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ALLIANCE for SAFE BIOLOGIC MEDICINES

Latin American Physician Perspectives on Biosimilars

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www.safebiologics.org

6th Latin American Forum on Biosimilars (2016)
7th Brazilian Forum on Biosimilars
Brasilia, Brasil
June 29, 2016

Disclosures

I have no relevant financial disclosures.

The Alliance for Safe Biologic Medicines (ASBM)

ASBM is an organization consisting of patient, physician, research and manufacturing organizations devoted to promoting the safe introduction and monitoring of biosimilar medications

- Steering Committee composed of patient and physician groups
- Advisory Board of physicians, researchers, pharmacists, and patients

The Alliance for Safe Biologic Medicines (ASBM)

ASBM Leadership

Harry L. Gewanter, MD, FAAP, FACR
Chairman
Pediatric Rheumatologist

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Advisory Board Chair
Dean, University of Arizona College of Pharmacy

Michael Reilly, Esq.
Executive Director
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STEERING COMMITTEE

Gathering the Perspectives of Providers Around the World

Canadian Physician Survey
(December 2014): 427 physicians

U.S. Physician Surveys
(September 2012): 376 physicians
(February 2015): 400 physicians (Labeling)
(November 2015): 400 physicians

E.U. (France, Italy, Spain, UK) Physician Survey
(November 2013): 470 physicians

U.S. Pharmacist Survey
(September 2015) 401 pharmacists

Latin America (Argentina, Brazil, Colombia, Mexico) Physician Survey
(May 2015): 399 physicians

All surveys available at www.SafeBiologics.org

Sharing Physician Perspectives With Regulators

INTERNATIONAL

- 2014-2016: 58th-62nd WHO INN Consultation and Frontpage meetings
- 2014: Int'l Regulator Conference (Pre-ICDRA), Brazil
- 2014: Presented country-specific survey data to Spain, Italian, and Canadian Health Regulators
- 2015: Presented Latin American survey data at two Biosimilars Conferences, Brazil.

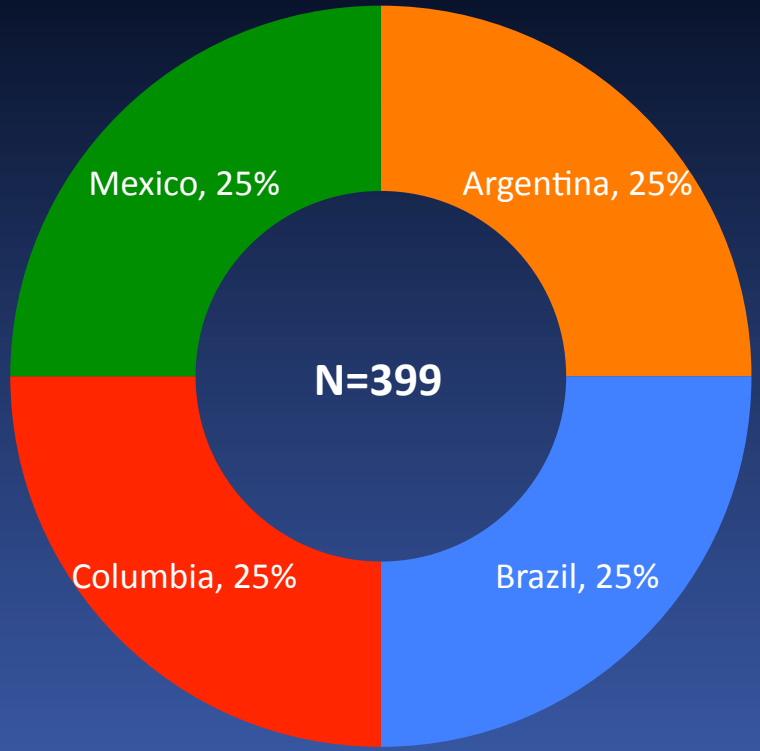
US:

- 2015: Shared U.S. data and recommendations with U.S. Dept. of Health and Human Services and other Administration officials.
- February 2016 FDA Arthritis Advisory Committee Hearing
- Numerous State Legislatures 2010-2016

