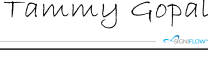


OF-CEO-04A	Document route form		
Revision 2.0	Compiler: Ms Ditshego Molefe	Approver: Ms Mukona Mphidi	Effective date:01 March 2021

DOCUMENT ROUTE FORM

Programme/Unit:	Complementary Medicines
Reference No:	Marico South Africa (Pty) Ltd - DL02-0d0bd4
Subject:	Issuing of Category D (Complementary Medicines) Licence

Name and Designation	Date	Signature	Comments
K Thembo Manager: CM Unit			
Silverani Padayachee Senior Manager: PEM			
Tammy Gopal CRO:SAHPRA			
Dr B Semete-Makokotlela CEO: SAHPRA			

Summary/Description

The above-referenced application is recommended for granting refers.

- An application to Import or export Complementary Medicines (CAT D) was received by the Complementary Medicines Unit via the CM Online Licence Portal
- The application was evaluated by the CM Unit and the CMC based on SAHPRA's acceptance of the applicant's attestation of compliance with minimum requirements at the time of application and the payment of the required desktop review fee.
- Following the evaluation, the application referenced herein is recommended to be granted for issuing a Category D medicines licence.
- The licence will undergo processing and the applicant will be advised of its availability for collection.

Attached please find:

- Combined applications representing the applicant application and all responses from the applicant including the final recommendation and signed product list (**Annexure A**);
- The SAHPRA resolution letter to issue licence to the applicant is attached (**Annexure B**) and
- A copy of the licence to be issued is attached (**Annexure C**)

Recommendation

OF-CEO-04A	Document route form		 South African Health Products Regulatory Authority
Revision 2.0	Compiler: Ms Ditshego Molefe	Approver: Ms Mukona Mphidi	Effective date: 01 March 2021

It is recommended that the Chief Executive Officer of the SAHPRA hereby note:

1. Approve and issue a Category D (Complementary Medicines) licence to the applicant **Marico South Africa (Pty) Ltd - DL02-0d0bd4**, valid for a period of 5 years from the date of approval
2. Approve the appending of Category D (Complementary Medicines) product list to licence of the applicant and
3. Approve the entering of details of the applicant as a licence holder in the Category D licence register together with a copy of the product list.

Dr B Semete-Makokotlela

Dr B Semete-Makokotlela

DR B SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER: SAHPRA

DATE:

Authorised:

Not Authorised:

Enquiries: Dr K.M Thembo
Reference: DL02-0d0bd4
Email: kaizer.thembo@sahpra.org.za

The Responsible Pharmacist
Unit B, 2 Jameson Drive,
JT Ross Park, Riverside Business Park
74 Prince Umhlangane Road,
Avoca, Durban, Kwa-Zulu Natal
4051
Email: john.mason@marico.com

Dear sir /madam

SAHPRA RESOLUTION: LICENCE ISSUED IN TERMS OF SECTION 22C(1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

Your application to Import or Export and Distribute Complementary Medicines (CAT D) refers.

Following evaluation of the applications based on SAHPRA's acceptance of the applicant's attestation of compliance with minimum requirements at the time of applications, the authority has resolved:

1. To approve and issue a Category D (Complementary Medicines) licence to the applicant **Marico South Africa (Pty) Ltd - DL02-0d0bd4** valid for a period of 5 years from the date of approval
2. To approve the appending of Category D (Complementary Medicines) product list to the applicant's licence;
3. To approve the entering of details of the applicant as a licence holder in the Category D licence register together with a copy of the product list.
4. The licence will now undergo processing and you will be advised of its availability for collection
5. Kindly note that a licence collection fee (R3 500) is payable in terms of the fees regulation 6(d) of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965)
6. Proof of payment for licence collection fee is to be mailed to Dr K Thembo (Email: kaizer.thembo@sahpra.org.za) and referenced accordingly

The resolution is based on the information available to SAHPRA at the time of its writing. SAHPRA maintains the right to alter this resolution should any information become available or is made known to the Authority.

Yours faithfully


Sherrani Padayachee

SENIOR MANAGER: PEM

LICENCE NUMBER: DL02-0d0bd4

**LICENCE TO
IMPORT AND EXPORT
COMPLEMENTARY MEDICINES (CATEGORY D)**

This licence is issued in terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and regulation 23 of General Regulations made in terms of the same Act, to the Licence Holder indicated herein and licenses this party to import or export Complementary medicines (Category D), inclusive of the activities stipulated herein.

Licence Holder

Address

**Marico South Africa (Pty) Ltd
Unit B, 2 Jameson Drive, JT Ross Park,
Riverside Business Park 74 Prince Umhlangane Road,
Avoca, Durban, Kwa Zulu Natal 4051**

LICENSED ACTIVITIES

Importing

Exporting

Storage

Testing / Laboratory Analysis

This licence consists of one page in addition to the letter of granting and the complete product list and is issued in terms of section 22C(1)(b) on the following conditions:

- The licence holder and the persons described and named in this licence must:
 - at all times ensure that all Complementary Medicines (Category D) associated with this licence, irrespective of registration status, comply with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended and the General Regulations made in terms of this Act;
 - be inspected at least once within a period of **FIVE (5) years** for verification of compliance with the minimum requirements as attested to; and
 - pay annual licence retention fees.
- Verification of appropriate standards and certification thereof will only be undertaken after successful inspection of the premises.
- Only products listed or attached to this licence will be permitted association with this licence as Category D medicines and continued rights of sale, provided that an application is submitted for their registration by the prescribed deadlines of the applicable notice issued in terms of section 14 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).
- This licence is issued to the licence holder based on SAHPRA's acceptance of the applicant's attestation of compliance with minimum requirements relevant to Category D medicines at the time of application and the payment of the required licence application and desktop evaluation fees.
- This licence is not a confirmation of applicable GMP standards, unless presented together with a valid SAHPRA GMP certificate.

The validity and content of this licence as the appended product list may be verified at

www.sahpracm.org.za – Registers – Category D Licences.

Boikarabo: Semofo Makoketjela
Boikarabo Semofo Makoketjela
SAHPRA

CHIEF EXECUTIVE OFFICER

DATE OF ISSUE: 01 May 2025

EXPIRY DATE: 31 April 2030

AMENDMENT DATE: N/A

*This licence remains the property of the South African Health Products Regulatory Authority. Upon amendment, voluntary withdrawal, recall, suspension or revocation of the licence, the original licence must be returned to the Office of the Chief Executive Officer.
[Licence to manufacture, import or export Complementary Medicines (Category D)]*