



# A Discussion on the Name Safety Tools used in the evaluation of an invented name.

EMA Interested Parties Meeting, 10 November 2021

**SAFEMARK**  
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# Agenda

The May 2014 Guidance Document entitled *Guideline on the acceptability of names for human medicinal products processed through the centralised procedure* does not specifically mention the “name safety testing tools” used by the Name Review Group (NRG) members in the review of invented names.

There are 3 specific name safety testing tools we want to discuss:

- FDA POCA System
- “Word Construction Analysis” – orthographic and phonetic letter similarity
- EMA Checklist

We propose that the inclusion of name safety testing tools in the EMA Guidance and clarification on their use will help reduce the number of objections based on a *similarity with other invented names*.

# Name Safety Tool #1: FDA POCA System

## Phonetic Orthographic Computer Analysis (POCA) software.

The FDA POCA System 4.3 is a *tool* used during the drug name safety evaluation process.

POCA compares *proposed* proprietary drug names to *existing* proprietary drug names and indicates “how similar” or the “degree of similarity” from a look-alike and sound-alike perspective.

The following aspects of POCA are used in the evaluation of an invented name:

- POCA output is based on a **specific data source** (i.e., Article 57 Public Database).
- POCA output provides an individual **orthographic** score and **phonetic** score ranging from 0-100%.
- POCA output provides a **Combined Similarity score** ranging from 0-100%.
- The POCA Combined Similarity scores are discussed in the FDA Guidance\* with **specific threshold values** to categorize a name pair as having low, moderate, or high similarity.

Combined Similarity Score POCA Thresholds by FDA		
Highly Similar Name Pair ≥ 70%	Moderately Similar Name Pair ≥ 55% to ≤ 69%	Low Similarity Name Pair ≤ 54%

# Name Safety Tool #2: Word Construction Analysis

**Word Construction Analysis (“WCA”)** is a name safety tool *coined by SafeMark* that can be used in the invented name review process to identify potential conflicts based on an in-depth evaluation of name pair similarity-based elements that incorporates the POCA scores and goes beyond.

The following similarity-based elements are evaluated for an invented name pair:

Similarity-Based Elements
Combined POCA Score
Individual Ortho or Phono Scores
Starting Letter Comparison
Prefix Comparison
Suffix Comparison
Character Count
Character Placement – 2 <sup>nd</sup> , 3 <sup>rd</sup> , 4 <sup>th</sup> position, etc.

In September 2021, there were 151,213 entries in Article 57 Public Database. WCA can help identify and prioritize look-alike/sound-alike cited names based on similarity-based elements.

# Name Safety Tool #3: EMA Decision-Making Checklist

Since January 2015, the **EMA checklist** is used to “discuss the link between orthographic / phonetic similarity and potential for medication errors.”\*

## **EMA Checklist is used during the invented name review process:**

- To support a potential objection by the reviewer.
- To help guide the discussions during the NRG meeting.
- To help review the potential for Patient Harm (e.g., risk assessment).

## **EMA Checklist is used after the invented name review process:**

- To help ensure the **same elements are consistently considered in all decisions.**
- To help ensure that **applicants are consistently informed of detailed grounds for rejection.**
- To help the sponsor target the discussion points in a rebuttal document.

# Name Safety Tool #3: EMA Decision-Making Checklist

An EMA Checklist example provided during the 2017 Interested Parties Meeting shows an “X” in Sections 1 and 4 indicating that **(P)rint**, **(S)peech**, and **(H)andwriting** similarity and **Potential for Harm** are HIGH. However, despite the HIGH values, the **proposed name is endorsed**.

Invented name/objection	1					2					3					4		Outcome	
	Degree of orthographic and/or phonetic similarity / Cognitive error (CE)					Setting of use					Elements that may increase or reduce the risk of confusion					Potential for harm in case of accidental mix-up			
	P	S	H		CE	Yes	No	n/a	Unclear		Same	Similar	Different	n/a			Endorsed	Not endorsed	
Name 1 Name 2	High	X	X	X		Pres.	X				Strength			X		High	X	X	
						Disp.	X				Ph.form			X		Medium			
	Medium					Prep.		X			RoA			X		Low			
						Admin.		X			L. status		X			N/A			
	Low					Controls		X			Labeling				X	Unknown			
											Orphan	Both	One	None					

- We note that the lack of profile similarities in settings of use as well as dosage strength, physical form, or route of administration *could be used* to mitigate concerns identified by POCA values or a risk assessment.
- Can this outcome be duplicated by someone in industry or another NRG reviewer? If not, then this outcome suggests a more subjective review of the data set.

