

13 July 2020

Therapeutic Goods Administration (TGA)
PO Box 100
Woden ACT 2606
info@tga.gov.au

To whom this may concern,

Re: Sinemet CR Shortage

Dear Sir / Madam

Introduction

This letter is written on behalf of Parkinson's Australia, The Australasian Neuroscience Nurses Association (ANNA) Movement Disorder Chapter (MDC) and The Movement Disorders Society of Australia and New Zealand (MDSANZ).

Request

We are seeking that the TGA reinstate the Section 19A listing for the Carbidopa/Levodopa Extended-Release (Sun Pharmaceuticals) product as a generic alternative to Sinemet CR® as a matter of urgency.

Background

Sinemet® (levodopa/carbidopa) is a mainstay therapy for the treatment of Parkinson's disease and other neurological disorders. As you are aware, from 23rd August, 2018, there has been a world-wide supply shortage of three forms of this vital medication including the controlled-release formulation.

The shortage was expected to continue until 31 December 2019 but to date, despite Merck Sharp and Dohme (MSD) temporarily supplying their UK formulation - Sinemet CR® 50/200 prolonged release, patients have been advised by their pharmacist that they cannot obtain this medication.

Impact on People with Parkinson's

As a result of these shortages, many clinicians have had to substitute medications and adjust complex treatment regimens and often with suboptimal symptom control. This has been disruptive and distressing to patients who have had to negotiate with multiple pharmacies, hoard emergency supplies and in extreme cases purposefully under-dose themselves to make their supplies last.

Cost to People with Parkinson's

Although there are registered and recommended substitute products for the immediate release formulations, there is only one suitable controlled-release alternative that was temporarily available under Section 19A of the Therapeutics Goods Act (TGA) "Carbidopa/ Levodopa Extended - release (Sun-Pharmaceuticals)".

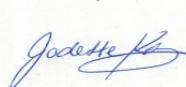
Unfortunately, the TGA listing and PBS approval has since expired and subsequently, people with Parkinson's must pay the full unsubsidised amount for their usual medications. It is crucial to ensure the accessibility and affordability of at least one generic extended-release alternative to Sinemet CR®.

Cost to the Government

Without the listing, it is likely there will be an influx of people with Parkinson's losing stability in their symptom control, with major consequences such as unnecessary hospital presentations.

We strongly urge for your consideration in this matter. For further correspondence in relation to this issue, please contact Jodette Kotz by email on ceo@parkinsons.org.au.

Sincerely,



Jodette Kotz
Parkinson's Australia
CEO



David Tsui
Australasian Neuroscience
Nurses Association (ANNA)
Movement Disorder Chapter
Chairperson



Dr Thomas Kimber
Movement Disorder Society
of Australia & New Zealand
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President