



PROPRIETARY NAMES FOR MEDICINES

This document provides guidance to applicants regarding the acceptability of proposed proprietary names of products submitted for registration as medicines. Approved by the Authority, 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 or of the relative weighting attached to any such factor. The Authority considers the information and any motivation provided by applicants when assessing proposed proprietary names of medicines and reserves the right to request any additional information or motivation. The same policies and principles apply in respect of proposed name changes as apply to the proposed names of new products. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of their applications. Guidelines and application forms are available from the office of the Chief Executive Officer of SAHPRA and on the SAHPRA website.

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CEO OF SAHPRA

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1 INTRODUCTION

1.1 Scope of the Guideline

This guideline should be read in conjunction with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, and its subordinate Regulations¹. It *inter alia* takes into consideration the provisions of the International Non-Proprietary Names (INN) policy of the WHO.

This document is intended to provide applicants, Holders of Certificates of Registration (HCR), Responsible Pharmacists, and regulatory pharmacists, *inter alia*, with information and guidance on the criteria and policies applied by the the South African Health Products Regulatory Authority (“SAHPRA” or “the Authority”) when evaluating the suitability of any proprietary name proposed to be used in connection with a medicine, whether intended for human or for veterinary use. It represents the current thinking of SAHPRA on the naming policy, how naming policy is intended to inform product selection, 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 the prescribing, dispensing, administration and usage of medicines by health care professionals and the public of South Africa.

Act 101 of 1965 and its Regulations define the statutory requirements against which a proposed proprietary name shall be adjudged to be compliant or non-compliant. Thereafter, and in addition, the 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 consumers² at risk.

The 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

The naming of medicines is a potentially complex process, on the one hand bringing to bear a host of marketing, promotional, commercial and competitive issues. On the other hand, medicines are not ordinary items of commerce or, at the very least, are highly specialised articles of commerce with the potential to literally ‘kill or cure’. For this latter reason the marketing and sale of medicines is strictly regulated in all mature modern economies and societies, including South Africa. Act 101 of 1965 is the statutory instrument governing this process and providing the framework for the subtle and nuanced consideration of all the issues regarding the appropriateness of proposed proprietary names.

These guidelines and the policies that inform them are constantly and necessarily evolving in response to local and global scientific, commercial and socio-political developments, as well as in keeping with international treaty obligations and geopolitical harmonisation initiatives and trends. SAHPRA actively endeavours to keep abreast of such developments; to interpret and consider their relevance in the South African context; and to keep its application requirements and evaluation procedures and policies appropriately aligned with what may be referred to as best regulatory practice.

¹ Medicines and Related Substances Act, 1965 (Act 101 of 1965), including Regulations published under the Act, (hereinafter collectively “Act 101 of 1965” or “the Medicines Act” or simply “the Act”)

² In policy development and 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.

1.3 A Primary Focus on the Public Interest

Protection of the consumer/patient and of the public interest enjoys primacy in regulatory policy and practice. Statutory regulation of medication product names is also an instrument of public health policy.

It is a given, therefore, that the evaluation of proposed proprietary names of medicines takes place in a dynamic statutory, commercial and scientific context. Importantly, it must also take place within an historic context. At the time of the promulgation of Act 101 of 1965 some thousands of medicines were marketed in the Republic and progressively became subject to regulation under the Act. Many thousands more have been registered in the half-century or so since that date. Many medicines currently available in SA have been actively marketed for more than 40 years.

Two issues regarding the naming of medicines immediately arise. 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 / limited-market products³. Information, explanations and motivations submitted by applicants in support of proposed proprietary names are carefully considered by the Names and Scheduling Advisory Committee. 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.

Assignment and registration of the proprietary name of a medicine under Act 101 of 1965 is a statutory dispensation conferring rights and privileges analogous to, though distinct from, the rights and privileges conferred by registration of a trade name under the Trade Marks Act⁴. The use of such name in any manner or in association with any product or medicine other than directly in connection with the registered medicine to which it refers and in connection with which the name is registered under Act 101 of 1965 (and subject to any such conditions as may be prescribed by the Authority from time to time) without the express authority of the SAHPRA is not permitted.

1.4 Abbreviations & Definitions

1.4.1 Abbreviations used in this document

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

³ Refer s 4.15 below

⁴ Trade Marks Act, 1993 (Act 194 of 1993).