# EMA Invented Names Approved in 2020 – Review

SafeMark reviewed 71 EMA invented name approvals in 2020\* using the Name Safety Tools of POCA, Word Construction Analysis, and the Article 57 Public Database. These tools were selected because they are usually used during the invented name review process. Table below shows the output evaluating the 71 name approvals.

Tool	At least 1 cited name from Article 57 Public Database with...	#	%
POCA	A <b>Combined POCA</b> score at <u>70% - 100%</u> indicating “high similarity”	41	<u>58%</u>
	An <b>Individual Orthographic POCA</b> score at <u>70%</u> or higher	71	<u>100%</u>
	An <b>Individual Phonetic POCA</b> score at <u>70%</u> or higher	60	<u>85%</u>
	An <b>Individual Orthographic POCA</b> score at <u>80%</u> or higher	25	35%
	An <b>Individual Phonetic POCA</b> score at <u>80%</u> or higher	19	27%
WCA	At least 1 cited name with the <i>same 3 letter prefix</i> (includes same starting letter)	49	<u>69%</u>
	At least 1 cited names with the <i>same 3 letter suffix</i>	48	<u>67%</u>

This step *can be duplicated* by anyone using the POCA 4.3 system and the same version of the Article 57 database and their version of word construction analysis.

# EMA Invented Names Approved in 2020 – Review(Cont.)

We identified 6 names (out of the 71) that had similar output to the 2017 EMA Checklist. All of the **POCA** scores were at or above 70% and there were similarities noted in character count, starting letter, and suffix. All 6 names were endorsed.

# Products	Test Name	Name of Concern	POCA			Word Construction Analysis								Overlaps
			O-Score	P-Score	C-Score	Character count Test Name	Character count Cited Name	Starting letter Test Name	Starting Letter Cited Name	Prefix Test Name	Prefix Cited Name	Suffix Test Name	Suffix Cited Name	Overlaps (See next slide)
1	Roclanda	Rosoland	81	75	78	8	8	R	R	Roc	Ros	nda	and	None
2	Idefirix	Nefrix	79	74	76	8	6	I	N	Ide	Nef	rix	rix	None
	Idefirix	Niferex	70	82	76	8	7	I	N	Ide	Nif	rix	rex	None
3	Xenleta	Zelleta	75	76	76	7	7	X	Z	Xen	Zel	eta	eta	Form/Route
4	Fintepla	Fentaplast	78	70	74	8	10	F	F	Fin	Fen	pla	ast	None
	Fintepla	Fentibel	72	77	74	8	8	F	F	Fin	Fen	pla	bel	None
	Fintepla	Fentinal	72	70	71	8	8	F	F	Fin	Fen	pla	nal	None
5	Oxlumo	Oxolam	75	74	74	6	6	O	O	Oxl	Oxo	umo	lam	None
6	Zolgensma	Solgekma	76	71	74	9	8	Z	S	Zol	Sol	sma	kma	Form/Route

- None of the identified name pairs had overlapping prefix (consideration of the first 3 letters).
- 4 Name Pairs had no overlapping characteristics.
- 2 Name Pairs shared 2 overlapping characteristics of dosage form and route.
- *Can the outcome of “endorsed name” be duplicated?* If not, then we ask for clarification.



# Name Safety Testing Tools – Discussion Questions

## FDA POCA SYSTEM

- What is the version of POCA being used by the NRG in their review?
- Is the Article 57 Public Database used by all NRG reviewers?
- Are the national databases listed on the EMA website used consistently by the NRG reviewers per region?
- Can you speak to whether products currently listed as marketed in the United Kingdom (Third Nation) be considered relevant in the invented name review?
- Is there a specific POCA threshold value for Combined Similarity Score used to identify Low, Moderate, or High Similarity?
- Is there a specific threshold value for the individual POCA Scores to help support Orthographic and Phonetic Similarity.

## WORD CONSTRUCTION ANALYSIS

- Does the invented name review process consider the same or similar starting letter(s), Prefix (e.g., 3 or more starting letters), Suffix Letters (e.g., 3 or more ending letters), and/or character count or character position *to distinguish a name pair*? If so, then when during the invented name review process is WCA conducted?

## SIMULATION STUDY

- Although not discussed in detail in this presentation, another name safety testing tool utilized by US FDA and Health Canada is the simulation study. Does the NRG find the data from a Simulation Study (submitted by a sponsor) useful in the invented name review?
- Should sponsors continue including simulation study data for EMA/NRG submission reports?

## OVERLAPPING PRODUCT CHARACTERISTICS

- Clarification is requested for reviewing overlapping product characteristics.  
Specifically, is there a list of overlapping characteristics that could be used...
  - To *minimize* the potential for confusion with a name pair
  - To *support* the potential for confusion with a name pair

# Thank You!

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