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MAY 2022

SAHPGL-CEM-NS-03_v7_GUIDELINE TO PROPRIETARY NAMES FOR MEDICINES

This document provides guidance to applicants regarding the acceptability of proposed proprietary names of products submitted for registration as medicines. It represents the current thinking of the South African Health Products Regulatory Authority [SAHPRA] on naming policy, how naming policy is intended to inform treatment choice, promote health and protect the public in the safe and effective use of medicines, and how it contributes to the safety, quality and efficacy of medicines prescribing, dispensing, administration and usage by health care professionals and the public of South Africa. It is not intended to be an exhaustive listing and elaboration of all of the factors considered during the registration process of the relative weighting attached to any such factor.

DOCUMENT HISTORY

Final Version	Reason for Amendment	Effective Date
1	Version 1: First publication released for comment	01 December 2008
2	Version 2 for further comment	13 July 2010
3	Version 3 – Final Version	31 March 2011
4	Version 4- Implementation Date	08 December 2011
5	Version 5- Implementation date	21 December 2014
6	Version 6- Implementation date	06 November 2019
7	Version 7- Implementation date	30 May 2022

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1 INTRODUCTION

1.1. Scope

This document is intended to provide applicants, Holders of Certificates of Registration (HCR), responsible pharmacists, and regulatory pharmacists, with guidance on the criteria applied by the South African Health Products Regulatory Authority ("SAHPRA" or "the Authority") when evaluating the suitability of a proposed proprietary name for a medicine intended for human or veterinary use. This guideline should be read in conjunction with the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (herein referred to as the Medicines Act), as amended, and the Regulations issued in terms of the Act. The guideline also takes the World Health Organization (WHO) International Non-Proprietary Names (INN) policy into consideration.

Any proposed proprietary name is tested against the proposition that it may directly or indirectly pose public health or safety concerns or may be misleading and may thereby place patients or consumers[1] at risk. This guideline is not intended to be an exhaustive listing and elaboration of all of the factors considered by SAHPRA during the registration process or of the relative weighting attached to any such factor. SAHPRA considers the information and any motivation provided by applicants when assessing the proposed proprietary names of medicines and may perceive a need to call for additional information or motivation from the applicant. The same policies and principles apply in respect of proposed name changes as apply to the proposed names of new products.

1.2 A dynamic environment, primarily focused on public interest

The naming of medicines is a potentially complex process, which requires consideration of marketing, promotional, commercial, and competitive issues. However, medicines are not ordinary items of commerce, so their marketing and sale is strictly regulated. Protection of the consumer/patient and of the public interest enjoys primacy in regulatory policy and practice. he evaluation of proposed proprietary names of medicines takes place in a dynamic statutory, commercial, and scientific context. At the time of the initial promulgation of the Medicines Act some thousands of medicines were marketed in the Republic. Many thousands more have been registered since that date. Many medicines currently available in SA have been actively marketed for more than 40 years. Some of the proprietary names of 'old' products would not be acceptable in terms of current policy. However, this should not be seen as setting a precedent. Although more restrictive criteria will be applied to new products compared with "old" products, this is not unfair or un-procedural. In order to advance the common good, and where it is in the public interest to do so, applicants may be required to amend previously registered names to bring them in line with current medicines regulatory policy. Where the public interest is not adjudged to be significantly prejudiced (where the potential risk/ benefit impact is judged to be marginal), SAHPRA may take into consideration the possible commercial impact of the change in proprietary name.

SAHPRA is always open to cogent and persuasive reasoning and motivation, particularly in special situations or with respect to highly specialised products with a limited market products. Applicants are strongly advised to provide motivations and supporting documentation (including foreign authority) for naming proposals. In addition, applicants are advised to always consult the latest information available.

Approval of a proprietary name of a medicine in terms of the Medicines Act confers rights and privileges analogous to, though distinct from, the rights and privileges conferred by registration of a trade name under the Trademarks Act (Act 194 of 1993). A proprietary name approved by SAHPRA for use in connection with a registered medicine may not be used for other purposes without the express authority of the Authority, regardless of its registration as a trade

1 In this Guideline, it is necessary to bear in mind a distinction between patients and consumers. Patients receive and use medicines prescribed by their practitioners; consumers select the medicines they intend using. In each case additional professional advice and assistance may or may not be sought.

name. Registration of a trade name will not be considered when assessing the acceptability of a proposed proprietary name for a medicine.

1.4 Abbreviations & Definitions

API	-	Active Pharmaceutical Ingredient
BAN	-	British Approved Name
HCR	-	Holder of Certificate of Registration
INN	-	International Non-Proprietary Name
SAHPRA		South African Health Products Regulatory Authority
MRA	-	Medicines Regulatory Authority
NCE	-	New Chemical Entity
WHA	-	World Health Assembly
WHO	-	World Health Organization

1.4.2 Definitions

"Approved name" in relation to a medicine means the international non-proprietary name (INN) of such medicine or, where no such name exists, such other name as the Authority may determine, not being a brand name or trade name registered in terms of the Trademarks Act, 1993 (Act 194 of 1993).

