

Sleep disorder drug modafinil linked to increased risk of birth defects and also to reduced effectiveness of contraception

Press release

Women using modafinil are being warned of an increased risk of birth defects associated with modafinil use during pregnancy.



- Modafinil (Provigil) causes an approximate 15% likelihood of birth defects when taken during pregnancy; this compares with 3% in the general population
- Evidence that modafinil also reduces effectiveness of oral contraception
- Healthcare professionals treating narcolepsy with modafinil are also being reminded of the need to ensure patients are taking effective measures to prevent pregnancy

The warning comes from the Medicines and Healthcare products Regulatory Agency (MHRA) following careful [ongoing review of the risks](#). The drug may also reduce the effectiveness of oral contraception. Women taking modafinil should take effective measures to prevent pregnancy and discuss their contraception options with their healthcare professional.

This new advice is based on reports from a US study (of 61 babies exposed to modafinil in pregnancy) which showed that use of modafinil during pregnancy by women with narcolepsy possibly caused congenital malformations (including congenital heart defects, hypospadias, and orofacial clefts) in affected children.

Modafinil is a prescription-only medicine that is licensed only for the treatment of narcolepsy, a chronic disorder associated with sudden sleep that can cause serious disturbances to a patient's quality of life. As with any drug, there can be side effects associated with its use, including for modafinil psychiatric disorders (depression, suicidal behaviours, and

psychosis) serious skin reactions and cardiovascular disorders.

Dr Sarah Branch, director of MHRA's Vigilance and Risk Management of Medicines division said:

It is important that women are aware of the increased risk of congenital malformations associated with taking modafinil during pregnancy.

Modafinil can reduce the effectiveness of many hormonal contraceptives, including the pill. Women should discuss their options with their healthcare professional and continue to use their contraceptive for 2 months after stopping modafinil.

If you have any concerns, you should speak to your healthcare professional.

Patient safety is our highest priority. We strongly encourage anyone to report any side effects, from this or any medicine, to our [Yellow Card scheme](#).

Minister for Women's Health and Patient Safety Nadine Dorries said:

It is crucial that everybody is aware of the potential side effects of any medication they are taking.

Modafinil should only be taken when prescribed by a healthcare professional to treat narcolepsy and it is important all women taking it are aware of the potential risks including reducing the effectiveness of oral contraceptives and possible birth defects.

I urge all those taking modafinil to educate themselves on the side effects and potential risks, and to contact a healthcare professional if they are concerned.

Published 16 November 2020

Mission Motorsport founder James Cameron Soldiering On Award

The 2020 Soldiering on Awards recognised many worthy winners including James Cameron, founder of Mission Motorsport, the Forces' Motorsport Charity.

The annual awards recognise the outstanding achievements of those who have served their country, and the diverse people and groups who work together in support of the Armed Forces Community. This year saw the inclusion of the Special Patron's Award, recognising the special contribution the Armed Forces Community has played in the UK's COVID-19 response efforts.

Soldiering On Awards Patron, The Rt Hon Earl Howe said:

Over the course of this incredibly challenging year, we have seen many acts of selflessness and compassion across the community, as we have all dealt with the current pandemic. Some of these acts of altruism will not have been visible to the wider community, so it is right that when we do recognise these valiant and humble actions that we acknowledge them.

Last week DRM National Account Manager Tony Matthews caught up (virtually) with James to congratulate him on the award and to discuss the impact of the veteran community since the beginning of the crisis.

Hear what James had to say about the award and what it means to him.

[What James had to say about the award.](#)

[What James had to say about the award video transcript](#) (ODT, 5.98KB)

While the award recognises James as an example of the veteran communities response efforts, he is quick to point out the impact of the community as a whole and how individuals came together, used their skills and access to equipment to identify the most effective way to contribute.

In particular James recognises the inspirational efforts of a veteran and Mission Motorsport beneficiary Darren Kamara who during the crisis was furloughed from his job within the airline industry. Owning 4 of his own 3D printers, Darren printed and supplied personal protective equipment to where it was needed most in his local community.

Listen to James talk about the inspirational response from Mission Motorsport beneficiaries who quickly mobilised to meet the needs of their local community.

[Response and impact from Mission Motorsport beneficiaries](#)

[Response and impact from Mission Motorsport beneficiaries video transcript](#) (ODT, 6.09KB)

In addition, James recognises the ongoing value Mission Motorsport can deliver through their engagement with the automotive industry.

James said:

Practically for a charity that manages relationships in to the automotive industry, it was, how can we help our industry to be able to support too?

