

# Comparison of International Regulatory Guidance on Pharmaceutical Naming

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Leaderboard  
Branding

# Agenda for Today

- ▶ A little about me
- ▶ The work we did to identify findings
- ▶ POCA tool evaluation
- ▶ Geography details
- ▶ Comparison and key learnings



# Leaderboard Branding

Leaderboard Branding is a global brand consultancy comprised of seasoned industry leaders with hundreds of years of collective experience.

Leaderboard delivers a detailed brand development roadmap, strategic insights, world-class creativity, hands-on relationship management and unwavering dedication to the success of our partners' branding goals.

# Leaderboard Experienced Senior Team



**Brannon Cashion**  
*Managing Partner*



**Vince Budd**  
*Managing Partner*



**Andy Cuykendall**  
*Managing Partner*



**Amy Baynard**  
*Creative Director*



**Susan Proulx, PharmD**  
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**Randall Scott**  
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**Jayne Butler**  
*Director, Strategic Initiatives*



**Shusei Ichikawa**  
*Director, Leaderboard Asia*



**RJ Clouse**  
*Director, Strategy*



**Christine McCluskey**  
*Director of Trademarks*



# Susan Proulx, PharmD

*Managing Director, Drug Safety*

Global Leader in Medication Safety.

**25**

years working in medication safety and regulatory arena

**19**

years leading Med-ERRS, an industry-focused medication safety company

**80+**

international speaking engagements at trademark & regulatory conferences

**20**

years teaching healthcare students and practitioners about medication safety and error prevention

## **PREVIOUS EXPERIENCE:**

Worked with over 200 pharma and biotech companies

## **RECENT SUCCESSES:**

Trained staff and developed name safety and package and label guidance for international regulatory agency.

Successful in helping overturn multiple name rejections globally.

## **EXPERTISE:**

Package and Label Development  
Safety & Regulatory Evaluation  
Regulatory Risk Assessments

# ► How We Uncovered Process Learnings



# Resources

How we got the information

## ► Online research

- Published guidance
- Additional regulatory body insight

## ► Communication with regulatory authorities

- Interviews with staff from regulatory agencies
- Email communication with regulatory agencies

## ► Past experience with regulatory agencies



# ▶ Looking into POCA

Phonetic and Orthographic Computer Analysis



# POCA

## Phonetic & Orthographic Computer Analysis

**The Phonetic and Orthographic Computer Analysis (POCA) program is a web-based software tool (and soon to be cloud-based) that uses an advanced algorithm to determine the orthographic and phonetic similarity between two drug names.**

The program can compare a drug name against multiple drug names found in several different “data sources” contained in the software

Depending on the country/region, different data sources can be used.

Originally developed by the FDA, it's now used by many regulatory authorities when evaluating drug name submissions.

The screenshot shows the login page for the POCA system. At the top left is the Department of Health and Human Services logo, followed by the FDA logo. To the right is a banner that reads "FDA Automated Method of Minimizing Medication Errors Due to Similar Proprietary and Established Names". Below the logos, there are two input fields: "User ID:" and "Password:". A "Submit" button is located to the right of the password field. At the bottom, there are three links: "Reset Password", "Change Password", and "Request Account".

Department of Health and Human Services  
FDA  
FDA Automated Method of  
Minimizing Medication Errors Due to  
Similar Proprietary and Established Names

User ID:   
Password:

Submit

[Reset Password](#) | [Change Password](#) | [Request Account](#)

# POCA

## How POCA is Used

A search will provide three data sets:

**PHONETIC** similarity

**ORTHOGRAPHIC** similarity

**COMBINED** orthographic & phonetic similarity

# POCA

## How POCA is Used

FDA reviews COMBINED POCA results to determine name similarity. The higher the score, the greater the similarity and risk for confusion.

<b>High</b> Similarity Pair	<b><math>\geq 70\%</math></b>	Low opportunity for approval unless there is a specific reason POCA should be ignored in pursuit of a name candidate.
<b>Moderate</b> Similarity Pair	<b><math>\geq 50\%</math> to <math>\leq 69\%</math></b> <i>(or <math>\geq 55\%</math> depending on the regulatory authority)</i>	Could create concern especially if names have clinical overlap or share form/dosing characteristics.
<b>LOW</b> Similarity Pair	<b><math>\leq 49\%</math></b>	Typically less concerning unless names are mentioned in simulation studies as consistently raising concern.

Several other regulatory agencies besides FDA use POCA with varying thresholds.