"Product qualifier" means terms, descriptors, or qualifiers which are used in association with a product name to provide additional information about the specific product for the purpose of differentiating it from:
(a) other products by the same name in the same product range and
(b) other products of similar or identical composition and formulation, but marketed under a different name and by a different manufacturer.
Typical qualifiers include a description of the dosage form (e.g., tablet, solution, injection) with the addition of a strength (e.g., 100 mg/ capsule: 25 mg/5 ml syrup).

"Product range" means a range of products bearing the same name and containing the same API(s) but differing in their strengths and/or formulation variants. Inter alia, these differences may be reflected in differing product qualifiers. Additional products added to the product range are sometimes referred to as 'line extensions'.

"Proprietary name", "brand name" or "trade name" means the name which is unique to a particular medicine and by which the medicine is generally identified and which in the case of a registered medicine is the name approved in terms of section 15(4) of the Act;

"Umbrella range (of products)" means a thematic selection of products chosen to comprise a range of co-branded, differentiated but complementary products which in their totality offer different therapeutic options to meet different (but related) therapeutic needs. Thematically the range might, for example, comprise 'cough & flu' medicines; or an 'anti-allergy' range.

2 THE STATUTORY CONTEXT

The Medicines Act includes the following key definitions:

"medicine" -
(a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—
(i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
(ii) restoring, correcting or modifying any somatic or psychic or organic function in humans; and
(b) includes any veterinary medicine.

"Scheduled substance" means any medicine or other substance prescribed by the Minister under section 22A.

The term "**medicines"** therefore includes both **"scheduled substances"**, which are active pharmaceutical ingredients (APIs), and finished pharmaceutical products (FPPs). APIs are known by their generic, scientific or "approved" names rather than by any proprietary or brand name. These names are generally in the form of international non-proprietary names (INN). The Schedules to the Medicines Act list medicinal **substances**. The scheduling status of medicines depends upon the scheduling status of their APIs. FPPs are not listed in the Schedules, not ae their proprietary names listed. However, the approved proprietary name is reflected on the certificate of registration and appears in the register maintained by SAHPRA (accessible at https://www.sahpra.org.za/registered-health-products/).

Medicines are known by both their proprietary names and by the non-proprietary names of their active ingredients. Medicines *per se* are not listed in the Schedules to the Act.

Where no INN exists, the Authority may determine an appropriate "approved name", as provided for in section 1 of the Medicines Act:

"approved name", in relation to a medicine means the international non-proprietary name (INN) of such medicine or, where no such name exists, such other name as the Authority may determine, not being a brand name or trade name registered in terms of the Trade Marks Act, 1993 (Act 194 of 1993);

The final phrase of the definition is peremptory, in that it instructs the Authority to select or compose an approved name which shall not be a registered trademark. That is, it shall be a name in the public domain. This characteristic clearly differentiates an approved name from a proprietary name.
Section 15(4) of the Medicines Act provides for the approval by the Authority of the proprietary names of registered medicines and states that *"every medicine, medical device or IVD shall be registered under such name as the Authority may approve".* The General Regulations [2] published in terms of the Act provide a definition of a **"proprietary name"**:

"proprietary name", "brand name" or "trade name" means the name which is unique to a particular medicine and by which the medicine is generally identified and which in the case of a registered medicine is the name approved in terms of section 15(4) of the Act;

In evaluating the safety, efficacy, and quality of a medicine during the registration process, SAHPRA considers whether the proposed proprietary name could potentially pose public health or safety concerns or whether it may be

2 Government Notice No. 859, published in Government Gazette No.41064, 25 August 2017.

misleading. It seeks to prevent, to the greatest extent possible, potential medication errors or medical misadventures that may occur because of look-alike or sound-alike proprietary names, or names which may imply an ingredient, benefit or use that may be misleading either in nature or in degree.

3 POLICIES FOR THE EVALUATION OF PROPOSED PROPRIETARY NAMES

3.1 General Principles and Safety Concerns

In assessing the merits of a proposed proprietary name, the first and overriding consideration is that of patient safety. The proposed proprietary name should not be liable to result in any confusion in print, handwriting or speech with the proprietary name of another medicine.

When assessing the likelihood and the potential consequences of such confusion, the following aspects are considered:

- the registered indication(s);
- intended patient population(s);
- the pharmaceutical dosage form(s);
- the route(s) of administration;
- the strength(s);
- the dosage(s);
- the setting(s) for dispensing and use;
- the marketing channel (e.g., general dealers & supermarkets; specialised hospital use);
- the scheduling status(es);
- an assessment of potential for harm to a patient in the event of a prescribing, dispensing or administration error; and
- (potential) new pharmaceutical forms and/or routes of administration for the medicine concerned, as appropriate.

In addition, invented names should not be misleading with respect to the following:

- therapeutic effects of the product;
- composition of the product; or
- safety of the product.

