

## DEPARTMENT OF HEALTH

NO. R. 1099

12 OCTOBER 2018

## MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

The Medicines Control Council, by virtue vested in it by Section 14(2) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), has by resolution approved by the Minister of Health, determined that, with effect from the date of publication of this notice, all oral preparations which-

- (1) contain a bacterial strain(s) as listed in the Schedule hereto, either as such or in combination with any other pharmacologically active ingredient(s); and
- (2) make a medicinal claim other than the general health claim provided for their use as a Schedule 0 substance.

shall be subject to registration as medicines falling under Category A referred to in regulation 9(1) of the regulations promulgated in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and more particularly, as medicines falling under Class 30.4 of Category A of Appendix 1 of the Regulations.

It is hereby further notified that, under section 14(2)(b) of Act 101 of 1965, the above-mentioned resolution shall relate to preparations that are available for sale in the Republic on or before the date on which this notice comes into operation and shall relate also to preparations that become available after the said date.

**Bacterial Strains**

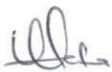
*Bifidobacterium adolescentis*,

*Bifidobacterium animalis subsp. animalis*,

*Bifidobacterium animalis subsp. lactis*,

*Bifidobacterium bifidum*,

Bifidobacterium breve,  
Bifidobacterium lactis,  
Bifidobacterium longum *subsp.* infantis,  
Bifidobacterium longum *subsp.* longum,  
Lactobacillus acidophilus,  
Lactobacillus brevis,  
Lactobacillus caucasicus,  
Lactobacillus casei,  
Lactobacillus delbrueckii (including Lactobacillus delbrueckii *subsp.* bulgaricus & Lactobacillus delbrueckii *subsp.* delbrueckii),  
Lactobacillus fermentum,  
Lactobacillus gasseri,  
Lactobacillus helveticus,  
Lactobacillus johnsonii,  
Lactobacillus paracasei,  
Lactobacillus plantarum,  
Lactobacillus reuteri,  
Lactobacillus rhamnosus,  
Lactobacillus salivarius,



**MS P NKAMBULE**

**ACTING CEO OF SAHPRA**

**DATE:** 25/04/2018