# ▶ Looking at Each Geography

# Geographies



# Geographies

## Reviewing Bodies by Geography

Australia	Brazil	Canada	European Union	Saudi Arabia	United States
Therapeutic Goods Administration (TGA)	General Management of Medicines & Biological Products (GMMBP) of ANVISA	Health Products and Food Branch (HPFB) of Health Canada	(Invented) Name Review Group (NRG) of EMA	Medication Errors Department of Saudi FDA	Division of Medication Error Prevention and Analysis (DMEPA) & Office of Prescription Drug Promotion (OPDP) of FDA

# United States

Regulatory Body & Submission



## Who reviews the application?

Division of Medication Error Prevention and Analysis (DMEPA, for LASA issues)

Office of Prescription Drug Promotion (OPDP, for promotional issues)

## What is reviewed?

Prescription and OTC drug product names can be reviewed prior to full submission

## How many names can be submitted?

One name at a time.

If found unacceptable, then another name can be submitted once the sponsor withdraws the first name.



# United States

## Review Timing



### Prescription Name Review

*(If submitted during IND/preBLA ) – CONDITIONAL APPROVAL*

180 days

### Prescription Name Review

*(If submitted during NDA/BLA )*

90 days

### Prescription Name Final Review

*(Final review triggered at 90 days prior to PDUFA)*

90 days

PDUFA

# United States

## Methodology



### Based on draft guidance

- Prescreening questions
- POCA using Rx Norm and Drugs @ FDA
- Simulation studies (minimum of 20 scenarios)

DMEPA now accepts the use of certain 2-letter stems (-ac, -aj-, ef-, fo-, io-, -io-)

### Reasons for rejection

*“...determines the name causes confusion with other products that can result in medication errors and preventable harm or is misleading with respect to the therapeutic effectiveness, composition, or the safety of the product.”*

# European Union

Regulatory Body & Submission



## Who reviews the application?

Name Review Group (NRG) of EMA

## What is reviewed?

Prescription and OTC drug products

## How many names can be submitted?

Two (2) names can be submitted; both will be reviewed with a decision for each made by NRG

# European Union

Review Timing



## Prescription Name Review

*(Reviewed as part of new drug submission )*

18 months

6

2-day Review Meetings per  
Year

*(for 2020 & 2021)*



75

Names Reviewed per  
Meeting

*(Name submission number  
76 will be reviewed at the  
next meeting)*

# European Union

## Methodology



POCA is referenced using Article 57

POCA is used as a supportive tool for NRG

- NRG does not utilize POCA during analysis but will employ it in justifications
- NRG will review clinical characteristics of products, especially advanced therapy names (like gene therapy) since the drug use process for these products is vastly different and restrictive

**Because it is English-language based, POCA is not used by member states as a method of side-by-side phonetic and orthographic comparison.**

**Only 30-35% of submissions have supporting documentation**

# European Union

## Methodology



### Reasons for rejection:

- Close to 90% for similarity to another name, but often there are additional issues raised
- Many names are too close to INN (not just stem, but actual INN)
- Brand names cannot contain more than 50% of its generic name in the name
  - Look at the total number of letters as well in the name comparatively to INN

**NRG is experiencing an increased number of rejections due to linguistic concerns cited by individual or multiple member states.**

# European Union

## Methodology



NRG has seen a decrease in quality of applications, especially with oral contraceptive names

- Increase in the number of “red flags” from members states per name
- Increase in the number of justifications per meeting (e.g. 20 at February meeting)

NRG accepts the use of 2-letter INN stems in brand names

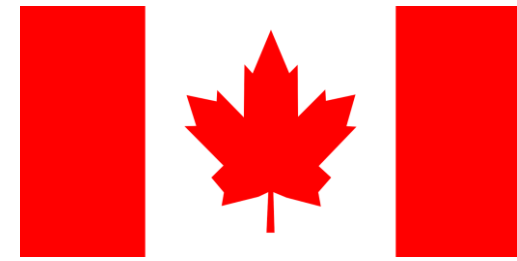
NRG has a process in place for different sponsors who have similar names in the queue, to facilitate discussion (if both parties agree) to determine if they will use the name in question

**Relating to Brexit, the NRG is still reviewing UK research.**



# Canada

Regulatory Body & Submission



## Who reviews the application?

Health Products and Food Branch (HPFB) of Health Canada (HC)

## What is reviewed?

Only prescription products (no OTC products).

Must submit proposed name plus a brand name assessment.

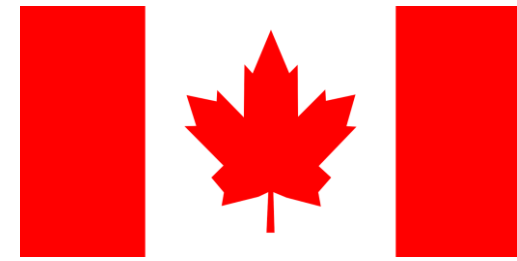
## How many names can be submitted?

