Public Summary

Summary for ARTG Entry: 163591 HMR Healthcare Pty Ltd - Walking aid, two arms, frame, wheeled

ARTG entry for	Medical Device Included Class 1
Sponsor	HMR Healthcare Pty Ltd
Postal Address	Po Box 2098, MOORABBIN, VIC, 3189 Australia
ARTG Start Date	21/07/2009
Product type:	Medical Device - Class 1 - Included
Status:	Active
Approval area:	Medical Devices

Conditions

The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.

The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.

For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.

Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.

It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Devices, Blood and Tissues, Therapeutic Goods Administration following inclusion of the device in the ARTG. (as specified in 5.8 of the regulations) Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints received by the manufacturer relating to problems with the use of the device that have been received by them over the year.

Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Manufacturers

Name	Address
Trust Care AB	Vikingaplan 1 Malmo, , 21618 Sweden

Products

1. Walking aid, two arms, frame, wheeled

Product Type	Single Device Product	**Effective date**	21/07/2009

GMDN	31119 Walking aid, two arms, frame, wheeled
Intended purpose	A mobility aid used to assist a disabled or infirm user in walking by providing a means of support and increasing their ability to move around without attendance from another person. It is a wheeled frame with built-in handgrips, brakes, tray and legs, which provide support whilst walking, predominantly for indoor use. It can be of fixed or adjustable height and collapsible or non-collapsible.

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
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