3.2 Application of the International Non-Proprietary Name (INN)

SAHPRA subscribes to the World Health Organization (WHO) guidelines regarding the protection of international non-proprietary names (INNs) by the use of INN stems.[3] The WHO policy was outlined in a World Health Assembly resolution,[4] which called upon Member States to adopt policies whereby *"… invented names were not derived from international non-proprietary names (INN) and … INN stems were not used in invented names".* Furthermore, that "*the name of the medicine shall not be liable to confusion with the approved INN name of the API(s)".*[5] The WHO policy stance is that "*INNs are selected only for the active part of the molecule which is usually the base, acid or alcohol."* WHO has explained the object of INN development as follows:

"As unique names, INN have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INN universally available they are formally placed by WHO in the public domain, hence

3 See WHO/EDM/QSM/99.6

4 World Health Assembly Resolution WHA46.19

5 Article 1(20) of Directive 2001/83/EC (ref2) of the European Union.

their designation as "non-proprietary". They can be used without any restriction whatsoever to identify pharmaceutical substances. Another important feature of the INN system is that the names of pharmacologically-related substances demonstrate their relationship by using a common "stem". By the use of common stems, the medical practitioner, the pharmacist, or anyone dealing with pharmaceutical products can recognize that the substance belongs to a group of substances having similar pharmacological activity".

Two particular areas of concern have been identified:

- potential similarity between a proposed proprietary name and either a complete INN or such part of an INN as to imply the complete INN; and
- inclusion of an INN stem in a proposed proprietary name.

As a general principle, the INN may only be used in constructing proprietary names by combination with an identifier which is specific to the applicant/ holder of a certificate of registration (HCR). Exceptions to this principle will be considered only on specific motivation by the applicant, justified primarily on the basis of patient safety. Proprietary names should not be derived from an INN by deletion or alteration of any component part of the INN or through use of a homophone or near-homophone of an INN. No invented proprietary name may contain more than 50% of the letters in the INN, in the order they appear in the INN.

Proprietary names may not include a protect INN stem, as defined by WHO. Exceptions to this rule will not usually be considered. A single exception has been recognised in relation to the "-vir" stem, when used to construct a proprietary name for an antiretroviral. Applicants/HCRs may indicate the approval of a proprietary name by another medicines regulatory authorities that offends the INN stem rule, when motivating for its acceptance by SAHPRA. However, approval by another medicines regulatory authority will not necessarily be considered sufficient reason to ignore the INN stem policy.

WHO lists protected INN stems in four different ways:

abc-
-abc
-abc-
abc

In the first (prefix) form, the stem cannot be at the beginning of the proprietary name (but could be hidden in the middle or at the end). In the second (suffix) form, the stem cannot be at the end of the proprietary name (but could be hidden in the middle or at the beginning). In the third (infix) form, the stem cannot be used anywhere in the middle of the proprietary name (but could be the beginning or end). In the last form, the stem is protected anywhere in the proprietary name, and cannot be used at all. The most recent WHO publication (in the "WHO Drug Information" series) must always be consulted in relation to the definition of INN stems, and in particular with regard to the position of the hyphen, if any, in relation to an INN stem.

The WHO has also expressed the following request: *"… inclusion of elements from biochemical nomenclature (like? feron from interferon, or ?leukin from interleukin) in trade marks in anticipation is discouraged since these elements are likely to be utilized as stems within the INN nomenclature. Their inclusion in trademarks could pre-empt the logical development of the INN nomenclature".*

Further guidance on these issues can be obtained from the following sources:

- http://www.who.int/medicines/services/inn/innquidance/en/index.html
- http://www.who.int/medicines/services/inn/GeneralprinciplesEn.pdf
- http://whqlibdoc.who.int/hq/2004/WHO_EDM_QSM_2004.5.pdf

- http://www.who.int/medicines/services/inn/StemBook2018.pdf

Appendix 9.4 lists identified INN pre-stems, which are reserved for formal adoption as INN stems and are accordingly to be regarded with immediate effect and until further notice as fully operative INN stems. **Appendix 9.5** lists stems that were formerly used but are no longer formally acknowledged as such.

The use of INNs for APIs and excipients (where applicable) shall be mandatory in Professional Information (PI), Patient Information Leaflets (PILs), product labelling, advertising and other product communications, whether of a marketing or a professional nature.

3.3 Three types of invented names

These guidelines deal with three broad types of proprietary names:

PRODUCT NAMES: the proprietary names of individual, unique, registered medicines and their line extensions;

UMBRELLA NAMES: being collective, invented names of umbrella ranges of co-branded, differentiated but similar products for specified targeted conditions and/or pharmaco-therapeutic goals (as distinct from line extensions of single-API products or multiple-API combination products); and

CORPORATE IDENTIFIERS: 'house brands' or 'corporate identifiers', which are broader than umbrella ranges.

3.4 General principles regarding invented, English or non-English words or names

A proprietary name, umbrella name or corporate identifier should preferably be comprised of a single invented word. Applicants are encouraged to propose names that are as short as practicable. Multiple word proprietary names are more likely to be confusing to patients, while prescribers, dispensers and users are tempted to abbreviate them, which increases the risk of misunderstanding and/or misadventure.