Survey Overview and Methodology

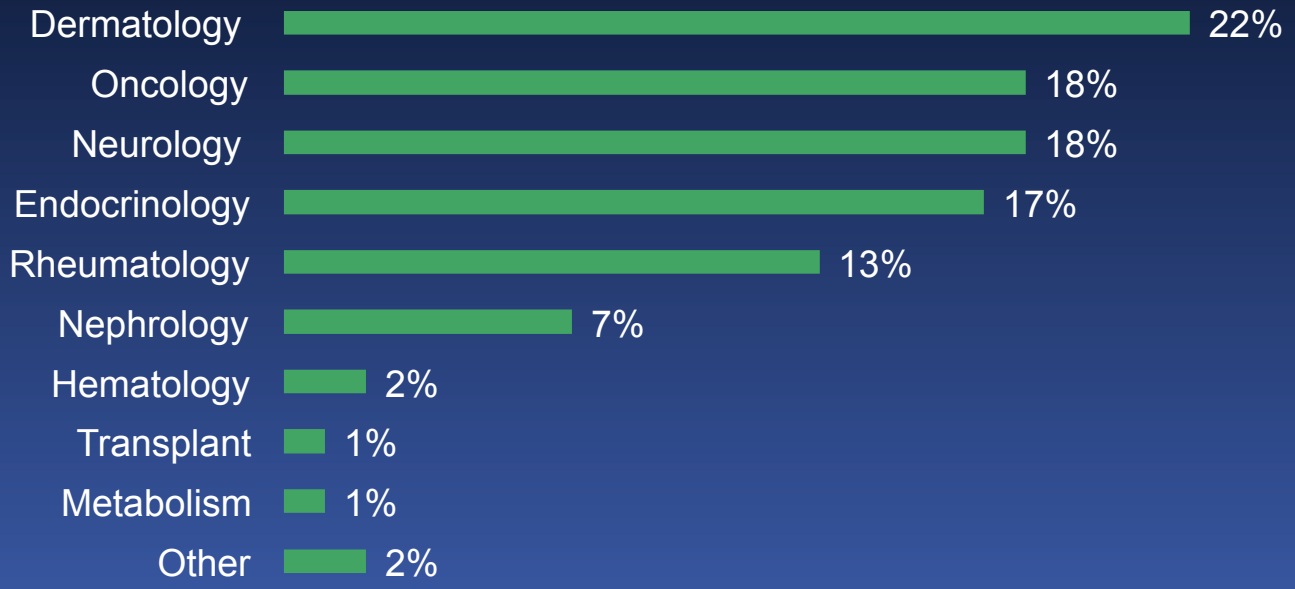
Latin American Survey: Overview

- 399 Prescribers were recruited from 4 countries in Latin America
  - Argentina (N=99)
  - Brazil (N=101)
  - Colombia (N=100)
  - Mexico (N=99)
- 15 minute web-based survey
- All surveys were administered in native languages
  - Argentina, Columbia, Mexico: Spanish
  - Brazil: Portuguese



