### **COVID-19 vaccination of children aged 5 to 11 and the use of bivalent vaccines**

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# **Executive summary**

Health Council of the Netherlands

In January 2022, the Health Council issued a recommendation on the vaccination of children aged 5 to 11 against COVID-19. Because the epidemiological situation has changed since then, and new scientific data is available, the COVID-19 Vaccinations Committee has re-examined the usefulness of and need for primary and booster vaccinations for this group. The committee based its re-examination on the fixed criteria applied by the Health Council when issuing recommendations about vaccinations and on the *Application framework for additional booster vaccinations against COVID-19*.

#### Reduced burden of disease

Since the Omicron variant became dominant, the risk of developing severe COVID-19 from a SARS-CoV-2 infection is now low for most children aged 5 to 11. The risk is higher for children with serious underlying medical conditions, but still low in absolute terms. This group includes children with Down's syndrome, a heart condition, an immune disorder or lung disease (other than asthma).

Multisystem inflammatory syndrome in children (MIS-C) is a rare but severe complication of COVID-19 that can also develop in children without an underlying medical condition. To provide protection against MIS-C, in late 2021 and early 2022 the Health Council recommended making COVID-19 vaccinations available to children aged 5 to 11. It was noted that children who had already had COVID-19 did not have to be vaccinated to protect against MIS-C. In nearly every case, MIS-C develops following an initial infection and rarely occurs on re-infection. Since at least 90% of all children aged 5 to 11 have now been infected with SARS-CoV-2, the number of children still at risk of MIS-C is very low, especially since the likelihood of MIS-C arising from an Omicron infection is much lower than from an infection with an earlier variant of the virus.

Following a severe course of COVID-19, children may develop long-term symptoms. There is not yet sufficient information on whether this so-called post-COVID syndrome also arises in children who have had mild COVID-19.

#### Vaccine efficacy and safety

We have now built up considerable experience of vaccinating children aged 5 to 11 using the Pfizer/BioNTech vaccine. The data shows that vaccination provides protection against severe COVID-19. It also shows that protection against the Omicron variant is lower than for the earlier Delta variant, and that that protection wanes more quickly over time. Experiences with vaccination have confirmed that adverse reactions to mRNA vaccines in children are generally mild and temporary. Myocarditis/ pericarditis, a rare adverse reaction that can occur as a result of vaccination with an mRNA vaccine, generally presents mild symptoms in children.

The protection obtained from vaccination with bivalent vaccines is expected to be at least as good as that obtained from monovalent vaccines, with a comparable level of safety. Research in adults shows that the combination of vaccination and previous infection leads to a broader immune response than vaccination alone. Whether that is also the case in children is unknown.

#### **Updated recommendation**

The committee is of the opinion that, given the current epidemiological situation and based on the current state of scientific knowledge, it would be appropriate to amend the policy on the vaccination of children aged 5 to 11 against COVID-19. Its recommendation is that vaccination should only be offered to children aged 5-11 who have a serious underlying medical condition. Vaccination can provide health benefits to children in this group, who have an increased risk of developing severe COVID-19. This recommendation is in line with the recent Health Council recommendation for children aged from 6 months to 6 years. The recommendation relates to both the primary course of vaccinations and to booster vaccinations.

In exceptional circumstances, the vaccination of a child (with a primary course or booster) may be considered in order to provide indirect protection to a vulnerable family member who cannot be vaccinated themselves. This could also provide an indirect benefit to the child, such as by reducing stress and social limitations. The committee recommends that both primary and booster vaccinations should be made available in such situations. The committee emphasises the importance of providing clear information to parents, enabling them to make a carefully considered decision and – if they decide to allow their child to be vaccinated – to give informed consent.

The committee expresses no preference for a monovalent or bivalent mRNA vaccine and, within the scope of this recommendation, it recommends leaving the selection of an mRNA vaccine for the primary course and booster vaccinations to the administering organisation, based on the currently circulating strains and the registration status and availability of vaccines.

This applies for both children and adults. However, the committee would prefer that children aged 5 to 11 be vaccinated using the Pfizer/BioNTech vaccine, given that the adverse reactions are milder than from vaccination with the Moderna vaccine.

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