



SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES



Provider Perspectives on A Global Biosimilar Naming Standard

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Presented at the 63rd Consultation on
International Nonproprietary Names

October 18th, 2016
Geneva, Switzerland

Introductions



Doug Badger

- ASBM President, Board Member
- Former Senior White House Health Policy Advisor
- Former Dep. Asst. Sec at US Dept. of HHS
- Former Senior Health Policy Advisor to US Senator Don Nickles

Philip Schneider, MS, FASHP

- ASBM Advisory Board Chair
- Professor/Dean, University of AZ College of Pharmacy
- Former President, American Society of Health-system Pharmacists

Alliance for Safe Biologic Medicines formed in 2010

- Steering Committee composed of patient groups, physicians, pharmacists
- Advisory board of physicians, researchers, pharmacists

Biologic Naming: An Urgent Global Health Issue

“The naming of SBPs needs to be addressed globally and soon while the number of registered SBPs remains relatively small and with the INN programme being the best forum to achieve this.”

*-Executive Summary, 55th INN Consultation
(October 2012)
Published Feb. 2013*



INN Working Doc. 13.329
February 2013
Doc.: PUBLIC
ENGLISH ONLY

55th Consultation on International Nonproprietary Names
for Pharmaceutical Substances
Geneva, 16-18 October 2012

Executive Summary

Programme on International Nonproprietary Names (INN)

Quality Assurance and Safety: Medicines (QSM)
Essential Medicines and Health Products (EMP)
World Health Organization, Geneva

© World Health Organization 2013

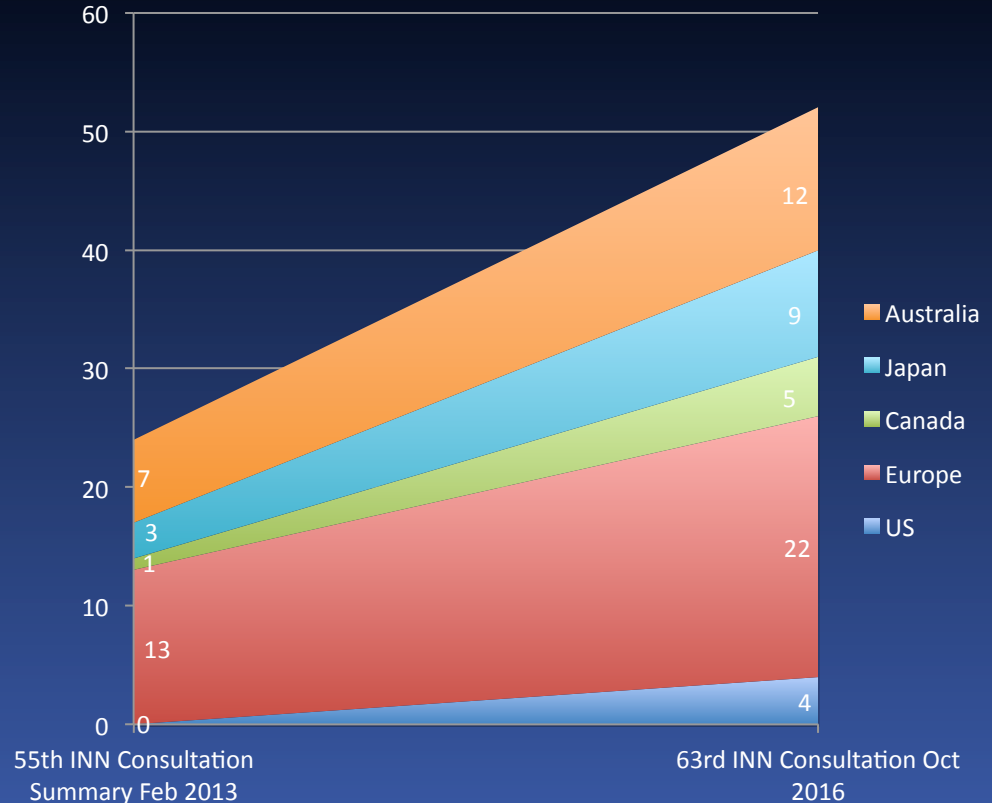
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Biosimilar Approvals 2013-2016

