**Clinical update – Safety of the AstraZeneca COVID-19 vaccine**

**What we know so far?**

The European Medicines Agency’s (EMA) safety committee have confirmed that the benefits of the AstraZeneca COVID-19 vaccine still outweigh the risks of developing COVID-19 following their meeting in March 2021.

The EMA’s Pharmacovigilance Risk Assessment Committee, responsible for reviewing vaccination data on an ongoing basis, have confirmed that the benefits of the AstraZeneca COVID-19 vaccine continue to outweigh the risk of side effects. They state, “the vaccine is not associated with an increase in the overall risk of blood clots in those who receive it”. (1) In their statement, the committee concluded that there is no evidence of a problem relating to specific batches of the vaccine or to any manufacturing sites. The publication restates that COVID-19 itself is known to cause blood clotting problems that can be fatal.

As of 16th March 2021, it is estimated that around 20 million people in the UK and Europe have received the AstraZeneca vaccine. The committee reviewed seven cases of blood clots in multiple blood vessels, and 18 cases of blood clots in vessels draining blood form the brain. The safety committee involved experts in blood disorders and worked closely with health authorities such as the UK’s MHRA. Overall, they found that there is no increase risk of blood clots compared to that expected in the general population.

The committee’s opinion was that the vaccines proven efficacy in preventing hospitalisation and death from COVID-19 outweighs the extremely small likelihood of developing clotting problems. However, given the small number of severe cases reported, the committee state that patients should be made aware of the remote possibility of such issues occurring, and any who suffer symptoms suggestive of blood clotting should seek medical attention immediately. Steps have since been taken to update product information for the vaccine to include additional information on the risks involved.

As with all medicines, close safety monitoring will continue with additional studies being instituted to provide more laboratory data, as well as real-world evidence. You can find further information on side-effects associated with COVID-19 vaccines by reading the C+D article: [What adverse reactions can occur with the COVID-19 vaccines?](https://www.chemistanddruggist.co.uk/cpd-article/what-adverse-reactions-can-occur-covid-19-vaccines).

**Were there safety concerns?**

The AstraZeneca COVID-19 vaccine, developed in conjunction with Oxford University, had published trial information that indicated high efficacy rates, and no safety concerns were raised. (2) The teams have been submitting trial data to the MHRA since September 2020 and continual review by the regulatory authorities remain positive. (3)

Despite this, Several EU and non-EU member countries temporarily halted use of the AstraZeneca vaccine after reports of blood clots began to circulate. (4) The EMA has now reviewed the cases and state the benefits of the AstraZeneca vaccine outweighed the risks. However, the reported events were a serious concern that required detailed scientific evaluation. The World Health Organisation has also backed the use of the AstraZeneca vaccine.

**What does this mean for Pharmacists?**

As a result of the detailed investigation undertaken, a [direct healthcare professional communication](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/direct-healthcare-professional-communications) has been send to healthcare professionals prescribing, dispensing or administering the vaccine. (5) The committee’s investigation has found that cases of thrombosis and thrombocytopenia have been reported in patients recently vaccinated with the AstraZeneca COVID-19 vaccine. However, the number of reported cases is lower than would be expected from the general population. Most of the reports involved women under 55 years, although it is though that this may be linked with the targeted nature of vaccination campaigns within the EU.

The number of cases reported, although small, cannot confirm a causal link between the vaccine and the clotting disorders and therefore the strength of association remains unclear. However, the benefit-risk balance of the vaccine is positive, and there is no association with thromboembolic disorders overall. (1) Therefore, healthcare professionals are advised to be alert for possible cases of thromboembolism, disseminated intravascular coagulation (blood clots in multiple vessels) or cerebral venous sinus thrombosis (blood clots in the vessels draining blood from the brain). Any patients who display signs of thrombocytopenia, thromboembolism, cerebral blood clots, such as bruising, bleeding, and persistent or severe headache, particularly three days after vaccination, should seek medical attention.

Further information on vaccine administration and safety can be found at the C+D articles: [Administration of COVID-19 vaccine in the UK](https://www.chemistanddruggist.co.uk/cpd-article/administration-covid-19-vaccine-uk?cid=AFF-CDNEW-RELATEDARTICLE-POSITION1) and [Latest Advice on COVID-19 vaccines](https://www.chemistanddruggist.co.uk/cpd-article/latest-advice-on-covid-19-vaccines).

