## **COVID-19 vaccination of young children in clinical risk groups**

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# **Executive summary**

Health Council of the Netherlands



The European Medicines Agency (EMA) has recently recommended approval of the BioNTech/Pfizer vaccine against COVID-19 for use in children aged 5 to 11 years. The vaccine dose will be lower than that used in people aged 12 and above (10 micrograms per dose).

The Minister of Health, Welfare and Sport asked the Health Council of the Netherlands to advise on which groups of children under 12 years of age would be recommended the vaccine.

The Subcommittee on COVID-19 Vaccinations has assessed which children in the 5-11 age group are at higher risk of developing severe COVID-19 and whether they would be recommended the BioNTech/Pfizer vaccine. The Committee performed this assessment on the basis of the fixed criteria used by the Health Council in its advice on vaccinations. In the near future, the Health Council will assess the issue of making the BioNTech/Pfizer vaccine available to children aged 5-11 who do not belong to clinical risk groups.

#### Underlying conditions increase the risk of severe symptoms

Children between 5 and 11 years of age with certain underlying conditions are at higher risk of developing severe COVID-19 than their peers without such conditions. This involves both a higher risk of hospitalisation due to COVID-19 and a higher risk of MIS-C, a serious condition where different body parts can become inflamed following SARS-CoV-2 infection. Examples include chronic lung conditions, congenital heart conditions, neurological conditions or serious developmental disorders. The COVID-19 pandemic also has an indirect negative impact on children's health. For example, limited access to school, sports and social contact with peers can result in poorer health outcomes and delayed social-emotional development.

### Efficacy and effectiveness of the vaccine are sufficient

A clinical trial among over 2,200 children between ages 5 to 11 has found an efficacy of 90.7% for the BioNTech/Pfizer vaccine. Immune response levels were comparable to those observed in adolescents and young adults. It is expected, therefore, that the vaccine offers good protection against COVID-19 for children in the 5-11 age group.

## The vaccine is sufficiently safe – any side effects are usually mild

Like all medicines, the BioNTech/Pfizer vaccine has side effects. The most common side effects in the 5-11 age group are pain at site of injection, fatigue and headache. Side effects are more frequently observed following the second dose and disappear after one or two days.

#### The benefits of vaccination outweigh the potential harms and burdens

According to the Committee, the benefits of vaccination among the group of 5 to 11-yearolds with an underlying condition outweigh the potential side effects. This is because children in this group are at higher risk of developing severe COVID-19 and a complication known as MIS-C. Vaccination can reduce this risk (direct health benefit) and can also reduce the indirect adverse health effects of the pandemic.

### Advice: vaccination of 5 to 11-year-olds in clinical risk groups

The Committee recommends making COVID-19 vaccination available to children in the 5-11 age group with underlying conditions that increase the risk of developing severe symptoms following SARS-CoV-2 infection. Since practically all of these children are under paediatric care due to their health condition, the Council recommends that paediatricians select these children.

The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is "to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research..." (Section 22, Health Act). The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

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