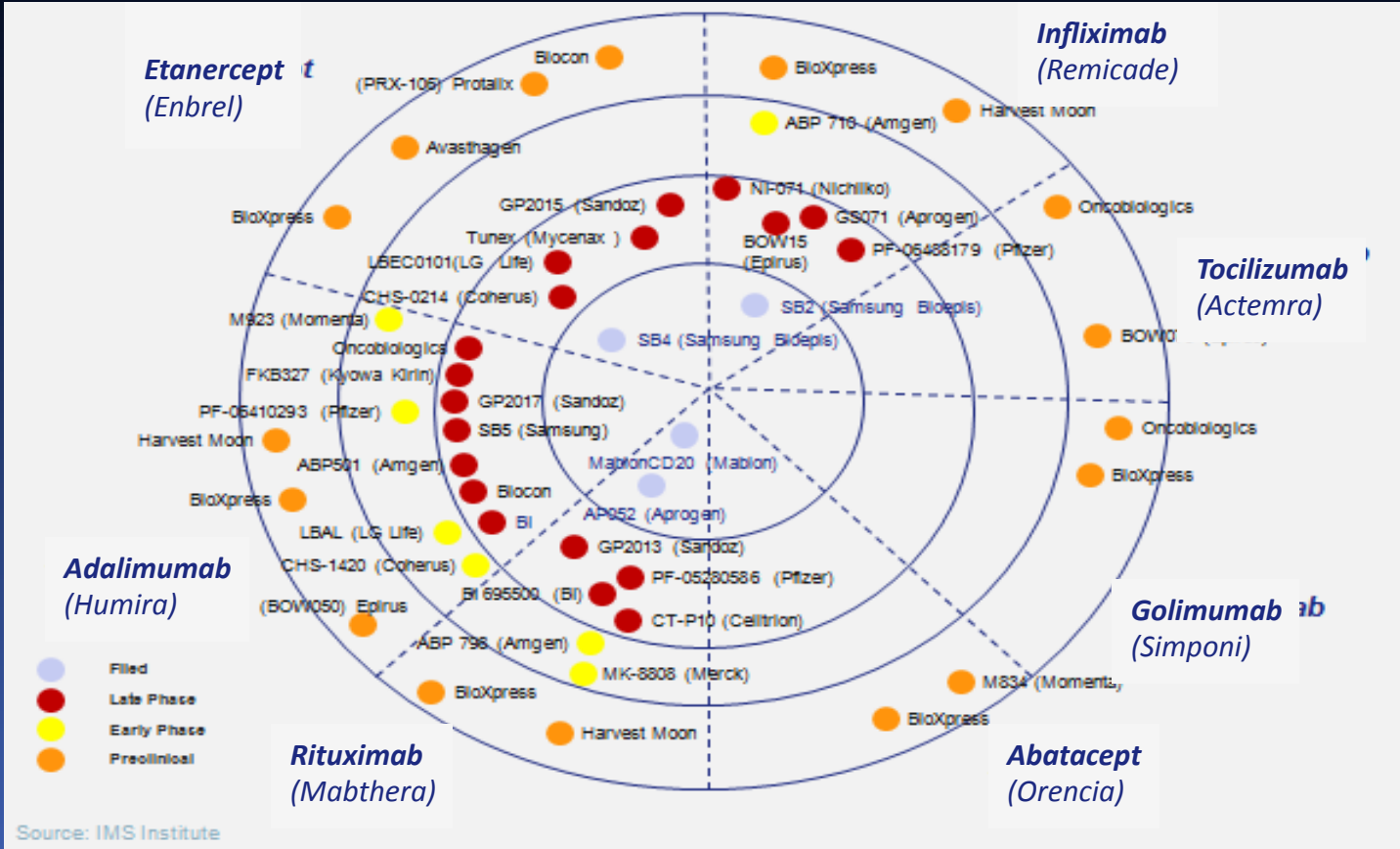
- Since that Executive Summary was published, the number of biosimilars in these countries has more than doubled, from 24 to 52.¹
- Biologics comprise more than 40% of INN applications and this number is increasing.
- More than 40 biosimilars are in development worldwide for seven key biologics.²



