EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 24 – 27 October

Comirnaty and Spikevax: heavy menstrual bleeding added as a side effect

The PRAC has recommended that heavy menstrual bleeding should be added to the product information as a side effect of unknown frequency of the mRNA COVID-19 vaccines Comirnaty and Spikevax.

Heavy menstrual bleeding (heavy periods) may be defined as bleeding characterised by an increased volume and/or duration which interferes with the person's physical, social, emotional and material quality of life. Cases of heavy menstrual bleeding have been reported after the first, second and booster doses of Comirnaty and Spikevax.

The PRAC finalised the assessment of this safety signal after reviewing the available data, including cases reported during clinical trials, cases spontaneously reported in Eudravigilance and findings from the medical literature.

After reviewing the data, the Committee concluded that there is at least a reasonable possibility that the occurrence of heavy menstrual bleeding is causally associated with these vaccines and therefore recommended the update of the product information.

The available data reviewed involved mostly cases which appeared to be non-serious and temporary in nature.

Menstrual disorders in general are quite common and they can occur for a wide range of reasons. This includes some underlying medical conditions. Any person who experiences postmenopausal bleeding or is concerned about a change in menstruation should consult their doctor.

There is no evidence to suggest the menstrual disorders experienced by some people have any impact on reproduction and fertility. Available data provides reassurance about the use of mRNA COVID-19 vaccines before and during pregnancy. A review carried out by EMA's Emergency Task Force showed that mRNA COVID-19 vaccines do not cause pregnancy complications for expectant mothers and their babies, and they are as effective at reducing the risk of hospitalisation and deaths in pregnant people as they are in non-pregnant people.

The Committee reiterates that the totality of data available confirms that the benefits of these vaccines greatly outweigh the risks.

Healthcare professionals and patients are encouraged to continue to report cases of heavy menstrual bleeding to their national authorities.

The PRAC will continue to monitor for cases of this condition and will communicate further if new recommendations are warranted.

Ustekinumab (Stelara): warning on use of live vaccines in infants whose mothers received ustekinumab during pregnancy

The PRAC has recommended adding a warning to the product information for ustekinumab (Stelara) on the use of live vaccines in infants whose mothers received ustekinumab during their pregnancy.

Ustekinumab is authorised in the European Union to treat severe plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

The product information already advises that it is preferable to avoid use of ustekinumab during pregnancy. People of childbearing potential are advised to avoid becoming pregnant and must use adequate contraception while using Stelara and for at least 15 weeks after the last Stelara treatment.

The Committee has reviewed the available evidence regarding use of ustekinumab during pregnancy, including observational studies from the EU, United States and Canada, as well as a cumulative review requested from the marketing authorisation holder.

Ustekinumab can cross the placenta. It has been detected in the serum (the fluid component of the blood) of infants who were exposed to ustekinumab in utero (infants whose mothers were treated with the medicine during pregnancy).

Although the data on ustekinumab are limited, the risk of infection may be increased after birth in infants who were exposed to ustekinumab in utero.

Therefore, the PRAC recommended that, in infants who were exposed to ustekinumab in utero, the administration of live vaccines (vaccines made from a virus or bacterium that has been weakened) is not recommended for six months following birth or until the infant's serum levels of ustekinumab are undetectable. In case of a clear clinical benefit for the individual infant, administration of a live vaccine might be considered earlier, if the infant's serum levels of ustekinumab are undetectable.

The PRAC's recommendation will be forwarded to EMA's human medicines committee (CHMP) for adoption.