One name at a time.

If rejected, a 2<sup>nd</sup> name must be submitted at least 90 days prior to review target date.

# Canada

## Review Timing



### Prescription Name Review

*(Reviewed as part of new drug submission )*

**90 days**

**30 days**

*Standard review within 1<sup>st</sup> 90 days of submission being accepted for review; 2<sup>nd</sup> abbreviated review done 30 days prior to issuance of DIN.*

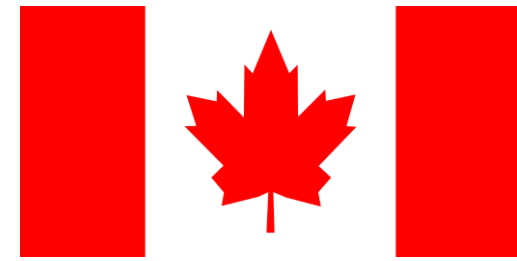
### Priority Review

*(For products/names deemed appropriate to fast track)*

**60 days**

# Canada

## Methodology



**Sponsors must follow guidelines set forth by HC or application and name will not be reviewed.**

“Search, simulate, synthesize” using at least 5 prescriptions simulations scenarios with 100 practitioners (of which 25% must speak French)

- Initial brand name review
- Look-alike/Sound-alike (LASA) Brand Name Assessment using POCA with Drug Product Database and Licensed Natural Health Products Database
- Develop process-use maps
- Perform Failure Mode & Effects Analysis (FMEA)
- Real-time POCA searches should be conducted up to time of submission

# Canada

## Methodology



HC will review the name submission document as well as HC's Drug Submission Tracking System

### Reason for rejection:

*“...if the name is likely to cause confusion with other health products,  
or is misleading with respect to the therapeutic effectiveness,  
composition or the safety of the product.”*

Health Canada accepts a sponsor's use of 2-letter stems in name candidates

# Brazil

Regulatory Body & Submission



## Who reviews the application?

General Management of Medicines & Biological Products (GMMBP) of ANVISA reviews all applications

## What is reviewed?

Prescription and non-prescription medicinal products

## How many names can be submitted?

Multiple names can be submitted, but with a clear primary candidate.

Subsequent names will only be reviewed if the 1<sup>st</sup> name is unacceptable.

ANVISA notifies sponsor of disapproval.

# Brazil

## Review Timing



### Prescription Name Review

365 days

### Priority Review

*(For products/names deemed appropriate to fast track)*

120 days

# Brazil

## Methodology



### Name review using POCA, which is available through ANVISA portal

- Search Datavisa Drug Database; Nat'l Institute of Industrial Property (for brand registration)

**If names have a high similarity score ( $\geq 70\%$  combined), then a risk matrix must be performed.** The risk matrix consists of 24 items – scored from 0.5 to 2 points depending on the relevance of the characteristic, totaling 30 points.

30 Point comparison	
<b>15 Points</b> Based on the name itself	<b>15 Points</b> Based on the characteristics of the drug
<b>DISAPPROVED</b> If 10 total points earned*	

\*If some of the results are based on POCA (which is English language-based), the company can make an argument that the names are dissimilar phonetically in Portuguese.



# Brazil

## Methodology



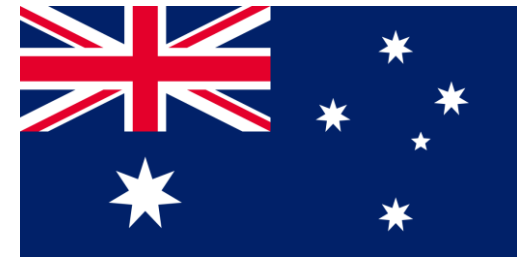
### **Reasons for rejection: Confusability/Promotional Issues (misbranding)**

- The name candidate may not have 50% of the name equal to the nonproprietary name
- Letters with the same sound will be considered equal
- The number of similar letters should be considered, as well as close or an exact number of syllables

**Foreign companies cannot get marketing authorization directly with ANVISA; they must have a partner company in Brazil for importation and distribution of their drug in Brazil.**

# Australia

Regulatory Body & Submission



## Who reviews the application?

Therapeutic Goods Administration (TGA) reviews all applications.

## What is reviewed?

Prescription and non-prescription medicinal products.

## When is name the reviewed?

Along with full drug application, there is no early name review.

## How many names can be submitted?

One name at a time. Additional names can be submitted only after 1st is rejected.

