



SAHPRA STATEMENT: BCG Vaccination and COVID-19 Disease

SAHPRA has become aware of recent local and international media reports on observational studies that link programmatic BCG vaccination with a reduced risk of COVID-19 disease and its complications. These reports have resulted in a panic-driven increase in interest and/or demand for BCG vaccinations globally, which may pose a public health risk if essential BCG vaccines were to be diverted from state vaccination programmes. Such observational studies are generally only able to identify associations between a particular treatment and a disease outcome but cannot prove that the treatment had any effect on the disease outcome, because other unknown factors could be responsible for that disease outcome. The best way to determine whether BCG vaccination affects the risk of acquiring COVID-19 disease or suffering from severe disease is to conduct a randomised controlled clinical trial.

While SAHPRA notes the reported link, randomised controlled clinical trials have yet to be conducted to prove or disprove the theory that BCG vaccination does in fact reduce the risk of COVID-19 disease and its complications. Until such a link is tested through randomised controlled clinical studies currently under development, SAHPRA cautions the public against seeking BCG vaccination with the hope of preventing or reducing the severity of COVID-19 disease because there is currently no clinical trial evidence to support this theory. Moreover, most of the South African public has been vaccinated with BCG vaccine at birth or early childhood and the reported observational studies did not show any link between **re-vaccination** after childhood with the BCG vaccine and a decreased risk of COVID-19 disease and its complications.