's commitment to a diverse maritime workforce. Launched in 2019, the <u>Maritime 2050 People route map</u> sets out how the government and industry will work together to diversify workforce over the coming decades.

The 2022 recipients are:

- Captain Ann Pletschke, services to diversity, inclusion and wellbeing in the maritime sector
- Captain David Warden-Owen, services to maritime charities
- Captain Andrew Shearer, services to supporting Sea Cadets
- Mr Paul James Scotter, services to safety in the fishing industry
- Captain Peter Scott Roberts, devotion to duty, services to training and contribution to charity
- Mr Mark Ranson, services to workboat safety standards and training
- Captain Iain Macneil DUNIV MNI AFRIN, services to maritime safety and technical publications
- Captain Les Hesketh CMMAR FNI, services to maritime education and training
- Captain Stephen G Gudgeon HCMM, services to seafarer welfare
- Mr Robert J Greenwood MNI, services to safety in the fishing industry
- Captain Heather Enness, services to promotion of diversity and wellbeing within the maritime sector
- Captain Daniel J Cross, services to the preservation of a maritime history and towage sector
- Captain Andrew K Cassels, services to the Merchant Navy Welfare Board
- Captain David Barnicoat, services to raising awareness of the maritime sector and supporting seafarer welfare in Falmouth