**What does this mean for patients?**

Patients should be advised that AstraZeneca COVID-19 vaccine is not associated with an increased overall risk of blood clotting disorders. It is important to note there have been very rare cases of unusual blood clots and low blood platelets in patients in the 14 days after vaccination and almost all reported cases were women under 55 years.

Patients that receive the AstraZeneca COVID-19 vaccine should be advised to seek medical help if they develop any of the following after vaccination:

* breathlessness
* pain in the chest or stomach
* swelling or coldness in a leg
* severe or worsening headache or blurred vision after vaccination
* persistent bleeding
* multiple small bruises, reddish or purplish spots, or blood blisters under the skin

Patients should also be advised that COVID-19 is such a threat to human life and health, that the benefits of receiving the vaccine to prevent it, continues to outweigh the risks of potential side effects.

**References**

1. European Medicines Agency 2021 [COVID-19 vaccine AstraZeneca benefits still outweigh risks despite possible link rare blood clots](https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots).
2. GOV.uk 2021 <https://www.gov.uk/government/news/oxford-universityastrazeneca-covid-19-vaccine-approved>
3. Oxford University 2021 <https://www.ox.ac.uk/news/2021-03-22-results-usa-trial-oxford-vaccine>
4. Henley, J. 2021 The Guardian <https://www.theguardian.com/world/2021/mar/18/eu-medicines-regulator-to-report-on-astrazeneca-covid-vaccine-safety>
5. European Medicines Agency 2021 [Direct healthcare professional communications | European Medicines Agency (europa.eu)](https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/direct-healthcare-professional-communications)

C+D links to articles used:

* <https://www.chemistanddruggist.co.uk/cpd-article/what-adverse-reactions-can-occur-covid-19-vaccines>
* <https://www.chemistanddruggist.co.uk/cpd-article/administration-covid-19-vaccine-uk?cid=AFF-CDNEW-RELATEDARTICLE-POSITION1>
* <https://www.chemistanddruggist.co.uk/cpd-article/latest-advice-on-covid-19-vaccines>

Unplanned log

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**Describe an unplanned event or activity that enabled you to learn something new or refresh your knowledge or skills.**

**Include a specific learning objective, why this learning is relevant to your role, and how the learning will affect people using your services.**

**(The following examples should be used as a guide for your planned learning, you should add in specific information relevant to your practice and your own learning needs for this topic).**

I reviewed the C+D clinical update regarding the safety of the AstraZeneca COVID-19 vaccine. I learned that there had been a small number of clotting disorders reported, that may have been linked to vaccination. The article detailed information on how the EMA have undertaken a review and concluded the risk-benefit profile of the AstraZeneca vaccine is still favourable. I learned that patients should be advised about the risks of vaccination, but that these risks should be viewed in the context of COVID-19 which itself is known to cause serious and life-threatening blood clotting in patients. Following this, I also reviewed the C+D article outlining adverse drug reactions that can occur within COVID-19 vaccination, and the direct healthcare communication issued by the EMA.

**Give an example of how this learning has benefited the people using your services.**

**Include the learning activities you plan to undertake, making sure you consider a range of options for achieving your learning across the breadth of your CPD entries.**

**(Other sources of information that you plan to use can be added to these learning suggestions).**

Reflecting on the information provided in this article, I am much better equipped to deal with patient questions relating to the AstraZeneca COVID-19 vaccine. One example of how this learning has been beneficial to my patients: A long-standing patient recently came to the pharmacy with a screenshot of an online media platform which showed inaccurate information regarding the AstraZeneca COVID-19 vaccine. The patient asked what my thoughts were about COVID-19 vaccination, based on the information shown from the online source. I was able to explain that the most up-to-date information available on the AstraZeneca vaccine showed no increased overall risk of clotting disorders. I described how, although there had been a small number of cases reported, the regulatory authorities were still confident that the benefits still outweighed the risks with regards to vaccination. I used my knowledge of the reports to explain that all medicines and vaccines have some risks, but that COVID-19 is known to cause serious and life-threatening blood clotting disorders, so on balance, vaccination is still a safe and positive healthcare action to take. This interaction was discussed at the weekly staff meeting, and I directed my pharmacy team to the C+D article, and to the EMA website for further information.