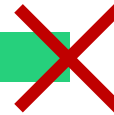
# Australia

## Review Timing



### Prescription Name Review

255 working days



*If name rejection*

45 working days

### OTC Drug Name Review

120 working days

### Priority Review

*(For products/names deemed appropriate to fast track)*

120 working days

# Australia

## Methodology



### Review using:

- The letters forming the name
- The sound of the name
- Handwriting review
- **Focus user testing should be conducted, and results provided to the TGA**

In Australia, for a drug product to be approved, it requires that the name has an Australian Approved Name (similar to INN in other regions).

For biologics, it requires an Australian Biologic Name.

# Saudi Arabia

Regulatory Body & Submission



## Who reviews the application?

Medication Errors Department of Saudi FDA

## What is reviewed?

Full application (5 modules) including submitted name.

There is no name pre-submission.

## How many names can be submitted?

One name at a time.

# Saudi Arabia

## Review Timing



### Prescription Name Review

**160 days**

- Follows name review guidance published in February 2020
- Name is approved with full submission
- When name module is completed, sponsor is notified but does not receive full approval until the entire application (all 5 modules) is approved
- During SFDA review, a sponsor can change its proposed drug name if a full review is not yet completed. This is called a “variation.”

# Saudi Arabia

## Methodology



**SFDA uses POCA and a checklist for reviewing names.**  
(for LASA similarity and clinical characteristics).

Sponsors can search SFDA drug list (all registered pharmaceuticals) and Martindale (international drug reference).

**All generic products have brand names in Saudi.**

It is not mandatory, but companies do this, therefore the list of names with potential for confusion is high.

### Reasons for rejection

- Overpromotion is the biggest reason for rejection
- Look-alike/sound-alike issues – Names are not evaluated properly, or at all



# Geographies

## Summary



Australia	Brazil	Canada	EU	Saudi Arabia	US
TGA	GMMBP	HPFB	NRG of EMA	Saudi FDA	DMEPA & OPDP
No published guidance	Published guidance	Mandatory guidance	Published Guidance	NEW! Published Guidance	Published Guidance
No POCA	POCA* <i>Recognizes challenges with English-based analysis</i>	POCA	POCA* <i>Recognizes challenges with English-based analysis</i>	POCA	POCA
Rx & OTC	Rx & OTC	Rx only	Rx & OTC	Rx & OTC	Rx & OTC
Single name submission	Prioritized name submission	Single name submission	Up to two names submitted	Single name submission	Single name submission
Requires Australian Approved Name	Risk matrix if high POCA score	Search, simulate, synthesize	Four review meetings	Variation possible mid-submission	Two reviewing bodies



# Key Learnings

How to maximize opportunity for success



# Key Learnings

Keys to be successful

## 1. FOLLOW THE GUIDANCE

Some agencies publish more specific guidance than others, but if available, they are clear about requirements to render an opinion.

## 2. PROVIDE INSIGHT

Even if no specific guidance is available, information can help regulatory bodies make well founded decisions. POCA is used on some level by many of the agencies, but if POCA was used early in the evaluation process it could be helpful to test again prior to submission.

## 3. ENGAGE AND ASK

Many agencies are open to having informational conversations before submission; take advantage of this opportunity.

## 4. BE PROACTIVE

Provide supporting documentation as part of a submission, especially if an issue arises during the evaluation, showing how challenges could be mitigated can help position a submission for success.



# Thank You

Obrigada

Gracias

Merci

شكرا

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# Appendix

# Reference Material

For further review

- **Best Practices in Developing Proprietary Names for Drugs**  
(FDA – May 2014)  
<https://www.fda.gov/media/88496/download>
- **Contents of a Complete Submission for the Evaluation of Proprietary Names**  
(FDA – April 2016)  
<https://www.fda.gov/media/72144/download>
- **Review of Drug Brand Names**  
(Health Canada – July 2014)  
[https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt\\_formats/pdf/pubs/medeff/guide/2014-review-examen\\_drug-medicament\\_names-marques/2014-review-examen\\_drug-medicament\\_names-marques-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/pubs/medeff/guide/2014-review-examen_drug-medicament_names-marques/2014-review-examen_drug-medicament_names-marques-eng.pdf)
- **Guideline on the acceptability of names for human medicinal products processed through the centralised procedure**  
(EMA/CHMP/287710/2014 Rev. 6)  
[https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure_en.pdf)
- **Resolucao da Diretoria Colegiada – RDC n 59**  
(Brazil – 10/2014)  
[http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2014/rdc0059\\_10\\_10\\_2014.pdf](http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2014/rdc0059_10_10_2014.pdf)
- **Guidance for Naming of Medicinal Products**  
(Saudi FDA – 02/2020)  
[https://sfda.gov.sa/en/drug/drug\\_reg/Pages/default.aspx](https://sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx)