MHRA response to JCVI advice on COVID-19 Vaccine AstraZeneca for people aged under 40

Government response

Statement from Dr June Raine, MHRA Chief Executive, following the Joint Committee on Vaccination and Immunisation's new advice



Dr June Raine, MHRA Chief Executive said:

Public safety is always at the forefront of our minds and we take every report seriously.

Our position remains that the benefits of the COVID-19 Vaccine AstraZeneca against COVID-19, with its associated risk of hospitalisation and death, continue to outweigh the risks for the vast majority of people. The balance of benefits and risks is very favourable for older people but is more finely balanced for younger people and we advise that this evolving evidence should be taken into account when considering the use of the vaccine, as JVCI has done.

We rigorously monitor the safety of COVID-19 vaccines and all reports of these extremely rare blood clots occurring together with thrombocytopenia have been scientifically scrutinised as soon as we have received them. We continue to publish the latest breakdown of all cases of these extremely rare side effects in our weekly summary of coronavirus Yellow Card reporting. We have also issued clear guidance for healthcare professionals on how to minimise risks, as well as further advice on symptoms for vaccine recipients to look out for 4 or more days after vaccination.

This continuous and rigorous safety monitoring has allowed us to provide scientifically based information, analysis and advice —

such as that provided to the JCVI — to enable continued judgements on the most effective use of the COVID-19 Vaccine AstraZeneca based on the data and the current UK context in terms of COVID-19 incidence and vaccine supply. What this shows is that, with support from the public and healthcare professionals, our safety monitoring systems are working effectively.

The public should be reassured of our continuing high standards when monitoring these vaccines for safety, quality and effectiveness.

It is still vitally important that people come forward for their vaccination when invited to do so.

We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the <u>Coronavirus Yellow Card website</u>.

Background:

- These reports have also been analysed by the Government's independent advisory body, the <u>Commission on Human Medicines</u> (CHM) and its COVID-19 Vaccines Benefit Risk Expert Working Group, which includes lay representatives and advice from leading haematologists.
- As a precautionary measure, anyone who has symptoms four days or more after vaccination is advised to seek prompt medical advice, such as:
 - a new onset of severe or persistent headache, blurred vision, confusion or seizures
 - develop shortness of breath, chest pain, leg swelling or persistent abdominal pain
 - unusual skin bruising or pinpoint round spots beyond the injection site

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