With partners such as Jaguar Land Rover and Mazda, Mission Motorsport were able to supply transport where it was needed, helping deliver PPE supplies throughout the country.

In terms of his own personal contribution, James took the opportunity (through an app called SpareHand) to volunteer with the South Central Ambulance Service. While he admits it felt amazing to be able to help others, he also acknowledges the positive impact being able to contribute had on his own mental health.

[Personal response efforts](#)

[Personal response efforts video transcript](#) (ODT, 6.08KB)

Finally, James and Tony discussed the overall impact of the Veteran Community and how the response to COVID-19 exemplifies the ongoing contribution veterans make to civilian society.

James said:

If you're wired in a certain way, and particularly if you've had that drilled and inculcated in to you, once you've stood up to serve, it is very natural to want to stand up and serve again. Our veterans are a national resource and if we allow them to be underemployed... we as a nation are letting ourselves down.

[UK Government Covid testing site opens in Perth](#)

The UK Government has today (Monday 16 November), opened a new walk-through coronavirus testing centre at Thimble Row Car Park (PH1 5QT), in Perth. The

centre is easily accessible for people without a car.

The new facility is being provided by the UK Government as part of a UK-wide drive to continue to improve the accessibility of coronavirus testing for local communities. It is operated by Mitie on behalf of the UK Government.

The test centre is part of the largest network of diagnostic testing facilities created in British history. In Scotland, this comprises of 6 drive through sites, 13 walk through sites, 21 mobile units, plus the Glasgow Lighthouse Lab which is working round the clock to process samples.

A new Scottish megalab was announced yesterday. This will provide capacity to process an extra 300,000 tests a day, create thousands of jobs and play a key part of the UK's national infrastructure response.

In Scotland, the UK Government is providing all Covid testing and test processing outside of the NHS. Around two thirds of all daily tests are provided by the UK Government, in support of Scotland's health services.

Tests must be booked in advance at [NHS Inform](#) or by calling 0800 028 2816. People should only book at test if they have coronavirus symptoms (a high temperature, a new and continuous cough, or a loss or change to their sense of smell or taste).

Health Minister Lord Bethell said:

To respond to the coronavirus, we have built a major testing and tracing system from scratch. We are constantly working to expand and improve it with new technologies and innovations so everyone with symptoms can get a test.

New walk-in sites like this one makes it even easier to get a test no matter where you live. If you have symptoms of coronavirus, I urge you to book a test today and follow the advice of NHS Test and Protect if you are contacted to protect others and stop the spread of the virus.

Baroness Dido Harding, Interim Executive Chair of the National Institute for Health Protection, said:

Walk through sites offer communities better access to coronavirus testing, so everyone with symptoms can get a test. This new site is part of our ongoing work to expand our testing network across the UK which is now has the capacity to process more than 500,000 tests a day. We will continue to expand capacity to improve test turnaround times and push forward testing innovations to make sure anyone who needs a test can get one.

Please book a test if you have coronavirus symptoms: a new continuous cough, a high temperature and a loss or change in sense

of smell or taste, and follow the advice of NHS Test and Protect if you are contacted.

UK Government Minister for Scotland, Iain Stewart, said:

The UK Government is helping all parts of the UK fight the coronavirus pandemic.

Testing is vital, helping to manage local outbreaks and protecting people's livelihoods. The UK Government is providing the bulk of Covid testing in Scotland, and this new walk-through centre is just the latest in our extensive testing network.

We are pleased to be working with local and commercial partners. These sites are not possible without the hard work of many people. I would like to thank everyone involved for their incredible efforts for the good of the country at this difficult time.

Dr Emma Fletcher, Director of Public Health for NHS Tayside said:

This new walk through testing centre is very welcome and provides an additional opportunity for people to access testing in the Tayside area. People are reminded that if they show any symptoms of COVID-19 they should isolate, along with their household, and seek testing immediately.

Simon Venn, Mitie Chief Government & Strategy Officer, said:

Our priority during the pandemic is to support the nation's efforts to fight COVID-19 and help keep the country running. Testing is a critical part of the UK's strategy to combat coronavirus and we're proud to support the UK Government with this vital task. A big thank you to all the NHS staff, Mitie employees and other frontline heroes in Perth, who are working tirelessly to keep us all safe.

[Matt Warman's speech on digital identity at Identity Week 2020](#)

Good morning. It's a great pleasure to be invited to speak at Identity Week 2020.

I truly believe that digital identity is one of the most exciting opportunities for growth and security in the UK economy, and I am excited to share my vision with you today.

