SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

UPDATE OF THE SOUTH AFRICAN APPROVED ACTIVE PHARMACEUTICAL INGREDIENT (API) NAMES IN THE SCHEDULES TO WHO INTERNATIONAL NON-PROPRIETARY NAMES (INN)

INTRODUCTION

The South African Health Products Regulatory Authority (SAHPRA) is updating certain active pharmaceutical ingredient (API) names used in South Africa to bring them into line with international nomenclature. Further name changes are also taking place – to improve consistency within South African approved terminology and remove non-harmonised, duplicate and out-of-date names.

The objective of harmonisation is to maintain clarity and consistency in API naming in order to support quality use of medicines. Consistency in naming supports the quality use of medicines by:

- minimising the risk of prescribing, dispensing and self-selection errors;
- enhancing consumer safety (through easier international information sharing); and
- avoiding consumer confusion and the potentially inappropriate use of medicines.

The use of non-harmonised, out-of-date or multiple API names can create significant problems for the pharmaceutical industry, consumers and healthcare professionals. South African consumers who travel internationally, healthcare professionals who have trained overseas or the public trying to access medicine information online may be unfamiliar with international medicine ingredient names and increase the risk of prescribing, dispensing and self-selection errors.

The WHO International Non-Proprietary Names (INN) are the global reference for medicine ingredient names. The list of WHO-approved INNs is updated twice a year. These updates include changes to the spelling or structure of existing ingredient names and the creation of new INN.

The process of amendment described in this communication has been undertaken by a number of other countries over the years, including the United Kingdom in 2003, New Zealand in 2008 and Australia in 2016.

SOUTH AFRICAN APPROACH

A five-year transition period to allow industry to bring medicine labelling in line with the policy will commence in June 2019 and will end in June 2024. Some changes are minor whilst others are more significant.

Change Type	**Examples**
Spelling (Does not change the pronunciation of the ingredient name)	Where appropriate using 'f' instead of 'ph'; 't' instead of 'th'; 'e' instead of 'ae' or 'oe'; 'i' instead of 'y'. Example: **oe**strogen to **e**strogen amox**y**cillin to amox**i**cillin
Hydration state	Example: carbidopa anhydrous to carbidopa
Dual labelling Both the old name and the new name to be included on the label to reduce the risk of the wrong medicine being used	Example: lignocaine will be dual labelled with lidocaine (lignocaine) and amethocaine with tetracaine (amethocaine). The old medicine ingredient name will appear in parentheses on the medicine labels and in the Register of Medicines. An exception is to be made for adrenaline and noradrenaline, where these will remain as the approved medicine ingredient name. The respective INN, epinephrine and norepinephrine, will appear in parentheses e.g. adrenaline (epinephrine).

These changes may be implemented as Type IA amendments. Both the old and the new name should be reflected on the medicines labelling for at least three years.

If the medicine package bears both an immediate container label and an outer label, the dual labelling requirements shall apply to the outer label as well. It shall be sufficient to provide only the new name on the immediate container label for small volume products.

All newly registered products launched after the implementation date of this notice must use the new API names on medicine labelling.

Please see attached Annex 1 for the Table of amendments to the active pharmaceutical ingredients in the Schedules.

ANNEX 1

Adrenaline and Noradrenaline

Old Name	New Name
adrenaline	adrenaline (epinephrine)
noradrenaline	noradrenaline (norepinephrine)

Dual Labelling

Old Name	New Name
actinomycin d	dactinomycin (actinomycin D)
amethocaine	tetracaine (amethocaine)
amylobarbitone sodium	amobarbital (amylobarbitone) sodium
bacillus calmette and guerin	mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)
benzhexol hydrochloride	trihexyphenidyl (benzhexol)
dothiepin hydrochloride	dosulepin (dothiepin)
glycopyrrolate	glycopyrronium bromide (glycopyrrolate)
hydroxyurea	hydroxycarbamide (hydroxyurea)
lignocaine	lidocaine (lignocaine)
phenobarbitone	phenobarbital (phenobarbitone)
procaine penicillin	procaine benzylpenicillin (procaine penicillin)
trimeprazine tartrate	alimemazine (trimeprazine)

Other Significant Changes

Old Name	New Name
chlorpheniramine	chlorphenamine
insulin - human	insulin
tetrahydrozoline hydrochloride	tetryzoline
triethanolamine lauryl sulfate	trolamine

Minor Spelling Changes

Old Name	New Name
alpha tocopherol	dl-alpha-tocopherol
amoxycillin	amoxicillin
beclomethasone dipropionate	beclometasone
cephalexin	cefalexin
cephalothin sodium	cefalotin
cephamandole	cefamandole
cephazolin	cefazolin
chlorthalidone	chlortalidone
cholecalciferol	colecalciferol
cholestyramine	colestyramine
clomiphene citrate	clomifene
cyclosporin	ciclosporin
dexamphetamine	dexamfetamine
dimethicone 350	dimeticone 350
ethacrynic acid	etacrynic acid
ethinyloestradiol	ethinylestradiol
flumethasone	flumetasone
flupenthixol	flupentixol
guaiphenesin	guafenesin
indomethacin	indometacin
oestradiol	estradiol
oestrogen – conjugated	conjugated estrogens
oestriol	estriol
thioguanine	tioguanine