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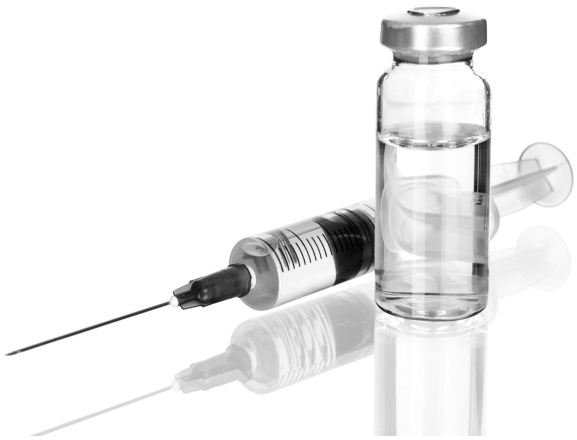
Australia grants provisional determination for Moderna bivalent COVID-19 vaccine

29 April 2022 | News

The bivalent vaccine includes the mRNA sequence encoding the spike protein of the Omicron variant



The Therapeutic Goods Administration (TGA), part of the Department of Health in Australia, has granted a provisional determination to Moderna Australia Pty Ltd in relation to its bivalent COVID-19 vaccine, elasomeran/elasomeran 0-omicron (SPIKEVAX Bivalent Zero/Omicron).

Currently, Moderna Australia has provisional approval for its COVID-19 vaccine, SPIKEVAX, for use in individuals aged 6 years and older.

This mRNA vaccine (mRNA-1273) is based on the original SARS-CoV-2 spike glycoprotein. With the emergence of COVID-19 variants of concern, Moderna has developed a bivalent vaccine that includes the mRNA sequence encoding the spike protein of the Omicron variant of concern and the same mRNA-1273 backbone as in the original SPIKEVAX vaccine.

The new provisional determination means that Moderna Australia is now able to apply for provisional registration for the bivalent vaccine for active immunisation to prevent COVID-19.

In making its decision to grant Moderna Australia a provisional determination, the TGA considered all eligibility criteria, including evidence of a plan to submit comprehensive clinical data and the seriousness of the COVID-19 pandemic.

Granting of the provisional determination precedes the market authorisation application and does not guarantee approval of the application. Moderna has six months during which time the authorisation application must be submitted.