1: gabi-online.net

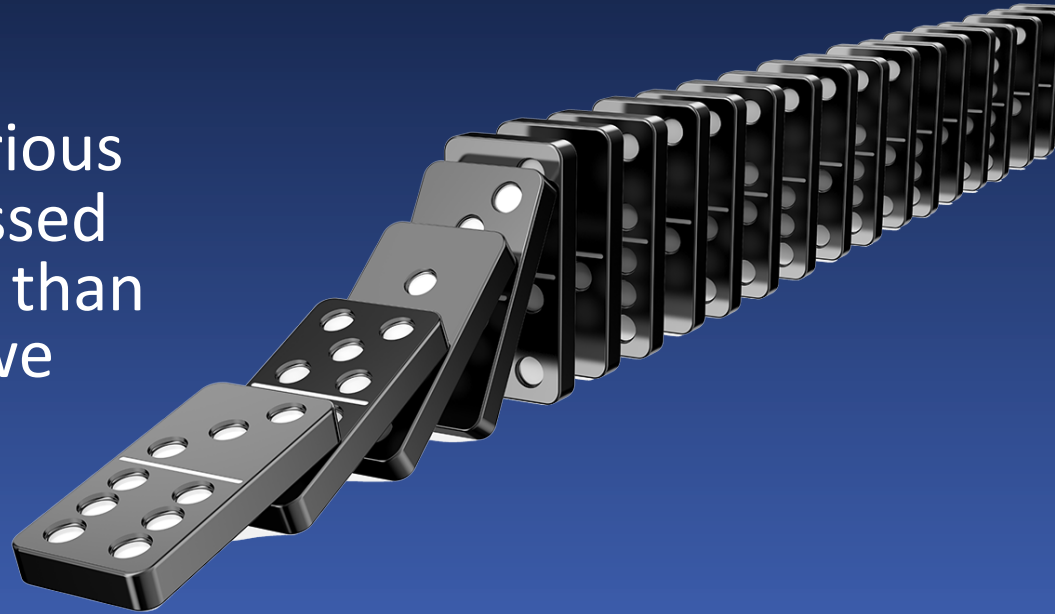
2: IMS Institute for Health Informatics, Jan 2016

The Biosimilars Pipeline is Extensive



Moving Forward

- No policy will ever be perfect, outliers and exceptions will always exist.
- But we must not let serious challenges go unaddressed entirely, growing larger than we can manage while we seek perfection.



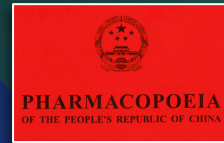
A Leadership Responsibility

- The WHO has been the leader on the issue of biologic naming and is the only entity uniquely situated to solve this global challenge.
- BQ implementation will bring worldwide benefit, but will particularly aid countries where no strong pharmacovigilance system has yet been developed for biologics.
- In effect, the BQ will establish a global baseline for traceability, a “floor” below which pharmacovigilance standards should not fall.



Regulators Worldwide Await WHO Leadership

Lack of WHO action has led to a lack of action among many regulators supportive of the WHO's efforts, as they await forward movement on BQ.



The Remaining Challenges Are Manageable...

Mergers/Acquisitions have been highlighted as a concern with assigning a BQ...

Yet in 10 years of European experience with biosimilars, no biosimilar has been sold to another entity after marketing approval. (The immense costs associated with biosimilar development and manufacture may make this a rarity.)

When entities have been acquired, they have retained their name (The acquisitions of Sandoz by Novartis, and Hospira by Pfizer, for example).

Thus, M&A can be accommodated by biologics retaining their original BQ, which will track back to the entity currently owning the asset.

Alternatively, any number of minor modifications could easily be made to the BQ in order to contain this information if tracking these corporate actions is deemed important to pharmacovigilance.



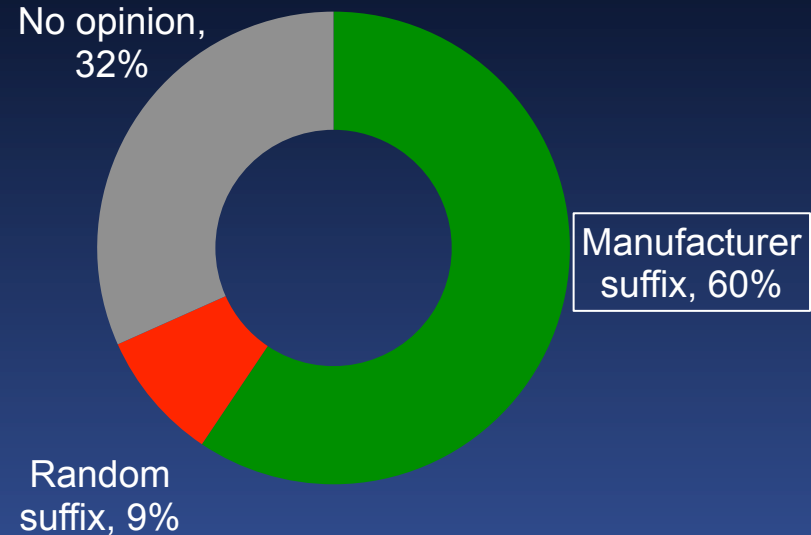
Examples: Three Potential BQ Modifications to Reflect Merger & Acquisition Activity