Digital identity products are a vital building block for the economy of the future. They will enable smoother, cheaper, and more secure online transactions; they will simplify people's lives, and boost business.

Digital identity solutions can also ensure that people have greater control of their identity data, and provide greater security and privacy standards.

It has the capacity to allow more people to open a bank account, to allow more people to start a new job faster, and to improve the safety and security of travel both within and beyond the UK – whether for business or pleasure.

Covid-19 has increased the demand for online services: 63% of people are learning a new skill online; 20% are buying groceries online; 20% are managing their money online; and 19% are now accessing health services online.

It is essential that all those in society who want to access services online are able to do so. Use of digital identity is key to unlocking this.

We want to enable the formation of a successful digital identity ecosystem in the UK so these benefits and those increased demands and expectations brought on by the pandemic can be fully realised.

The government is committed to enabling a digital identity system fit for the UK's growing digital economy – without the need for identity cards – by working in partnership across government, the private sector, academia and civil society.

I want to ensure that UK values will be at the heart of this thinking to ensure that digital identity works for all who wish to use it, and that will be interoperable with as many markets and sectors as possible.

Last year we undertook a [call for evidence](#) so we could better understand the potential of digital identity to unlock the digital economy, improve user experience and access to services.

Respondents felt strongly that the government has an essential role to play in enabling secure digital identity solutions for the wider economy, and that the setting of standards is integral to this.

When we published [our response to the call for evidence](#), we also published a set of principles that would underpin our approach to developing policy, namely: privacy; transparency; inclusivity; interoperability, proportionality; and good governance.

Security and consent underpin our approach. I don't use these words lightly.

While we have been working with our international stakeholders to understand their approach to the development of digital identity policy, these

principles have been developed deliberately and specifically to ensure that British values – your values – are the foundation upon which our digital world is built in the UK.

Policy on something as personal as the way in which we identify ourselves online can only be developed in this way.

By ensuring that the principles set out in our call for evidence response are at the heart of the UK's digital identity ecosystem, those who choose to make use of a digital identity in the future will have confidence that there are measures in place to protect them.

Consumers will be assured that data confidentiality and privacy are at the centre of their digital identity and will be able to understand who, why, and when their data is being used for digital identity verification.

Over the past few months we have been working closely with experts throughout the private sector, academia and civil society to fully understand the ways we can balance these key principles, mitigate the effect of associated risks, and ensure that digital identities will truly work for those who wish to use them.

I know from my own engagement with these experts that we need agreed standards, ways of working, and a way to check they are being adhered to.

We will do this by establishing a trust framework of standards, rules, assurance and governance for the use of digital identity, in one place, that different organisations using or consuming digital identity can follow.

Such a framework would also enable people to reuse their digital identity to access a range of products and services.

This trust framework will help organisations check identities and share attributes in a trusted and consistent way enabling interoperability, maintaining high levels of privacy, and increasing public confidence.

Because the foundation of this market will be based on trust, how we establish the framework is as important as what it says.

I have held a number of meetings with experts across the digital identity ecosystem – from supportive providers to hopeful private sector organisations to sceptical lobbyists. We are engaging openly with players across the ecosystem to hear your ideas – and your concerns – and incorporate them into our approach.

The development of this trust framework must be a collaborative, informed process to ensure that what we develop represents the very best of British innovation and British values.

We must also ensure that we work to enable an open, competitive market. The standards, regulations, and legislation that we are seeking to implement will not restrict innovation but, instead, will enable the implementation of safe and secure solutions that work for business and society alike.

This unique approach – building on lessons of those who have gone before us and developing an approach that works for the UK – will be critical in making us the world's leading digital economy.

We are keen to engage with our international partners too, who are developing their own rules and regulations to establish a framework that allows us all to work together.

We are exploring the ways in which we can make direct links to other markets and nations to establish and build international recognition and interoperability.

I am excited to announce that we will be publishing the digital identity Trust Framework as an alpha in the new year.

You've now heard from me that I have been working diligently to understand the needs of citizens, civil society, and private sector stakeholders, and now I would like to invite you all to continue to give feedback and contribute to the development of the alpha once it is published.

Publishing the framework as an alpha gives us a unique opportunity to test digital identity standards in practice, highlighting their strengths, their challenges and together, identifying areas for improvement and agreement.

With your input into the alpha, we can together truly enable a successful digital identity ecosystem in the UK that works for everyone.

The trust framework is just one part of our commitment to establishing a vibrant digital identity market.

What became clear from my conversations with experts from industry, academia and civil society is that the ability to check trusted government data sources is a key priority for them.

However, it has to be something that the person being checked agrees to. It is vital that people who choose to use a digital identity understand and control when, why, and how their digital identity data is being used.

Confirmation from Government-assured datasets about individuals, such as their name or date of birth, are all important aspects of building trust in identity.

Government has always played this important role in the paper-based world – by issuing trusted documents like passports and driving licenses – and will continue to work with the private sector and civil society to enable this to happen digitally.

Let's take the busy world of a student as an example. They often have to prove their age by showing their passport, for instances like onboarding at their university, applying for a part time job, for renting accommodation, or for purchasing alcohol.

Your passport is a critically important record about you and showing the

whole record to a range of organisations gives away far more data than is really needed.

We are already working to improve this situation, and not just for students. We have been working closely with the Government Digital Service and Her Majesty's Passport Office to see whether organisations outside of government can use real-time passport validity checks to build useful digital services by [making the Document Checking Service available to a group of companies through a pilot](#). The pilot will run until summer 2021.

No organisation has been given direct access to Government-held data – instead, they receive a 'yes' or 'no' response as to whether their customers' passport is valid. This helps to protect people's privacy while clamping down on opportunities for identity theft and fraud.

I am pleased to announce that these digital passport checks have begun to be made, with over 500 checks completed over the last few weeks.

Six pioneering companies have been onboarded and are either preparing to connect to the Document Checking Service via this pilot or are now offering a live service; and more will be joining shortly.

This is an important step in testing industry demand for these kinds of services. It also shows how the government can work with industry to ensure that privacy is central to policy development and delivery, and ensure trusted identity verification.

This work marks the beginning of progress to ensure that digital identities are as inclusive as possible. We would like to take this work further by enabling digital identity checks to take place against a range of datasets.

In future, this will allow for more people to be able to utilise their digital identity within their day- to-day lives. With permission from the user, identity providers will be able to draw on a range of data, whether with regard to government documents, financial history, or other personal information to build digital services.

Digital identity is a crucial part of supporting the development of the digital economy in the UK. It will make life easier and more secure for people and businesses alike. And I am committed to creating a framework of standards and oversight, and to remove legal barriers where necessary.

We can't do this alone in Government, just as private companies can't do it alone either. And we need to listen and be proactive to meet the needs of the end user, whatever their circumstance.

The answer lies in working together to create the conditions for success, and I look forward to working with you to make our collective ambition a reality.

Thank you very much.

UK government's response to Moderna's publication of efficacy data for its COVID-19 vaccine

Government response

Biotech company Moderna has published positive efficacy results from its Phase 3 studies of its potential COVID-19 vaccine.



Biotech company Moderna today (Monday 16 November) published positive efficacy results from its Phase 3 studies of its potential COVID-19 vaccine, showing it to be nearly 95% effective in preventing coronavirus.

A government spokesperson said:

The news from Moderna appears to be good and represents another significant step towards finding an effective COVID19 vaccine. As part of the ongoing work of the Vaccines Taskforce, the government is in advanced discussions with Moderna to ensure UK access to their vaccine as part of the wider UK portfolio.

Moderna are currently scaling up their European supply chain which means these doses would become available in spring 2021 in the UK at the earliest.

To date, the UK government has secured early access to 350 million vaccines doses through agreements with six separate vaccine developers. This includes 40 million doses of Pfizer/BioNTech's vaccine, which is based on the same platform as Moderna's vaccine and if approved by the medicines regulator, is expected to begin delivery as early as December 2020.

[Read Moderna's full announcement.](#)

We will know whether the vaccine meets robust standards of safety and effectiveness once their safety data has been published, and only then can the medicines regulator can consider whether it can be made it available to the public

We have secured early access to over 350 million vaccines doses through agreements with several separate vaccine developers at various stages of trials, including:

- 100 million doses of University of Oxford/AstraZeneca vaccine – phase 3 clinical trials
- 40 million doses of BioNTech/Pfizer vaccine – phase 3 clinical trials
- 60 million doses of Novavax vaccine – phase 3 clinical trials
- 60 million doses of Valneva vaccine – pre-clinical trials
- 60 million doses of GSK/Sanofi Pasteur vaccine – phase 1 clinical trials
- 30 million doses of Janssen vaccine – phase 2 clinical trials

We have invested over £230 million into manufacturing any successful vaccine and an enormous amount of planning and preparation has taken place across government to be able to quickly roll out the vaccine, including ensuring we have adequate provision, transport, PPE and logistical expertise to do so. We are also working at pace to prepare for the delivery of any potential COVID-19 vaccination programme as quickly as possible.

Published 16 November 2020