EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

An update on the new Name Review Group (NRG) Guideline

PTMG conference – Athens, Greece

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Presented by Alexios M. Skarlatos on 05 October 2023
Head of Labeling Office

Name Review Group (NRG)

- Established by the Committee on Human Medicinal Products (CHMP) in 1999 to assess (invented) names (IN) of medicines submitted in the centralised procedure.

- Composed of ≈50 contact points in all Member States; of those, 15 regular attendees representing the main language groups + two experts on patient safety

- Chaired by an EMA representative

1 Draft guideline on the acceptability of names for human medicinal products processed through the CP (rev. 7)

Language family	Member States	Population (millions)
Romance	IT, FR, ES, PT, RO	180.7
Slavic	BG, PL, CZ, SK, SI, HR	89.5
Baltic	LT, LV	13.9
Greek	EL, CY	12
Semitic	MT	0.4
Uralic	HU, EE, FI	16.6
Germanic	BE, DK, SE, IE, LU, DE, NL, AT, IS, NO	148.9

+ 2 experts on patient safety

EC and WHO consulted on a case-by-case basis

Guidance update

- Supersedes version 6 (2014).
- Extensive review due to time elapsed since last update.
- Supported by consultation with Healthcare Professionals and Patients & Consumers Working Parties; EMA Legal and Regulatory departments.
- Currently at the stage of finalisation => aiming to publish by Q1 2024.

Clarification of criteria applied to address safety and public health concerns with proposed invented names

- The whole name of another medicine should not be included in the proposed one;
- Lifecycle of the medicine to be taken into account in the name creation;
- Promotional message: definition included;
- Pronunciation aspects may lead to rejection (e.g. use of consecutive vowels and consonants ➔ supported by HCPs, Patient and consumer consultation);
- Expanded information on qualifiers which should not be used, e.g. symbols, medical abbreviations. Translation may be possible in exceptional circumstances;
- Provision to reject a name if considered too long to fit on very small immediate containers;
- Cognitive error: definition added.
- The name of the MAH* (as part of the naming proposal) may also trigger safety concerns and lead to rejection.

** Marketing Authorisation Holder*

INN concerns in proposed invented names

- **50% rule** for assessment of INN similarity: 50% or more of the invented name is made up of INN parts, and/or 50% or more of the INN is included in the invented name. Case-by-case review. The NRG will also consider:
  - shared letter strings and their sequence;
  - inclusion of INN stems.
- In case of generics using INN+MAH/TM names, the **order of the active substances** should be aligned with that of the reference medicinal product.
- In case of established active substances where the strength has **traditionally** been expressed on the basis of an **unpublished INNM*** instead of the WHO recommended INN, the unpublished INNM shall be used if the applicant/MAH can justify the extensive and well-known use of the INNM versus the recommended INN.

** Modified INN*

Regulatory/submission aspects

- Stop the review of an invented name considered of unacceptable quality once it is ascertained that the name will be rejected, with no chance of objections being withdrawn in case of justification (e.g. VOLOSAL versus VOLOSSAL);
- Initial validity period maintained to 3 years; reduction of extension period of validity to 1 year (from current 3);
  - Objective: to reduce the number of names which are valid in the database, but not in use, which complicate the creation of names and management of the procedure.
  - Analysis showed the rate of requests for reconfirmation of accepted names is very low.
- Introduction of a new section on conditional acceptability and bilateral negotiations.

Regulatory/submission aspects

- Creation of a section on re-use and reconfirmation.
- (Invented) name 'in use': definition added ➔ once the marketing authorisation has been submitted and successfully validated.
- Clarifications on validity of accepted INs after withdrawal/negative opinion => the 'in-use' IN remains valid until its expiry date.

Submission aspects

- Information on use of 'Public data from Article 57 database';
- Once two names have been accepted (fully/conditionally), no further names will be reviewed. Order of preference always requested before review;
- If applicants wish to retain a conditionally accepted name together with a fully accepted one (i.e. 1st or 2nd in order of preference), no further submissions will be accepted;
- Restrictions imposed on endless withdrawals of accepted names and re-submissions of new proposals to control the abusive use of such option;
- Introduction of NRG decision-making checklist for similarity-based objections as appendix.