	ORIGINATOR + RANDOM BQ	BIOSIMILAR + RANDOM BQ	POST- M&A MODIFICATION
4-letter BQ + Number	ultramab-xxxx	ultramab-xyyx (456,976 possible biologics of same class)	ultramab-xyyx1, -xyyx2 -xyyx3... (10 possible sales for each biologic)
4-letter BQ + Alpha Capital	ultramab-xxxx	ultramab-xyyx (456,976 possible possible biologics of same class)	ultramab-xyyxA, xyxxB, xyxxC... (26 possible sales for each biologic)
3-letter BQ + Alpha CAPITAL	ultramab-xxxx	ultramab-xyya (here "a" represents a biosimilar) (17,576 possible biologics of same class)	ultramab-xyyB -xyyC, xyyD... (26 possible sales for each biologic)

A system can be designed for the (thus-far) rare occasion where a biologic is sold.

Meaningful vs. Random

- Our data has shown (and continues to show) a strong preference among health care providers not only for distinguishable naming, but for meaningful rather than random suffixes.
- Advantages include increased manufacturer accountability.



400 U.S. BIOLOGIC PRESCRIBERS, 2015

Even Those Who Do Not Support Distinguishable Names Prefer Meaningful Suffixes over Random:

“We were negotiating with [the FDA] over the weekend before [filgrastim-sndz] was approved...and having phone calls because they initially gave us **four random letters that didn't make sense**, like they have done with [recently approved Remicade biosimilar] infliximab-dyyb.”

*-Mark McCamish, Global Head of Biopharmaceutical Development, Sandoz
BioPharma-Reporter.com interview, 6/22/2016*

 **SANDOZ**
a Novartis company

A photograph of a modern, multi-story building with a curved facade, illuminated at dusk. The building features large windows and a prominent entrance. In the foreground, there are trees and a grassy area. The sky is dark with some clouds.

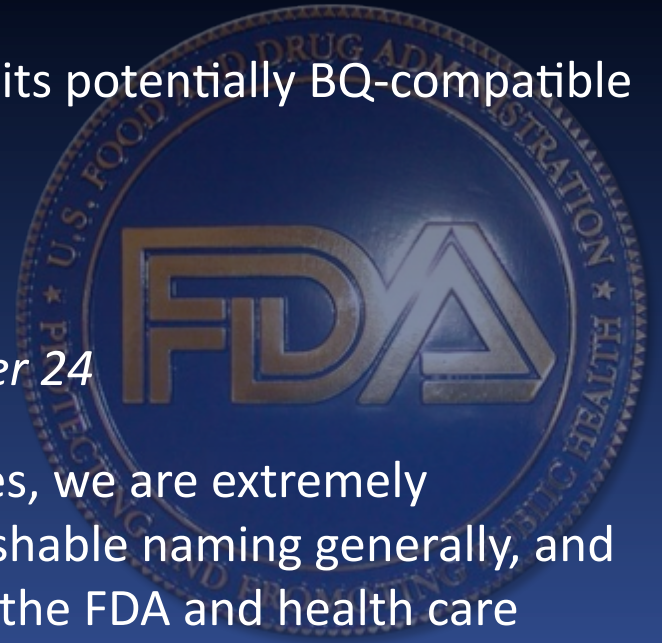
Since the 62nd INN Consultation, April 2016

FDA has approved its 3rd and 4th biosimilars using its potentially BQ-compatible scheme:

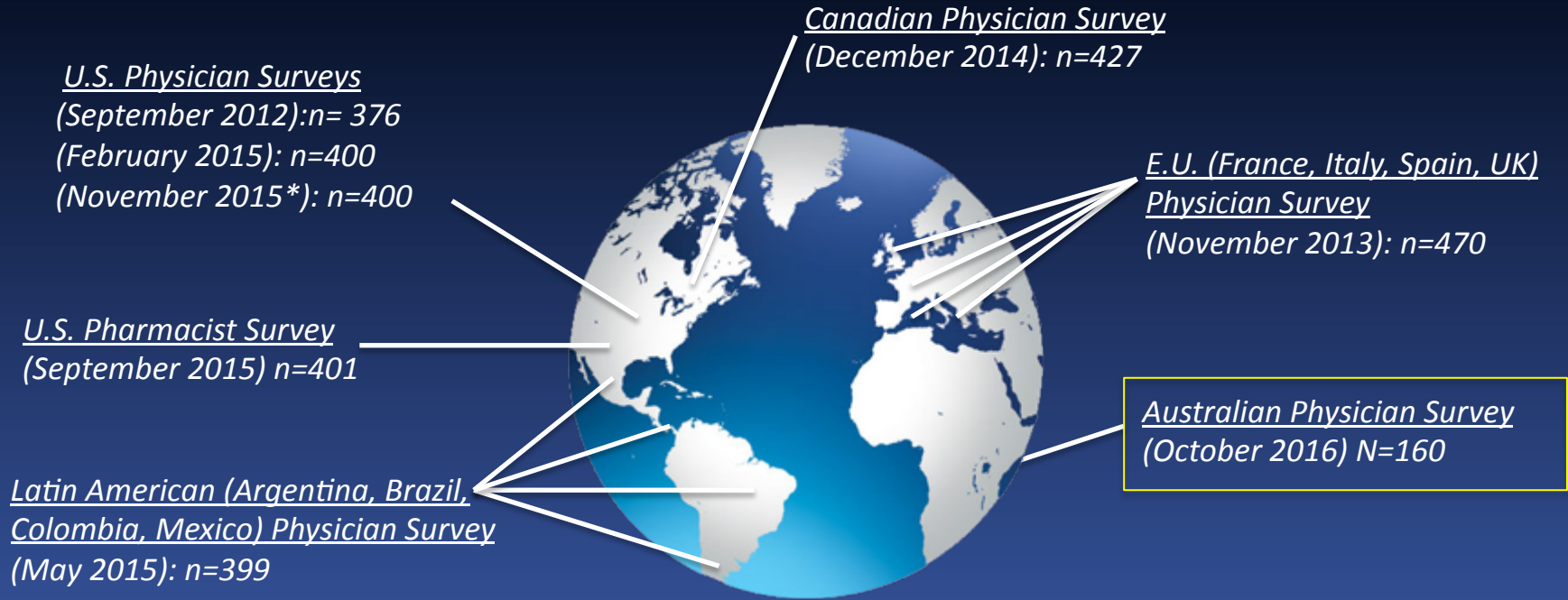
- Erelzi (etanercept-szszs) *August 30*
- Amjevita (adalimumab-atto) *September 24*

While our preference is still for meaningful suffixes, we are extremely encouraged by the positive reception of distinguishable naming generally, and a BQ-compatible system specifically, among both the FDA and health care providers globally.

Again, *the perfect should not be the enemy of the good.*



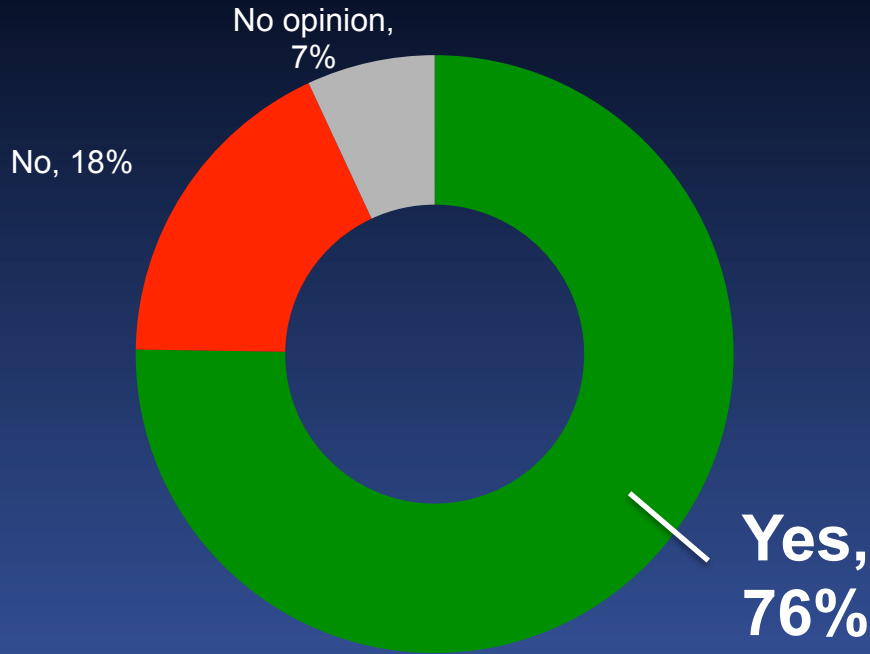
Gathering Perspectives from Biologic Prescribers Worldwide



All surveys available at www.SafeBiologics.org



Australian Biologic Prescribers Support Distinct Naming



“In your opinion, should the TGA insist on a distinct non-proprietary scientific name for every biologic or biosimilar medicine that it approves?”



Australian Results are Consistent With Those of Physicians Worldwide



79% of Canadian physicians support Health Canada issuing distinct names. (2014)



66% of US physicians support FDA issuing distinct names. (2015)

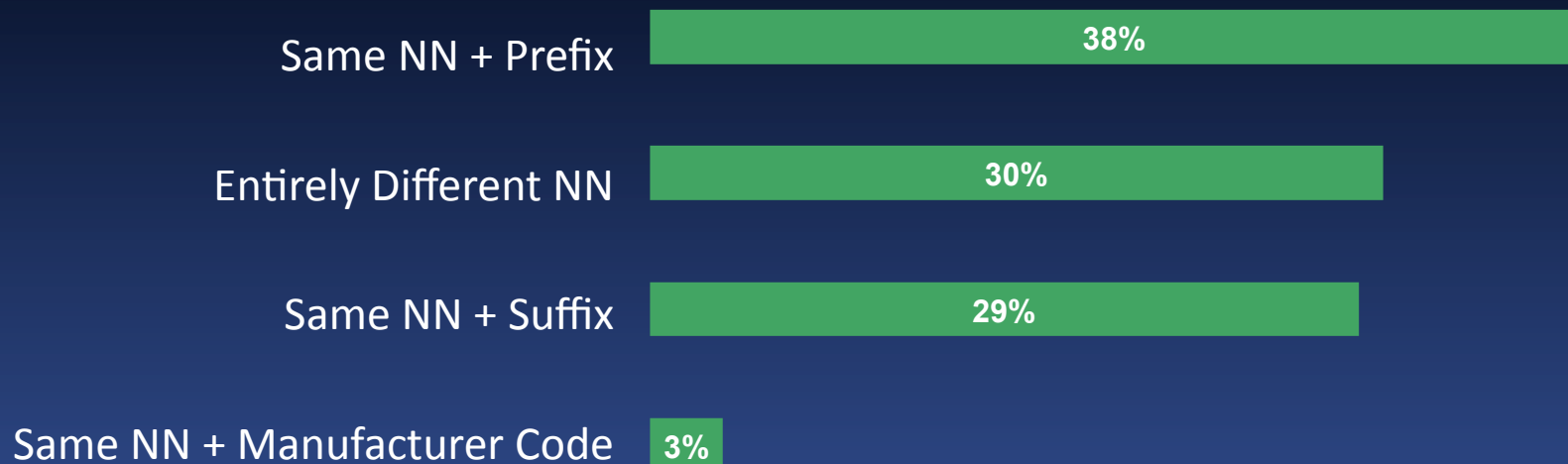


94% of Latin American Physicians consider WHO's BQ Proposal to be "useful" in helping patients receive the correct medicine. (2015)



76% of Australian physicians support TGA issuing distinct names (2016)

Australian Physicians Supportive of Distinct Names, But Have No Strong Preference on Method:

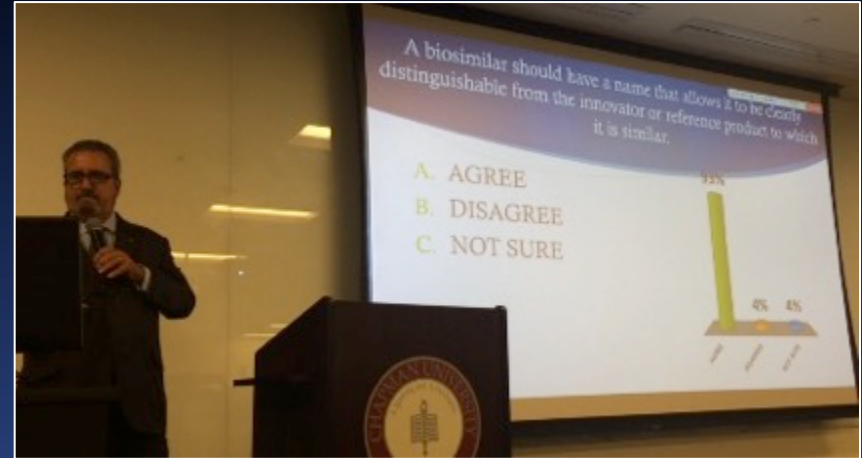


In recent years, TGA has discussed using several naming systems, ranging from prefixes to suffixes to trade names. These data illustrate the time is right for the global leadership the INN's BQ will provide.



Pharmacists and Distinct Naming

- Pharmacists have a long history of avoiding look-alike, or sound-alike names for medicines.
- Yet a disconnect remains between practicing pharmacists and their professional associations.
- U.S. Pharmacist Associations (APhA and ASHP) have opposed distinct nonproprietary names, including the WHO and FDA proposals.
- Yet we found through our continuing education courses, that pharmacists were very supportive.



