26 August 2021

Investigation into possible risk of developing multisystem inflammatory syndrome in children (MIS-C) after vaccination with Comirnaty (the COVID-19 vaccine from Pfizer/BioNTech)

Dear healthcare professional,

The Danish Medicines Agency wishes to inform you of a suspicion about a possible link between the development of multisystem inflammatory syndrome in children (MIS-C) and vaccination with Comirnaty (the COVID-19 vaccine from Pfizer/BioNTech). The suspected connection between MIS-C and Comirnaty is being investigated by the European Pharmacovigilance Risk Assessment Committee (PRAC). At present, a link between the vaccine and MIS-C cannot be excluded. We therefore advise you to pay attention to this syndrome in the weeks after vaccination.

The suspicion is based on a case reported to the Danish Medicines Agency involving a 17-year-old boy who developed symptoms consistent with MIS-C after vaccination with Comirnaty. In the specific case, the 17-year-old suffered diarrhoea, vomiting, headache, a rash with fine spots, dehydration and severe low blood pressure with subsequent adverse effects on the kidneys, heart and lungs. The symptoms occurred 6 ½ weeks after the first vaccine shot and 5 days after the second vaccine shot. The boy's condition was life-threatening and required hospitalisation. The boy was treated with steroids and immunoglobulin and has since recovered. The MIS-C diagnosis was subsequently confirmed. Alternative, including infectious, causes were ruled out, e.g. previous COVID-19 infection. The patient had high titres of anti-SARS-CoV-2 antibodies (IgA, IgM, IgG), but tested negative for anti-SARS-CoV-2-nucleoside IgG interpreted as vaccine-induced antibody response. The Danish Medicines Agency finds that a connection between MIS-C and vaccination with Comirnaty cannot be excluded in the specific case. The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has been informed of the incidence, and an investigation of a general possible connection between Comirnaty and MIS-C has been launched.

MIS-C is a condition described in persons under 21 years of age who have had a SARS-CoV-2 infection. The common symptoms and clinical findings of MIS-C are persistent high fever, diarrhoea, vomiting, abdominal pain, headache, tiredness, chest pain and breathing difficulty, confirmed infection (e.g. elevated levels of CRP, procalcitonin, ferritin, and more) as well as multisystem organ involvement (cardiovascular, respiratory, nephrological, neurological, gastrointestinal, and more). The estimated frequency of MIS-C in children and adolescents after SARS-CoV-2 infection is 1:4000[1].

Patients who experience the above symptoms need to be referred for evaluation and treatment.

Information from the Danish Health Authority

The Danish Health Authority maintains its overall assessment that the benefits of vaccinating children outweigh the possible risks, and that the risk of developing MIS-C after a COVID-19 infection is greater than the possible risk of vaccination.

[1] Multisystem inflammatory syndrome in children occurred in one of four thousand children with severe acute respiratory syndrome coronavirus 2 - Holm - 2021 - Acta Paediatrica - Wiley Online Library

For information on treatment, please see the treatment guide from the Danish Paediatric Society: DPS Guideline MIS-C.

This guideline concerns SARS-CoV-2-induced MIS-C, but regardless of the disease triggers, the treatment is the same.

Reporting of suspected adverse reactions

This medicinal product is subject to additional monitoring, which means that new safety information can be provided fast. Healthcare professionals are asked to report any suspected adverse reactions.

In Denmark, Comirnaty is subject to stricter reporting requirements. This means doctors are required to report all suspected adverse reactions (except for suspected adverse reactions caused by medication errors). Serious adverse reactions must be reported to the Danish Medicines Agency no later than 15 days after the doctor became aware of an occurrence.

Doctors in general practice can report via the ADR service from their medical practice systems. Other healthcare professionals are requested to report all suspected adverse reactions via the:

Danish Medicines Agency
Axel Heides Gade 1
2300 Copenhagen S
Denmark
Website: www.meldenbivirkning.dk (Report a side effect from medicines)
Telephone: +45 44 88 95 95
Please remember to include the batch/lot number if available

Your sincerely,

Line Michan

Head of Pharmacovigilance

Danish Medicines Agency