Where more than one word is included in the proprietary name, hyphenated words are to be avoided. The following symbols may not be included in a proprietary name: +, &, #, @, =, [ ]. In addition, full stops, forward-slashes and colons should be avoided, where possible. However, the combination of the letters of the English alphabet with Arabic numerals,

The proprietary name of a medicine should not be misleading with respect to the composition of the medicine. This is particularly important in relation to umbrella names. The proprietary name of a medicine should not convey misleading therapeutic and/or pharmaceutical connotations. The following examples are provided to illustrate this point: A proposed proprietary name of "SEDINAX" for a medicine intended to treat pain and fever, and containing only an analgesic, might imply the inclusion of a "sedative". This could be considered to be potentially misleading. Similarly, a proposed proprietary name of "PAINKID" for a medicine not indicated for paediatric use could result in unsafe use of the product. The use of terms such as "Rapid" or "Fast Acting" in a name will not be permitted unless such claims are supported by scientific data attesting thereto and demonstrating the clinical and practical significance of the more rapid onset of action. Care should be taken to ensure that the proprietary name does not give rise to ambiguity or to inappropriate impressions or implicit claims of superiority or of greater potency or efficacy or speed of action. Terms which imply absolute efficacy, such as "MAX", "CURE" or "STOP" are discouraged.

Reference to non-medicine products or the use of terms, which imply that the product is not a medicine and tends to trivialise its medicinal properties in a manner inappropriate for a medicine or for the treatment of a medical condition, should be avoided. An example would be a term that implied that the product is a confection (a sweet) rather than a

medicine.

Ordinary English words or phrases as listed, for example, in a standard dictionary will not usually be considered for use as proprietary names of medicines (e.g. “WHISPER”). Personal names of people, whether first names and/or last names and relating to persons living, dead, or fictional, will not usually be considered for use as proprietary names of medicines (e.g. “HIPPOCRATES”). While a number of personal names have been approved in the past for inclusion in proprietary names, all future applications will be considered on their merits.

Applicants are advised to ascertain the meaning of non-English words included in proposed proprietary names, to ensure that these are not misleading in any way. Non-English words may be considered misleading because of their meaning in the original language, or in their English translation, when the name is taken at face-value, or in apparent transliteration. Any application for a proprietary name which includes a word or phrase in a language other than English must be accompanied by an English interpretation, translation, back-translation, and explanation and/or motivation for the word or phrase, such elucidation being provided and certified by a suitably qualified person in the relevant language(s), and the back-translator (who shall be a person other than the translator) being similarly qualified. In respect of each a *curriculum vitae* must be provided.

4 PRODUCT NAMES

4.1 Branded Medicines

South Africa is a country rich in its diversities, including eleven official languages, additional home languages and colloquial variants; variable literacy and educational status; and wide ranges of social and cultural expression. Obviously these factors weigh heavily on a statutory body whose brief with respect to the people of South Africa is to promote health, to protect from harm, and to foster access to appropriate, quality medicines for all in urban, rural and customary settings. This challenge is hardly lessened at the healthcare professional prescriber-dispenser interface, where the medium of communication between two people perhaps of different home language and exhibiting their own traits of dialect and pronunciation, must by word of mouth exchange highly technical data over, say, less than perfect telephone connections. The need for ‘unique, distinctive and differentiable’ product naming is pertinent.

All approved proprietary names shall be unique and distinctive. Each strength and/or dosage form variant of a product requires a unique, distinctive and differentiated name. Applicants should examine all available resources to establish that proposed names are unique and distinctive. “Unique and distinctive” in respect of a proprietary name means a name not the same or substantially similar to any other proprietary name and one readily recognizable by its characteristic form and component parts as being distinct and differentiable from every other proprietary name to the extent that it is unlikely to be mistaken or confused in speech or in writing with any other such name. Distinctiveness and differentiability require that look-alike and sound-alike names be avoided and distinctiveness and differentiability in the name must be evident with respect to its orthography, morphology and phonetics, and the name shall not be homophonic, homonymic or otherwise similar in sound, while anagrams and phonemic and morphemic anagrams or rearrangements should be avoided. In the creation of INNs, WHO has also encouraged the following practices: to make pronunciation possible in various languages, the letters “h” and “k” should be avoided; “e” should be used instead of “ae” and “oe”, “i” instead of “y”, “t” instead of “th” and “f” instead of “ph”.

Proposed proprietary names should ideally include the strength and/or dosage form especially if there are other strengths or dosage forms available for a particular active ingredient.

When the proprietary name being applied for is either identical to, or similar to a name previously approved, the applicant will be advised accordingly. Names which are identical to or which are similar to the names of medicines previously marketed and/or registered but subsequently withdrawn, discontinued, or no longer marketed will generally not be favourably considered, regardless of whether or not such products are dormant or are not currently marketed. Exceptions to this principle will be considered only upon specific motivation by the applicant, evaluated primarily on the basis of patient safety issues.

Disputes regarding similarity of names not identified by SAHPRA at the time of registration/ amendment are the responsibility of applicants, not SAHPRA. If, however, valid safety concerns are identified at a later time, applicants may be advised that a proprietary name previously approved must be changed with preference being accorded the earlier-registered of the products whose names are in conflict. Any issues regarding their respective products reported to either applicant to date will be considered.

The scheduling status of products will influence the evaluation of proposed proprietary names. In respect of Schedule 0 products, intended for general sales, self-selection of medicines by consumers/ patients should be regarded as the norm and proprietary names would be clear and unambiguous. The criteria for pharmacy-only medicines take into account the availability of professional advice at the point of sale, but the criteria are still consumer-focussed, though perhaps less stringently so. In the case of prescription-only medicines, the needs are somewhat different, being more technical/ professional (information-rich) regarding APIs, strengths and special factors, for example, route of administration or dosage form.

A proprietary name may, therefore, include a reference to a pharmacological/ therapeutic class or indication, provided that it is consistent with and of appropriate specificity with regard to the registered indications included in the professional information. However, each application of this nature will be evaluated on its merits.

4.2 Generic Brands

As every medicine registered in terms of the Medicines Act must be identified by a unique and distinctive product name which differentiates it from all other products, previously or currently on the market, unbranded generic names are not possible. Generic medicines are commonly named in exactly the same manner as other branded medicines. An additional option is, however, available to marketers of generic medicines. The INN name may be combined with a Corporate Identifier to create a composite proprietary name. In accordance with resolution WHA46.19[6], the inclusion of the entire INN in a proprietary name together with a word that identifies the applicant/ HCR, in the form a "Company Identifier" or "House Brand", is allowed. The composite name may not be hyphenated. Authorisation in this form does not preclude the inclusion of the same INN in another proprietary name by another applicant.

In the case of single component multisource medicines, applicants are encouraged to create proprietary names by combining the INN with a company identifier, which is the name of the applicant/ HCR. Since June 2019, all new applications must be in the format "INN identifier". All existing proprietary names in the form "Identifier INN) must be changed to the preferred format by June 2024 (five years after the date of publication of the guideline in June 2019).

In addition, by June 2024, all INNs are to comply with the updated spelling published in June 2019 (see **Appendix 9.6**).

Proprietary names which combine a company identifier and an invented name have the potential to lead to confusion amongst patients. Such composite names are discouraged, and approval would only be considered on motivation by the applicant/HCR.

6 WHA46.19. Resolution 46.19 of the World Health Assembly.

4.4 Product Qualifiers and Abbreviations

The proprietary name should preferably consist of only one word and should avoid qualification by letters or numbers, except where necessary to differentiate between different strengths or routes of administration. The use of qualifiers or abbreviations comprising letters and/or numerals as part of a product name is acceptable, as it serves to provide additional product information, thereby assisting consumer/ patient or health professional selection, and further differentiating the product from any other products. Typically, product qualifiers and abbreviations, when appended to product names, perform the function of indicating strength or dosage, route of administration and/ or dosage form. They are also a reference to formulation or therapeutic goal and can assist health care professionals or consumers/ patients to select or recall to memory the medicine they wish to prescribe or purchase.

Where the strength of a medicine is stated, this should be in the form of an Arabic numeral followed by an acceptable abbreviation of the unit of measure or strength concerned. Where the medicine contains more than one active ingredient and the strength is to be included in the proprietary name, the strength of each active ingredient will need to be listed. While the inclusion of more than two such strengths will not usually be considered, each application will be considered on its merits. Qualifiers consisting of a single letter or numeric are not recommended as they provide no context for conveying meaning or for the recall of information. A single numeral, for example, without qualification could be perceived to represent a strength, a number in a series, or a pack size. Where a qualifier is included in the form "INN identifier", it should precede the identifier.
If qualifications/ abbreviations are included in a proposed proprietary name, appropriate justification should be provided by the applicant explaining the meaning of the abbreviation or qualifier and the need for the benefit or its inclusion. When assessing the acceptability of a proposed qualifier/ abbreviation, SAHPRA will take into consideration whether the qualifier/ abbreviation conveys characteristics of the medicine which may help healthcare professionals and/or patients to prescribe/ dispense/ select the most appropriate medicine.

While a number of abbreviations have been approved in the past for inclusion in proprietary names, all future applications will be considered on their merits. The intention of SAHPRA is to not extend the use of abbreviations beyond those that have traditionally been associated with specific dosage forms or routes of administration. The use of promotional qualifications/ abbreviations or manufacturer's own codes would not be acceptable. A list of the most common, acceptable abbreviations is provided in **Appendix 9.2**.

4.5 Prescription to Non-Prescription Switch

In the case of a switch from prescription to non-prescription scheduling status for limited indications only, when a prescription product still exists on the market, a new application for registration together with a new proprietary name for the newly down-scheduled product must be submitted to SAHPRA. Exceptions to the above policy will only be considered on receipt of a fully justified application. In all cases, decisions will be guided primarily by patient safety concerns.

4.6 Approved Names of Standard API Combinations

In a small number of instances, a number of APIs are customarily combined to produce a single product. The British Pharmacopoeia Commission, responsible for formulating British Approved Names (BANs) in the United Kingdom, has recognised this phenomenon and the fact that in practice the need to write out in full the names of two or more actives has not surprisingly led to many, differing 'short form' versions of names being used to represent the more-frequently used combinations. Recognising the advantages to all concerned in formalising and standardising these 'short form' names for the compounded substances, the Commission has commenced publishing lists of certain standard combinations and assigning standardised names to them. Employment of these terms has all the advantages of the INN approach and their universal recognition. A number are also listed in Martindale, and the US Pharmacopoeial

Commission has adopted a similar approach. SAHPRA has decided in principle to adopt this system (though not necessarily the same 'short form' names) and will formalise the process from time to time by publishing a listing of approved names for "standard" generic combinations which applicants are encouraged to use in combination with their company identifiers or house brands as is commonly done with respect to the use of INN names for generic medicines. The currently approved list is provided in **Appendix 9.3**.

5 COMPANY IDENTIFIERS / HOUSE BRANDS

SAHPRA recognises that applicants/ HCRs place great importance on the significance and market value of their own names or trading titles in a competitive market economy. In certain instances, manufacturers/ marketers would wish to associate the company name with that of their products in the minds of patients, healthcare professionals and the public at large. Accordingly, provision is made to facilitate such an approach by permitting the use of "Company Identifiers" (also referred to simply as "identifiers") or "house brands". A "company identifier" or "house brand" may be provided by the use of the name of an applicant/ HCR or by a shortened form, contraction or abbreviation thereof. If this is not suitable, then a symbolic name used strategically and consistently in the manner in which a trademark, brand, or logo may be deployed to identify the company *per se*. As outlined above **(section 4.3)**, SAHPRA requires the use of a standardised format for the proprietary names of multisource/generic medicines which combine the INN with a company identifier.

The following principles will guide the approval of such identifiers:

- The identifier should be either the name of the Holder of the Certificate of Registration (HCR) or should clearly be derived from that name.
- Abbreviations of the name of the HCR will be considered on their own merits, with due regard to the principles outlined hereunder.
- The use of the name of a foreign licensee or other business entity not licensed as an applicant/ HCR in South Africa will not ordinarily be permitted without compelling motivation.
- Applicants are cautioned against using an identifier that could be construed as conveying misleading therapeutic and/or pharmaceutical connotations. Care should be taken to ensure that the identifier does not give rise to ambiguity or to inappropriate impressions or implicit claims of superiority.
- Placement of the company identifier in the invented name must be consistent, and care must be taken to avoid sound-alike and look-alike names which may lead to prescribing and dispensing errors.
- The use of a company identifier with a description of the indication, pharmacological category or therapeutic class is likely to be construed as not being sufficiently unique and distinctive and will in such event be considered as not meeting the requirement that a proprietary name shall be unique and distinctive (e.g., HCR cough syrup, HCR painkiller).
- In addition to the issues raised in this section, the criteria for the acceptability of Company Identifiers include the criteria applied to proprietary names as set out in 3.1 (General principles and safety concerns), 3.2 (INN Requirements) herein.

The name of an HCR may not be suitable for use as an identifier in the construction of the proprietary name of a medicine in the pharmaceutical environment. Accordingly, even though registered with the Companies and Intellectual Property Commission (CIPC), the name of the HCR as an identifier proposed to be used as part of the proprietary name may not necessarily be approved.

6 UMBRELLA NAMES FOR USE IN UMBRELLA PRODUCT RANGES

6.1 What is an Umbrella Range Name?

An umbrella name means: *a proprietary name intended for use not in connection with a single product (and its strength / form variants) but in connection with a range of products, the range typically being defined by the broad commonality of its targeted conditions, or pharmaco-therapeutic goals, etc.*

Examples may be a range of cough and cold medicines or a range of eye care products.

6.2 Features and Criteria for use of an Umbrella Name

An umbrella name is a brand name (i.e., an invented, stand-alone name) shared by a group of products by incorporation of the umbrella name into each of their names, and each of the latter names thereby becoming the (new) composite registered name of that product. The umbrella name is employed and is intended to increase the awareness and familiarity of consumers with the medicines as a group used to treat related ailments and conditions, i.e., conditions within a single broad therapeutic range, or with a cluster of symptoms associated with given ailments - such as cold and flu or seasonal allergies. An umbrella name is a stand-alone word and not a word-element such as a prefix or suffix. As a stand-alone word, it is used along with other words and possibly name elements (e.g., strength) to form an integral and unique name for a product.

An umbrella name is recognised by SAHPRA and is used to denote a specific range of registered medicines. Umbrella names must be compliant with all requirements relating to the composition of proprietary names, e.g., compliant with the rules regulating the use of INN stems; not misleading as to therapeutic effects, efficacy, safety or special patient populations; not offensive to any group; and not implying superiority of performance or effect; not liable or susceptible to confusion with any other umbrella or product name when spoken, written or printed.

An umbrella name typically originates from the existing, established (invented) proprietary name of a product, and in its new role is intended to designate a range of a type described in **Section 3.3** above. It is therefore distinct from the company identifier or house brand, as described in **Section 5.**

SAHPRA is concerned that the use of an umbrella name may have the effect of blurring product differentiation for consumers with a resultant negative impact on appropriate product selection optimal to the therapeutic needs of the patient. In general, the broad categorisation for all medicines with the same umbrella name should be the same. In addition, medicines covered by the same umbrella name should ideally contain a single common ingredient, with additional active ingredients suitably identified. Exceptions to this requirement will be considered on their merits. Particular problems arise when an umbrella name is to be used in the proprietary name which contains different active ingredient(s) and/or is for use in a different therapeutic area than the existing medicine using the same umbrella name. When an umbrella name is to be used in the proprietary name of a medicine which contains additional active ingredients and is for use in the same broad therapeutic category as one or more existing medicine(s) using the same umbrella name, the proprietary name of the new product should be clearly differentiated from the name(s) of the existing medicine(s), and should be indicated by the use of a suitable suffix or prefix more narrowly specifying the indications of that particular product within the broader range. Applicants are encouraged to give less prominence to the umbrella name and greater prominence to the active ingredient(s) or the differentiating features or indications as a means of guiding patients in their selection of the most appropriate product for their specific, individual needs.

Every proposal for an umbrella name will be considered by SAHPRA on a case-by-case basis taking the above-mentioned considerations and concerns into account, with public interest and patient safety being the paramount considerations.

6.3 Launching or Extending an Umbrella Range of Products

Whenever an applicant wishes to establish a new umbrella name, alter an existing umbrella name, or extend a range of medicines for which the proprietary names include an umbrella name, a motivation is required, which should address the following points:

- the rationale for the proposal;
- a full description of other registered medicines within the company's own range or from another company with a similar (either in spelling or phonetic terms) "umbrella name";
- indications for each relevant medicine;
- a full discussion of any safety issues that may arise from use of the "umbrella name" for the new application, should the new medicine be confused with other medicines with a similar "umbrella name", based on consideration of the safety profile of the active ingredients;
- implications for specific populations of patients/consumers where differences between medicines with the same umbrella name exist e.g. children, pregnant women, elderly people, those with renal or hepatic impairment;
- differences in interaction with other medicines;
- differences in indications, contra-indications, warnings, recommended doses (including dosing frequency, different strength);
- differences in effects and management of overdose;
- differences in the mode and speed of action between active ingredients in medicines sharing the same umbrella name in their product name and how the proposed use of different suffixes/ prefixes may differentiate between medicines, including details of the packaging design, and the placement, prominence and legibility of active ingredient data and usage information.
- Differences in the composition such as flavourants and other descriptive details must be included in the umbrella names.

6.4 Advertising of Umbrella Product Ranges

The extent to which umbrella product ranges may be advertised is determined by, and equal to, the advertising rights normally applicable to the highest Scheduled product within the umbrella product range. The use of an umbrella name and/or the establishment of a quasi-product range with the apparent intention or for the facilitation of conducting advertising by proxy will not be condoned. Thus, where a product in a higher Schedule (perhaps Schedule 2, in the case of a non-prescription brand, or Schedule 3 or higher, in the case of a prescription-only medicine) is used to spawn an umbrella name based upon the name of the higher-Scheduled product with the intention of registering a Schedule 0 or Schedule 1 medicine as a product in the range which includes the Schedule 2 or the prescription-only medicine, advertising rights may be withheld for the lower-Scheduled product as a condition for its registration. The creation of an umbrella name based upon a registered prescription-only medicine will not be permitted. No umbrella range that includes Scheduled or Registered medicines within the range of the products included under the umbrella name shall include unregistered or complementary medicines or *vice versa*.

7 OTHER MATTERS AND CONCERNS

7.1 Trade Mark Disclaimer

The issue of whether a particular proprietary name may constitute an infringement of another entity's intellectual property rights cannot be one of SAHPRA's concerns and is therefore not taken into account during consideration of the acceptability of a proposed proprietary name. Similarly, approval by SAHPRA of the use of any proprietary name shall not be relied upon in support of claims in respect of intellectual property rights over such proprietary name.

7.2 Submission by Applicants of Lists of Possible Proprietary Names

Proprietary names will usually be evaluated as part of a new application for the registration of a new medicine or as a subsequent separate application for a name change. Requests to SAHPRA to evaluate a list of possible alternative proprietary names, prior to the applicant submitting a formal application, are not encouraged.

7.3 Foreign Authority or Precedent

Where more than one major regulatory authority (defined as a regulatory authority that SAHPRA aligns itself with) has approved a proprietary name for use within their respective jurisdictions, this will be taken into account when considering an application for registration of the same name by the local subsidiary of the foreign principal or a local holder of a licensing agreement with such principal.

7.4 Changes of New Name Applications for Products still in the Process of Registration

Changes to proprietary names approved by SAHPRA in respect of applications for new medicine registrations which are still in progress can only be considered once the process for the registration of the new medicine has been completed.

7.5 Applications for Proprietary Name Changes to be accompanied by Professional Information

Applications to change an approved proprietary name must be accompanied by the currently approved professional information. Also refer to the BAU Variation Communication in this connection.

7.6 Prior Use

In the event that the previously registered proprietary name of a product has been amended and a new name been approved for the given product, SAHPRA will not consider use of the old (previously registered) name in connection with a new product application from any Applicant unless the formulation (in respect of its active ingredients and registered indications) of the proposed new product is identical to that of the previously approved old product.

8 VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces 2.15 Proprietary Names Guideline_v6_Nov2019. It will be reviewed on this timeframe or as and when required.