May 25, 2015

Chapman University College of Pharmacy; Irvine, CA
40 pharmacists, 93% support for distinct naming

U.S. Pharmacist Survey: Distinguishable Naming



23%
OPPOSE
FDA issuing
distinguishable
names



68%
SUPPORT
FDA issuing
distinguishable names

8%
No
Opinion



15%
PREFER
RANDOM
SUFFIX

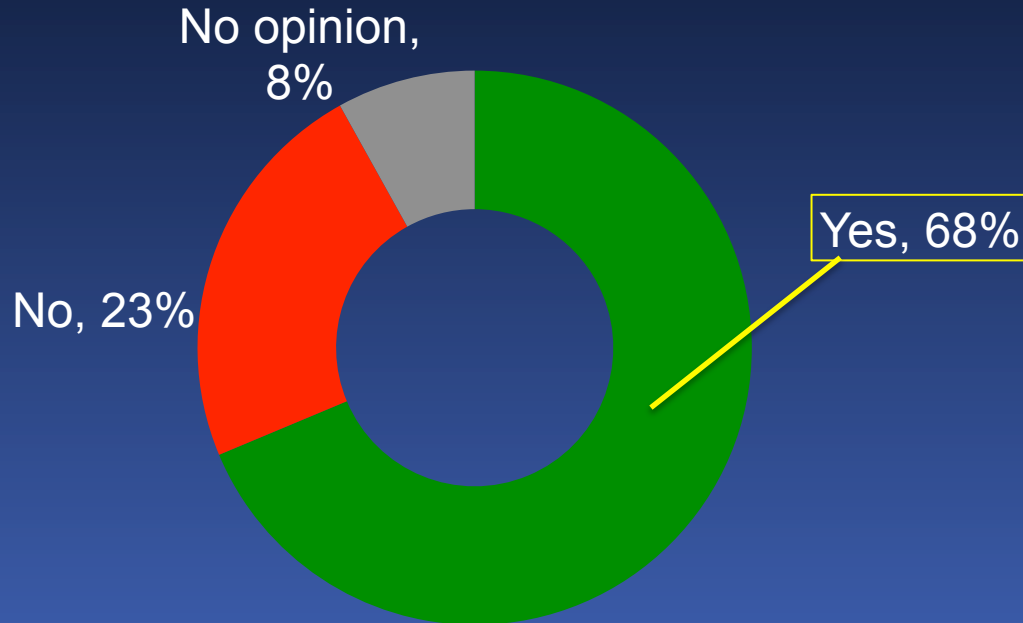


77%
PREFER MANUFACTURER-BASED
SUFFIX

8%
No
Opinion

ASBM's 2015 Survey of U.S. Pharmacists Confirmed Strong Support for Distinct Names

Should the FDA Require Distinguishable Names for All Biologics, Including Biosimilars? (n= 401)

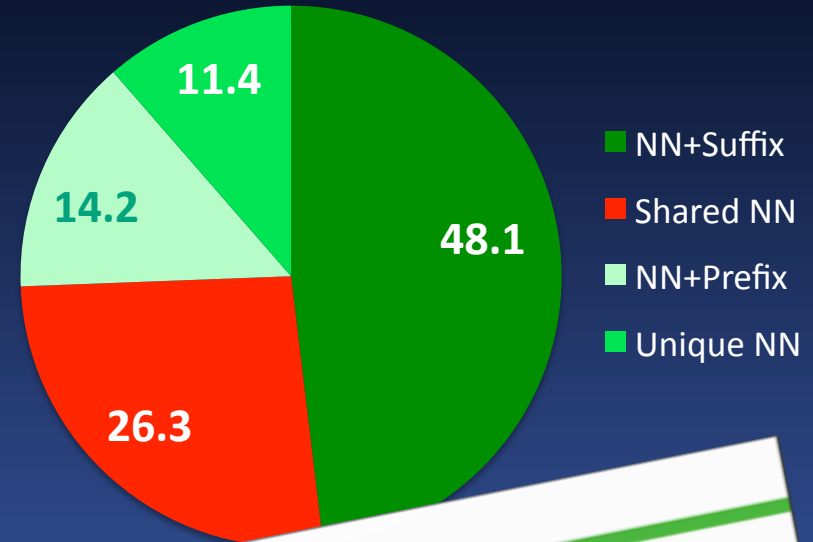


These results will be published in Q3 2016 issue of *GaBi Journal*

New Data Confirms ASBM's Results

- Published August 2016 in *Journal of Managed Care and Specialty Pharmacy*, Vol. 22 (8)
- Funded by Academy of Managed Care Pharmacy (AMCP); Surveyed 781 members of AMCP and the Hematology/Oncology Pharmacy Association (HOPA)
- Again we see a disconnect between the professional organizations and the rank-and-file pharmacists... While AMCP does not support distinct naming, their constituents do.
- 74% support distinct naming, 48% support distinguishing suffixes.

