Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Synthes Australia Pty Ltd

for approval to supply

Musculoskeletal Tissue - DBX Putty - Synthes Australia Pty Ltd - Paste - Syringe

ARTG Identifier	211454
ARTG Start date	26/06/2013
Product Category	Biological Included Class 3
Therapeutic Indication	DBX is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury. DBX can be used as an extender in orthopaedic spine and trauma use with autograft, allograft and bone marrow aspirate.

Manufacturer Details	Address	Manufacturing Steps
Musculoskeletal Transplant Foundation	1795-A-Orange Tree Lane Redlands, California, 92374 United States Of America	Storage on site
Musculoskeletal Transplant Foundation	1232 Mid Valley Drive Jessup, Pennsylvania, 18434-1823 United States Of America	Testing chemical and physical, Packaging and labelling, Processing, Release for supply, Storage on site
Musculoskeletal Transplant Foundation	Suite 300 / 125 May Street Edison, NJ, 08837 United States Of America	Packaging and labelling, Release for supply, Manufacture of Misculo-Skeletal Tissue
Steris Isomedix Services	2500 Commerce Drive Libertyville, Illinois, 60048 United States Of America	Sterilization - Gamma Irradiation
VRL Laboratories	6665 S Kenton Street Suite 205 Centennial, Colorado, 80111 United States Of America	NAT Testing for HIV, HCV and HBV, Virology Screening and Syphilis Testing
Wuxi Apptec Inc	1265-B Kennestone Circle Marietta, Georgia, 30066 United States Of America	Testing sterility
Wuxi Apptec Inc	2540 Executive Drive St Paul, MN, 55120 United States Of America	Testing chemical and physical

ARTG Standard Conditions

The above Biological Included Class 3 has been entered on the Register subject to the following conditions:

No conditions have been recorded against this entry.

Products Covered by This Entry

1. DBX Putty

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Syringe	Glass	Not recorded	Not recorded	2 Years	Store between 15-30 degrees Celsius	Store at room temperature

Product Specific Conditions

- 1) The therapeutic good must be supplied with the Product Insert at Attachment 4. Any proposed changes to the approved text of the PI must be submitted to, and be approved by, the TGA prior to distribution,
- 2) Changes or variations in respect of any information concerning the therapeutic good that would have been relevant to a decision to include the goods in the ARTG, shall be notified to the Secretary, or the Secretary's delegate appointed for the purposes of section 32ED of the Act. This includes information on the formulation of the goods or other aspects of their manufacture and the labelling of the goods. The change or variation shall not be implemented until approved by the Secretary,
- 3) Promotional material relating to the therapeutic good must comply with the requirements outlined in the Code of Conduct of Medicines Australia, Edition 17 effective 11 January 2013 (http://medicinesaustralia.com.au/code-of-conduct/),
- 4) The actual date of commencement of supply of the therapeutic good must be notified to the Director, Biological Sciences Section of the TGA. Should it be decided not to proceed to supply the therapeutic good in Australia, notification to this effect must be provided to the Director, Biological Sciences Section of the TGA. A copy of the notification form has been provided as Attachment 5,
- 5) The DBX Putty Risk Management Plan (RMP), version AE, dated 06 June 2013, included with submission BIO-2011-BA-00004-3, and any subsequent revisions, as agreed with the TGA must be implemented in Australia. An obligatory component of the Risk Management Plan applicable to this therapeutic good is Routine Pharmacovigilance. Routine Pharmacovigilance includes the submission of Periodic Safety Update Reports (PSURs). The reports must meet the requirements for Periodic Safety Update Reports as described in the European Medicines Agency's Guideline on Good Pharmacovigilance Practices (GVP) Module VII-Periodic Safety Update Report. Each report must have been prepared within seventy calendar days of the data lock point for that report, as required by the European Medicines Agency's Guideline for PSUR's covering intervals up to 12 months (including intervals of exactly 12 months). Unless agreed separately between the supplier who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than 15 calendar months after the date of this letter. The subsequent reports must be submitted no less frequently than annually from the date of the first submitted report until the period covered by such reports is not less than three years from the date of this approval letter. No fewer than three annual reports are required. The annual submission may be made up of two Periodic Safety Update Reports each covering six months. If the sponsor wishes, the six monthly reports may be submitted separately as they become available. Another obligatory component of the Risk Management Plan applicable to the therapeutic good is traceability of the biological material from the point of collection of donor tissue through to the recipient,
- 6) The sponsor must comply with any reporting requirements that are prescribed. For the purpose of this condition the reporting requirements set out in section 32 DQ of the Act must be complied with, specifically the Sponsor must inform the Secretary in writing, within the periods specified in the regulations, of: a) information that contradicts information already given by the person under this Act in relation to the biological (including information given about the quality, safety or efficacy of the biological): b) information that indicates that the use of the biological in accordance with the recommendations for its use may have an unintended harmful effect and: c) information that indicates that the biological, when used in accordance with the recommendations for its use, may not be as effective as the application for inclusion of the biological in the Register or information already given by the person under this Act suggests. Note: Section 32DQ of the Act also provides for penalties where the Sponsor of the goods fails to inform the Secretary in writing of the matters set out in section 32DQ.