9 APPENDICES

9.1 Standardised Reasons for Rejection of a Proposed Proprietary Name

Any rejection by SAHPRA of a proprietary name proposed by an applicant will indicate a reason for such rejection. The following are the more common reasons for rejection of proposed names:

- Proposed proprietary name is not unique and distinctive.
- Proposed proprietary name is similar to an existing proprietary name [*cite name*] when spoken or written.
- Proposed proprietary name contains too great a proportion of an international non-proprietary name (INN) or is a homophone of an international non-proprietary name. Proposed proprietary name contains a WHO International Non-proprietary Name (INN) stem.
- Proposed proprietary names may contain popular names of people, places or items.
- Proposed proprietary name is misleading in relation to the composition, the pharmacological action or the expected therapeutic effect.
- Proposed proprietary name contains an inappropriate promotional element or makes or implies a medicinal claim that is not in line with the approved professional information.
- Proposed proprietary name contains an unacceptable/unknown/unexplained abbreviation or qualifier.
- Proposed proprietary name contains an unacceptable company identifier or umbrella name.
- Proposed proprietary name contains “CO”, “Plus”, “Forte” or another identifier that indicates this is a variant but the principal name(s) has not been evaluated and approved, this is subject to motivation.
- Proposed proprietary name contains any word that may imply superiority over other products.
- Proposed proprietary name contains insufficient motivation for the use of an umbrella name.

9.2 Acceptable Abbreviations and Qualifiers

Aq	Aqueous
BD	Twice daily
CFC	Chloro-Fluoro-Carbons (as in 'CFC-free')
Co	Combination (contains more than one active ingredient)
CP	Chromatographically purified
CR	Controlled release
D	Dispersible
DPI	Dry Powder Inhaler
DS	Double Strength
EC	Enteric coated
FC	Film Coated
FDC	Fixed Dose Combination
Forte	Higher strength of same active, or additional active
HS	Half Strength
IM	Intramuscular
IV	Intravenous
LA	Long Acting
MDI	Metered Dose Inhaler
MR	Modified Release
MS	Metered Spray
ND	Non Drowsy
NS	Nasal Spray
OD	Once Daily
ODT	Oral Dispersible Tablet
ORS	Oral Rehydration Solution
OTC	Over The Counter
PS	Prefilled Syringe
S	Suspension
SF	Suspension Forte
SC	Subcutaneous
SL	Sublingual
SR	Slow Release or Sustained Release
XL	Extended release
XR	Extended release

9.3 Approved Names of Standard API Combinations

- Co-amoxiclav *x/y* – amoxicillin (as the trihydrate or the sodium salt) and potassium clavulanate. *x* and *y* are the strengths in milligrams of amoxicillin and clavulanic acid respectively.
- Cotrimoxazole – sulfamethoxazole 5 parts and trimethoprim 1 part *m/m*.

9.4 Terms which may be included in future INNs

-feron-
-leukin-

Refer to WHO pre-stems policy.

9.5 Stems that were formerly used, but are no longer formally acknowledged by the INN Programme

These stems were initially used in the INN programme, but are no longer acknowledged or used in new medicine names. This is indicated by a '(d)' after the stem in Part IV of the Stem book and the stems included in this category are listed below.

-al (d)	aldehydes
andr (d)	steroids, androgens (USAN)
Under andr, ii. -stan- (d):	no definition
-arol (d)	anticoagulants, dicoumarol derivatives (USAN)
barb (d)	hypnotics, barbituric acid derivatives (BAN & USAN)
-crine (d)	acridine derivatives (USAN)
-cycline (d)	antibiotics, protein-synthesis inhibitors, tetracycline derivatives (BAN & USAN)
-formin (d)	antihyperglycaemics, phenformin derivatives (USAN)
-imex (d)	Immunostimulants (USAN)
-ine (d)	alkaloids and organic bases (note that approximatively 17.5% of proposed INN in Lists 1-119 end in -ine as it is included in various other stems)
curium (d)	curare-like substances
mer- or -mer- (d)	mercury-containing drugs, antimicrobial or diuretic (note that the suffix –mer is the INN stem for polymers)
mito- (d)	antineoplastics, nucleotoxic agents
-moxin (d)	onoamine oxidase inhibitors, hydrazine derivatives (USAN)
nifur- (d)	-nitrofuran derivatives (USAN)
-ol (d)	for alcohols and phenol
-one (d)	ketones (note that 635 INN ending in -one are included in Lists 1-105 of proposed INN – It is also included in various other stems)
-quine (d)	quinoline derivatives (some current antimalarial drugs in use)
-serpine (d)	derivatives of Rauwolfia alkaloids (USAN)
-stigmine (d)	acetylcholinesterase inhibitors (USAN)
-toin (d)	antiepileptics, hydantoin derivatives (USAN)

*USAN/BAN included in brackets indicates that the stem might still be included in USAN or BAN names not harmonised with the INN

9.6 Update of API names

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	epinephrine (adrenaline)
noradrenaline	norepinephrine (noradrenaline)

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)
dothiepinhydrochloride	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
gentamycin	gentamicin
guaiphenesin	guafenesin
indomethacin	indometacin
oestradiol	estradiol
oestrogen – conjugated	conjugated estrogens
oestriol	estriol
thioguanine	tioguanine