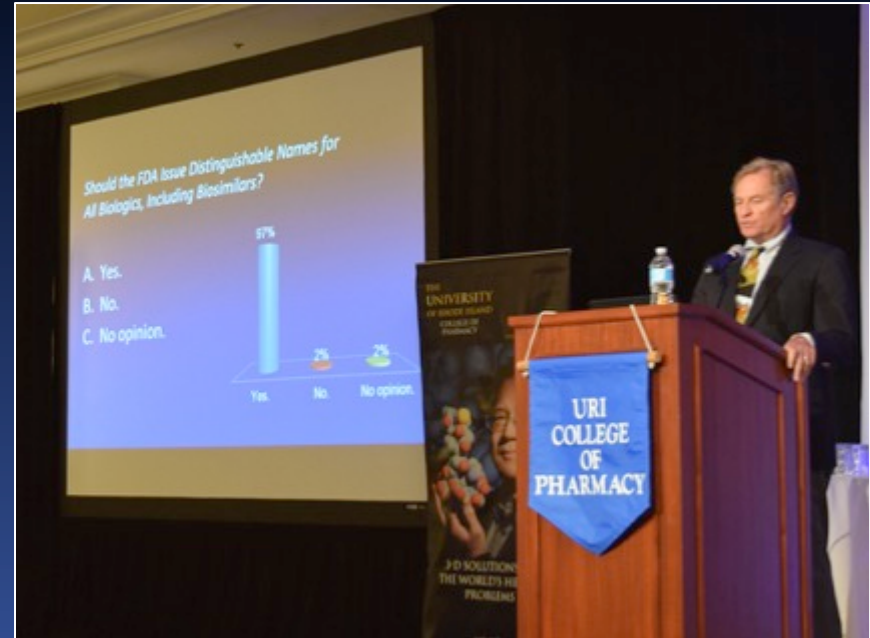
Biosimilar Naming Preference (n=781)



Findings from 2016 Educational Forums

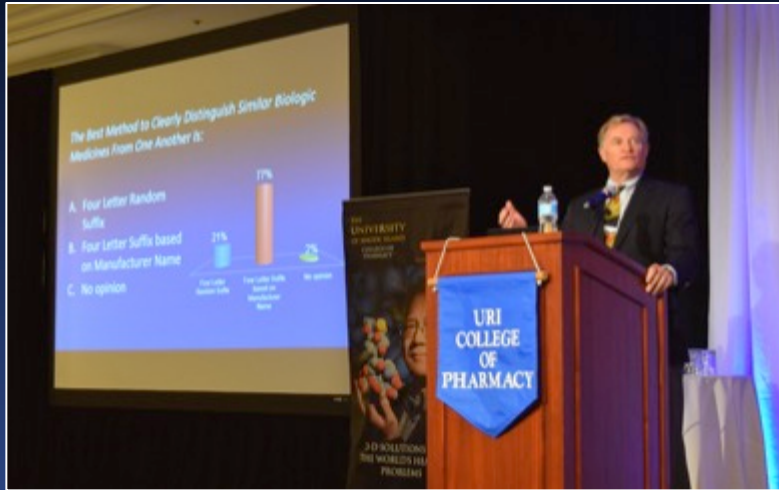
ASBM has conducted many educational forums this year, including several at Colleges of Pharmacy in RI, NY, OH, PA, with more scheduled.

Informal polls are showing an increase in support for distinct names among pharmacists.



Newport, RI March 31st, 2016
Univ. of Rhode Island College of Pharmacy
97% in favor of distinct names, (n=150)

Preference Remains for Meaningful Over Random Suffixes



Newport, RI March 31st

University of Rhode Island College of Pharmacy

n=150

77% support meaningful suffixes, 21% random.



Philadelphia, PA September 14th

University of the Sciences, College of Pharmacy

n=50

One hand goes up in support of random suffixes.

Toward Implementation

- As data continues to accumulate worldwide in support of distinct naming, we have confidence in the BQ as a global solution.
- Both empirical and anecdotal – this support is a testament to the value of WHO’s open, inclusive, and collaborative process.
- Yet this process has been a long one, and urgency grows to address this issue.
- Adjustments can be made to the BQ to cover the rare outlier if necessary.
- BQ Implementation should begin soon before further proliferation of national naming schemes, some of which will not be BQ-compatible.



Safe**Biologics**

ALLIANCE *for* SAFE BIOLOGIC MEDICINES

Thank You For Your Attention