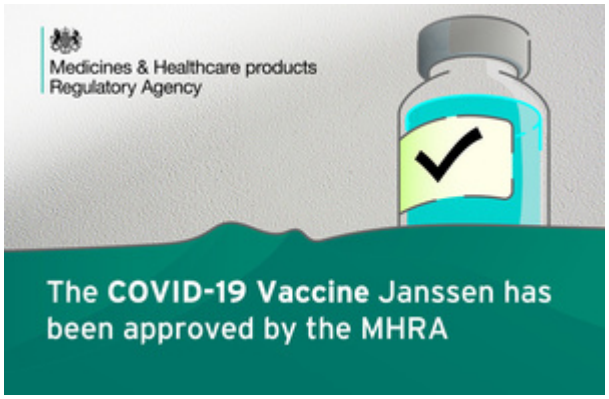
One-dose Janssen COVID-19 vaccine approved by the MHRA

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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