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Australia approves CSL - Seqirus to manufacture AstraZeneca COVID-19 vaccine

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The Therapeutic Goods Administration (TGA) has approved manufacture of the AstraZeneca COVID-19 Vaccine (ChAdOx1-S) in Australia. This follows on from the 16 February 2021 approval by TGA of the overseas-manufactured AstraZeneca vaccine.

Manufacture of biological medicines such as vaccines is a highly-specialised process and the establishment of Australian manufacture of COVID-19 Vaccine AstraZeneca by CSL - Seqirus has involved extensive work by both industry and the TGA over the last six months.

Specific approval of Australian manufacturing by TGA was required to ensure that the locally-manufactured vaccine had exactly the same composition and performance as overseas-manufactured vaccine, was made to the same quality and is free of contaminants.

The vaccine is being manufactured at two sites in suburban Melbourne. CSL-Behring Australia in Broadmeadows are manufacturing the active raw vaccine material, while the final vaccine doses are being manufactured, vials filled and packaged at Seqirus in Parkville (a CSL company). Quality control testing of the raw material and product is also being carried out in these facilities.

The final step for the Australian-manufactured vaccine is TGA batch release, which is required for each and every batch of any vaccine supplied in Australia. This involves a review of documents supplied by the commercial sponsor describing how the vaccine batch was made, tested, shipped and stored as well as TGA's in-house laboratory testing to ensure the vaccine has been manufactured according to the required standards.

The Australian Government has purchased 50 million doses of the AstraZeneca vaccine, to be manufactured on their behalf by CSL, and, subject to individual batches passing TGA batch release requirements, these will form the mainstay of Australia's COVID-19 vaccination program over the coming months, and complement imported vaccine supplies.