Post-authorisation issues related to (invented) names

- Re-introduction of the requirement for MAHs to communicate medication errors related to the (invented) name of a medicinal product (e.g. product name confusion) when no adverse reaction occurred (i.e. near-misses), as there is no requirement to report this information to Eudravigilance.

Appendix: NRG checklist for assessment of objections on the basis of name similarities

			High	Medium	Low	
1	Degree of orthographic and phonetic similarity	Print				
		Speech				
		Handwriting				
		Cognitive error				

			Yes	No	n/a	Unclear	Are any medicine management process controls in place	Yes	No
2	Setting of use	Possible risk identified at **PRESCRIPTION** level?							
		e.g. - Same therapeutic area/indication - Same prescriber - Close on electronic prescribing lists - Handwritten prescriptions - Emergency situations							
		Possible risk identified at **DISPENSING** level?	Yes	No	n/a	Unclear			
		e.g. - Same storage conditions and proximity (e.g. shelf, fridge, controlled drugs locked cupboard, etc.) - Close on electronic dispensing lists. - Same dispensing facility (hospital pharmacy, community pharmacy, aseptic department, directly from ward stock, directly shipped by manufacturer on patient named basis, etc.) -Emergency situations							
		Possible risk identified at **PREPARATION** level?	Yes	No	n/a	Unclear			
		e.g. - Both to be mixed together prior to administration (e.g. error of dosing)? - Can they both be put in a Monitored Dosage System (MDS)/Individualised dosing system?							
		Possible risk identified at **ADMINISTRATION** level?	Yes	No	n/a	Unclear			
		e.g. - Self-administration in same patient population? (patient may confuse both products at home) - Emergency situations - Administered by HCP							

			Same	Similar	Different	n/a				
3	Elements that may increase/reduce the risk of confusion	Strengths								
		Pharmaceutical forms								
		Route of administration								
		Legal status								
		Proposed labeling								

4	Potential for harm in case of accidental mix-up	High	e.g. death or major injury.
		Medium	e.g. minor injury.
		Low	e.g. no injury.
		n/a	e.g. no risk of confusion identified.
		Unknown	e.g. when the actual potential for harm is unknown.

Name A

ENTRILIO, Entrillio, EMTRILLIO,

Emtrilio, Entrillio, Entrilio,

Entrilion, EMTRILIO, entryllio,

Emtrylio, Emptrilio, Emtrileo, Entrelio, emtrylio,

Phonetic information versus orthographic information

Verbal communication	identification
Mtryylio	ENTRILIO, Entrillio, EMTRILLIO, Emtrilio, Entrillio, Entrilio, Entrilion, EMTRILIO, entryllio, Emtrylio, Emptrilio, Emtrileo, Entrelio, emtrylio,

Name B

ACCUFLIN, akitlin, Ekiflin,

Akfilin, Akiffling, Akiffylyn, aqqislin,

Akiflyn, AKISLIN, AKIFLIN,

Akyflin, Aquiflin, Akiffling,

Phonetic information versus orthographic information

Verbal communication	identification
Ackeyfln	ACCUFLIN, akitlin, Ekiflin, Akfilin, Akiffling, Akiffylyn, aqqislin, Akiflyn, AKISLIN, AKIFLIN, Akyflin, Aquiflin, Akiffling,

Name C

Mondreen, Mondrys, MONGDREEZ

Mohndreez, mondreez, mongdrez or mongdreeze, Moindris,

Moondris, mondrise, maundresse, mounddries

Maandreez, mawntries,mongdriz, Mongdreez, mondriz, Mnondreez,

MONDRIEZ, MNDREZ, mondries, Moindrin

Phonetic information versus orthographic information

Verbal communication	identification
Maungdreeys	Mondreen, Mondrys, MONGDREEZ Mohndreez, mondreez, mongdrez or mongdreeze, Moindris, mounddries Moondris, mondrise, maundresse, Maandreez, mawntries,mongdriz, Mongdreez, mondriz, Mnondreez, MONDRIEZ, MNDREZ, mondries moindrin

Any questions?

Further information

alexios.skarlatos@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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