1.4.2 Definitions applicable to the contents of this document

“**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 Council may determine, not being a brand name or trade name registered in terms of the Trade Marks 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 the addition of strength (e.g. 100 mg/ capsule; 25 mg/5 ml syrup), etc.

“**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**”: refer to *Statutory Context*, below

“**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

2.1 Statutory Interpretation of Act 101 of 1965 and the Regulations made under the Act

The Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the Regulations as amended made under the Act provide the statutory framework in terms of which the South African Health Products Authority exercises its authority and responsibility for administering the names of medicines in South Africa. Textual and contextual interpretation of the statute is necessary to clarify the intended meaning and consequential implications of the law. A key issue is the two different meanings ascribed to the word “medicine(s)”. The meaning depends on the context in which the word is being used.

Contextual statutory interpretation distinguishes the term ‘medicines’:

Firstly, the Medicines and Related Substances Act defines '**medicine**' as follows:
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,

Further, the Medicines and Related Substances Act defines '**scheduled substance**' as follows:

“**Scheduled substance**’ means any medicine or other substance prescribed by the Minister under section 22A”

The term '**medicines**' therefore includes both:

- (i) medicinal *substances*, which are active pharmaceutical ingredients ('APIs') or raw materials and/or excipients used or purporting to be suitable for use as ingredients or components in the preparation or manufacture of finished pharmaceutical products; and
- (j) medicines, which are finished pharmaceutical products containing medicinal substances, ready for use by health professionals, patients or carers.

Medicinal *substances* are known by their generic, scientific or 'approved' names rather than by any commercial or brand name. These names are generally in the form of international non-proprietary names (INN). The Schedules to Act 101 of 1965 list medicinal *substances*.

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. The Scheduling status of medicines depends upon the Scheduling status of their active ingredients.

Act 101 of 1965, as amended, provides for the approval by the Authority of the non-proprietary ('approved name' or "generic name") name of a medicinal substance as follows:

In section 1 of the Medicines Act the "approved name" is defined as follows:

"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 of approved name above, "not being a brand name or trade name registered in terms of the Trade Marks Act, 1993 (Act 194 of 1993)" is, in the first instance, peremptory. It instructs the Authority to select or compose an approved name which shall not be a registered Trade Mark. That is, it shall be a name in the public domain. Implicitly, the alternative name shall (as is the case with the INN) remain in the public domain. This characteristic clearly differentiates an approved name from a proprietary name.

Section 15(4) of the 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 ⁵ 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;

The proprietary name referred to above is thus the brand name applied for by an applicant or HCR for application to this registered product, and the use of which for such purpose is subject to approval

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

⁵ Government Notice R.510, published in Government Gazette No. 25727, 10 April 2003.

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 International Non-Proprietary Names (INN): Requirements

South Africa and SAHPRA subscribe to the WHO guidelines regarding the protection of INN stems, and encourage the pharmaceutical industry to be continually aware of this issue.⁶

The WHO policy on the protection of INN stems was outlined in a World Health Assembly resolution⁷ 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, *the name of the medicine shall not be liable to confusion with the approved INN name of the API(s)*.⁸

The WHO system is based on the global recognition and protection of international non-proprietary names (INNs) and adoption of a common nomenclature as one of the fundamental elements in setting standards of pharmaceutical care based upon essential medicines lists and treatment protocols.

⁶ See WHO/EDM/QSM/99.6

⁷ World Health Assembly Resolution WHA46.19

⁸ Article 1(20) of Directive 2001/83/EC (ref2) of the European Union.

The WHO has explained the object of name 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 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”.

It is a policy requirement that the use of INN nomenclature for APIs and excipients (where applicable) shall be mandatory in Professional Information for Medicines inserts (PIM) for Human Use, Patient Information Leaflets (PILs), product labelling, advertising and other product communications, whether of a marketing or a professional nature.

The WHO has expressed the following policy stance: *“In principle, INNs are selected only for the active part of the molecule which is usually the base, acid or alcohol.”*

As a general principle, only INN, may be used in constructing proprietary names by combination (or ‘use-in-association’) with a company identifier of the applicant/ HCR. Exceptions to this principle will be considered only on specific motivation by the applicant, justified primarily on the basis of patient safety.

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.

The most recent publication of INN (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.⁹

For example, “-ac” is an INN stem for anti-inflammatory agents of the ibufenac group, and a proprietary name ending with “ac” would not be acceptable. A proprietary name commencing with, or containing “ac” in another position within the name could, however, be considered.

Exceptions to the rule on the inclusion of INN stems will not usually be considered. A single exception has been recognised in relation to the “-vir” stem, which was commonly applied in the proprietary names of antiretrovirals. Each application should, nonetheless, indicate which competent regulatory authority has already approved the use of a proprietary name that offends this policy when motivating for its acceptance by SAHPRA.

As a general principle, 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.

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 trade-marks could pre-empt the logical development of the INN nomenclature”.*

⁹ An INN stem may have a hyphen to its left, a hyphen to its right, or may have two hyphens or no hyphens. The hyphen(s) indicates whether the disallowed position of the INN stem in a name is prefixal or suffixal to the root name, or that its inclusion within the root name is allowed. Any other position is permissible.

Appendix 9.4 contains stems which have been identified as INN pre-stems 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.

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>

3.3 Three Types of Invented Names

These guidelines deal with three classes of proprietary names and hence with three classes of intellectual property in the form of trademark-able and, most commonly, invented names. These are:

- PRODUCT NAMES; the proprietary names of individual, unique, registered medicines and their line extensions;
- UMBRELLA RANGE NAMES; 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 or Non-English Words or Names

An invented product name (or umbrella name or corporate identifier) may comprise one or more natural or invented words in English or in any official South African language. The name may be used with any letters and numbers, and with certain punctuation marks, namely, full stops, hyphens, forward-slashes, and colons. Round brackets may be acceptable in pairs to isolate any part of the name as per standard grammatical and semantic usage. None of the following symbols, or any other, may be used as part of an invented name: +, &, #, @, =, [].

A combination of the letters of the English alphabet, Arabic numerals, and the punctuation marks listed above, and round brackets may thus be used in a name.

The invented 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” (see below).

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.

Reference in the name 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, is unlikely to be approved. An example would be a term that implied that the product is a confection (a sweet) rather than a medicine.

Applicants are advised to ascertain the meaning of non-English names derived from local and international languages to ensure that these are not misleading in any way, either in their own tongue or in their English translation, the name 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 vita 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.

When the proprietary name being applied for is either identical to or similar to a name previously approved, the applicant will be advised accordingly.

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.

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.

The scheduling status of products will influence the evaluation of proposed proprietary names. Of specific relevance is whether the product is likely or is intended to be designated Schedule 0, that is, for open sale through non-pharmacy general dealers; Schedule 1 or 2, being Pharmacy-only; or Schedule 3 – 6, being prescription-only. In respect of general sales category products, the focus is strongly on a context wherein self-selection of medicines by consumers/ patients should be regarded as the norm and an enhanced requirement for transparency and objectivity in naming practice is perceived to exist. 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, as allusion, 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 package insert. However, each application will be evaluated on its merits.

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.

4.2 What will not work as or in a Proprietary Name

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 de novo on their merits.

Names comprising one or two letters and/or other characters, or names comprising an abbreviation, cipher or acronym, will not ordinarily be considered for use as proprietary names of medicines (e.g. "Q", "TPN").

The invented 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.

4.3 Generic Brands

It is a statutory requirement in South Africa that every product registered under Act 101 of 1965 must be identified by a unique and distinctive product name which differentiates it from all other products, previously or currently on the market. This provision of the Act does not exempt generics from the requirement. Thus the generic medicines policy is one based on branded generic products and a product may not legally be marketed under a purely generic name – a policy referred to as commodity generic marketing.

In the first instance, then, generic medicine products are commonly named in exactly the same manner as all other branded medicines are, and the entire contents of 4.1 above (*'Branded Medicines'*) applies also to generic medicine products.

Another option, however, is available to marketers of generic products. The INN name may be

combined with the Corporate Identifier to create a composite. In accordance with resolution WHA46.19¹⁰, the inclusion of the entire INN in a proprietary name together with a word that identifies the applicant/ Holder of Certificate of Registration (HCR) (“Company Identifier” or “House Brand”) is allowed.

Naturally the format is available to all applicants and cannot be available exclusively to any single company. Hence a condition of approval is that authorisation does not preclude the inclusion of the same INN in another proprietary product 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. All new applications must be in the format “INN identifier” and all existing names must be changed to this format within 5 years of the date of publication of this guideline.” The composite name may NOT be hyphenated.

It is also considered that applications which combine an identifier and an invented name have the potential to lead to confusion amongst patients. Approval of such proposed names is therefore not automatic and still requires the consideration of the Names and Scheduling Advisory Committee.

4.4 Product Qualifiers and Abbreviations

The use of qualifiers or abbreviations comprising letters and/or numerals as part of a product name is in principle acceptable insofar 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.

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; it is believed that they are distracting rather than cognitively enriching. A single numeral, for example, without qualification could be perceived to represent a strength, a number in a series, or a pack size.

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.

Where the strength of a medicine is stated, this should be in the form of either an Arabic numeral at the end of the proprietary name, or 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.

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

¹⁰ WHA46.19. Resolution 46.19 of the World Health Assembly.

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 de novo on their merits. The intention of SAHPRA is not to 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" 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 the CEO of 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 significant instances, a number of active pharmaceutical ingredients (APIs) are customarily compounded to produce a single product, which combination comes to be widely used in clinical practice.

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 the CEO will formalise the process by from time to time 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.

Please refer to Appendix 9.3 for initial proposals in this regard.

5 COMPANY IDENTIFIERS / HOUSE BRANDS

More details on the appropriate construction of company identifiers are provided in sections 3 and 4 above.

SAHPRA recognises that applicants/ HCRs place great importance on the significance and market value (the 'goodwill') of their own names or trading titles in a competitive market economy. In certain instances, such as are provided for herein 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" (herein also referred to simply as "identifiers") or "house brands" as follows:

"A 'company identifier' or 'house brand' may be provided by the use of the name of an applicant/ HCR or or by a shortened-form, contracted or abbreviation thereof, if this is not suitable, then a symbolic name used strategically and consistently in the manner in which a trade mark, brand, or logo may be deployed to identify the company per se and, in respect of the company's products, to indicate their source of supply, the character and reputation of the supplier, and the extent and quality of its product range."

As outlined above (section 4.3), SAHPRA requires the use of a standardised format for the proprietary names of multisource 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.
- 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 Registrar of Companies, 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; 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; seasonal allergies; diarrhoea or ‘upset stomachs’.

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 thereby accorded statutory approval and formal recognition. It is intended to be

- used to denote a specific range of registered medicines;
- unique amongst product names, umbrella names and company identifiers (or “House brands”);
- invented and constructed and/or selected in a manner analogous to the rules of construction and use as are afforded proprietary names of products registered under the Act;
- 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 must not be confused with a company identifier or house brand, as described in Section 5.

It is of fundamental importance that SAHPRA requires applicants to develop unique and distinctive proprietary names for their medicines. The concern of SAHPRA is 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. Accordingly, the use of umbrella names and the development of product ranges – non-homogenous with respect to their APIs – is not encouraged.

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. A proprietary name that includes an umbrella name should not be misleading with respect to the therapeutic effects of the medicine, the composition of the product or its safety profile. It should also not lead to confusion of one medicine with other

medicines and, in particular, special care should be taken to differentiate products within the range from one another.

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. Such applications would not easily be approved without extensive and convincing motivation.

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. Neither the umbrella name nor any suffix or prefix within the overall name should give rise to ambiguity or to inappropriate impressions or implicit claims of superior therapeutic efficacy, superior quality, or a superior safety profile.

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.

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 the Names and Scheduling Advisory Committee 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 Amendments guideline 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 UPDATE HISTORY

Date	Reason for update	Version & Publication
Dec 2008	First publication released for comment	v1 Dec 2008
28 Feb 2009	Due date for comment	
28 Feb 2010	Call for additional Comment from Professional Bodies	
July 2010	Published for further comment	v2 July 2010
30 Sept 2010	Due date for comment	
31 March 2011	Final Version	v3 March 2011
30 Sept 2011	Alignment with Legal Opinion	v4 Sept 2011
Dec 2011	Implementation Date	v4 Dec 2011
March 2014	Review of entire document: Amendments to all sections	v5 April 2014
08 May 2014	Due date for comment	
Dec 2014	Implementation Date	V5 Dec2014
Dec 2018	Review Date	v6 Dec2018
May 2019	Draft for Public Comment	v6 May2019
Nov 2019	Implementation Date	v6 Nov2019

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 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 package insert.
- 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 an invented name together with a company identifier.

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
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
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 INN

- -feron-
- -leukin-
- Refer to WHO pre-stems