IMPORTANT MEDICINE SAFETY INFORMATION

25 June 2018

Dear Healthcare Professional

Re: MIRCERA® (METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA) and RECORMON® (EPOETIN BETA): NEW WARNINGS ON SEVERE CUTANEOUS ADVERSE REACTIONS

Dear Healthcare Professional,

In collaboration with the NAMIBIAN MEDICINES REGULATORY COUNCIL (NMRC), Roche Products (Pty) Ltd, would like to inform you of the risk of severe cutaneous adverse reactions in patients treated with **Mircera®** and **Recormon®**.

Summary

- Severe cutaneous adverse reactions (SCARs) have been reported in patients treated with Mircera® or Recormon®. These included cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) some of which have been fatal.
- Severe cutaneous adverse reactions are considered to be a class effect of all epoetins; including Mircera® or Recormon®.
- The frequency of these severe cutaneous reactions could not be calculated but they occur rarely.
- Patients should be advised of the following signs and symptoms of severe skin reactions when starting treatment with Mircera® or Recormon®
    - widespread rash with reddening and blistering of the skin and oral mucosa, eyes, nose, throat, or genital area, which follow flu-like symptoms including fever, tiredness, muscle and joint pain. This often leads to peeling and shedding of the affected skin which looks like a severe burn
- **Patients who develop these signs and symptoms should be instructed to contact their doctor immediately and stop Mircera® or Recormon®.**
- If the patient has developed severe cutaneous adverse reactions such as SJS or TEN which is considered to be related to the use of an epoetin, the patient **must never** be given an epoetin, including Mircera® or Recormon® again.

Background of the safety concern

Following post-marketing reports of severe cutaneous adverse reactions in particular SJS, TEN and blistering and exfoliative reactions with some epoetins including Mircera® or Recormon®, a detailed analysis of all cases (including data from the EudraVigilance database and data from the Marketing Authorisation Holders) has been performed for all epoetin-containing medicines.

This analysis has revealed that severe cutaneous reactions including SJS and TEN can be considered a class risk for all epoetins, including Mircera® or Recormon®. The more severe reactions were reported with long-acting epoetins and included cases with positive dechallenge and positive rechallenge.

Roche is in the process of updating the local professional information and patient information leaflet of Mircera® (methoxy polyethylene glycol-epoetin beta) and Recormon® (epoetin beta) to reflect the risk of severe cutaneous adverse reactions.

Any suspected adverse reactions associated with the use of Mircera® and/or Recormon® can be reported to Roche Products (Pty) Ltd, or alternatively to the TIPC Office, indicated below:

Company	**Contact details**
Roche Products (Pty) Ltd	Drug Safety Unit Tel: +27 11 502 5009 Fax: +27 11 268 5748 email: sa_ssa.drugsafety@roche.com
Therapeutics Information and Pharmacovigilance Centre (TIPC)	Tel: +264 61 203 2406 Fax: +264 86 451 8283 email: info.TIPC@mhss.gov.na

If you have any questions or require additional information, please contact Roche Products (Pty) Ltd as mentioned above.

Yours faithfully,

(Dr) Kgothatso Motumi
Management Centre Medical Head

(Dr.) Clinton Rambanapasi
Snr Regulatory Affairs Pharmacist