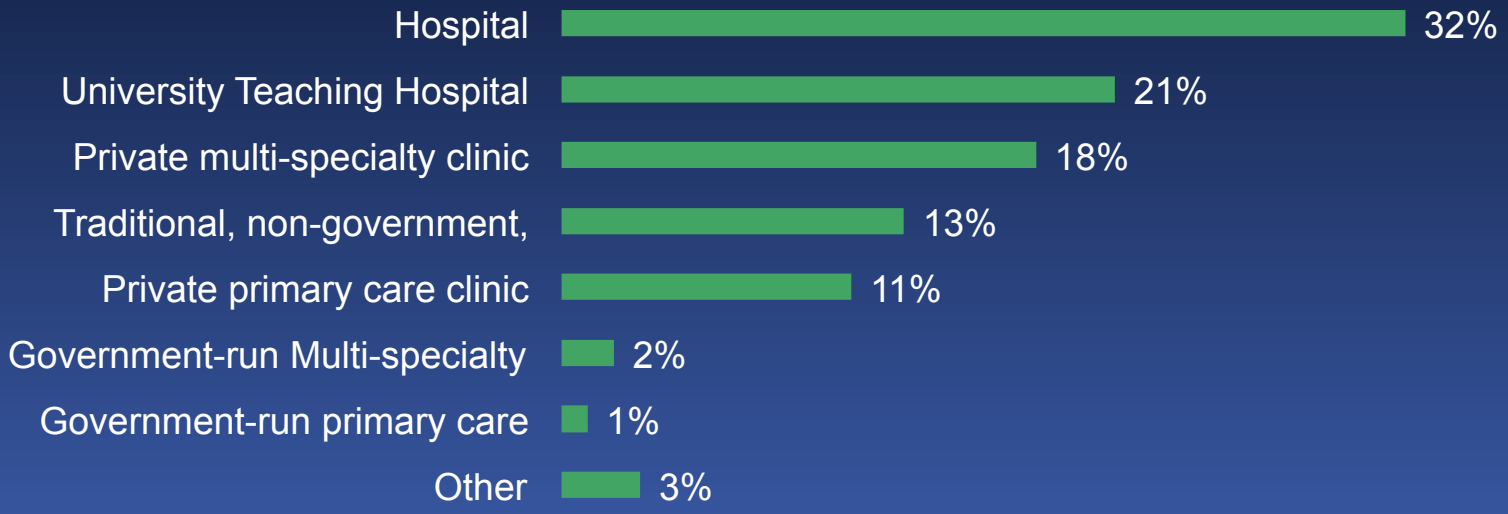
Primary Therapeutic Area

"Please indicate your primary practice area or therapeutic area in which you practice?" (N=399)



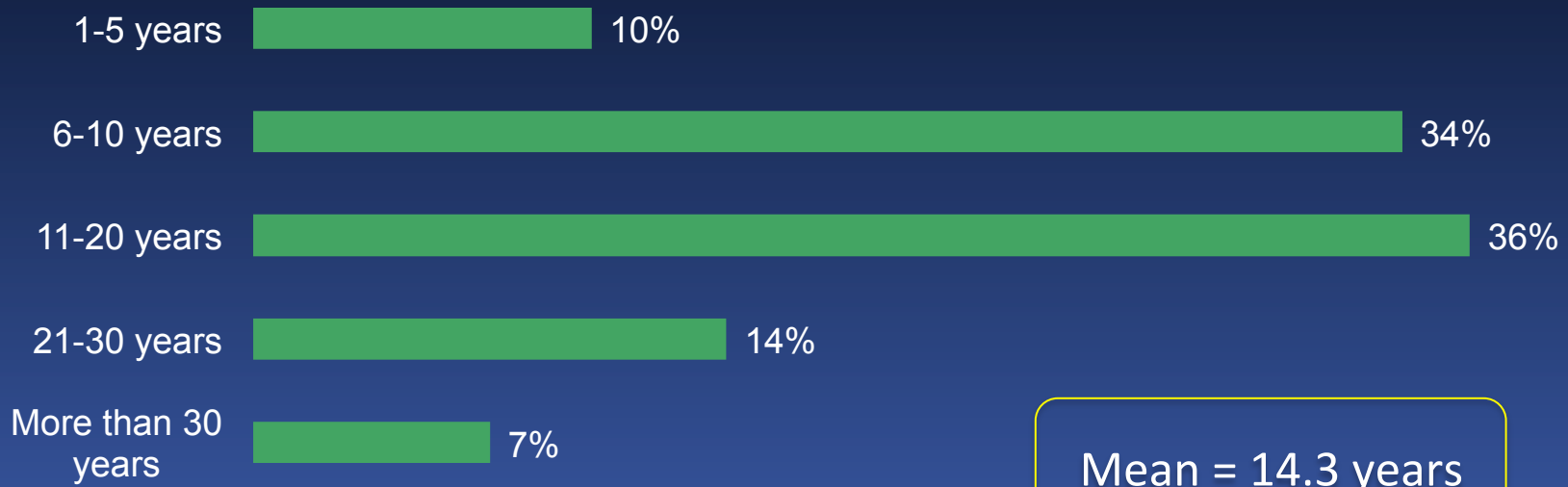
Practice Setting

"Which of the following best describes the type of practice in which you work?" (N=399)

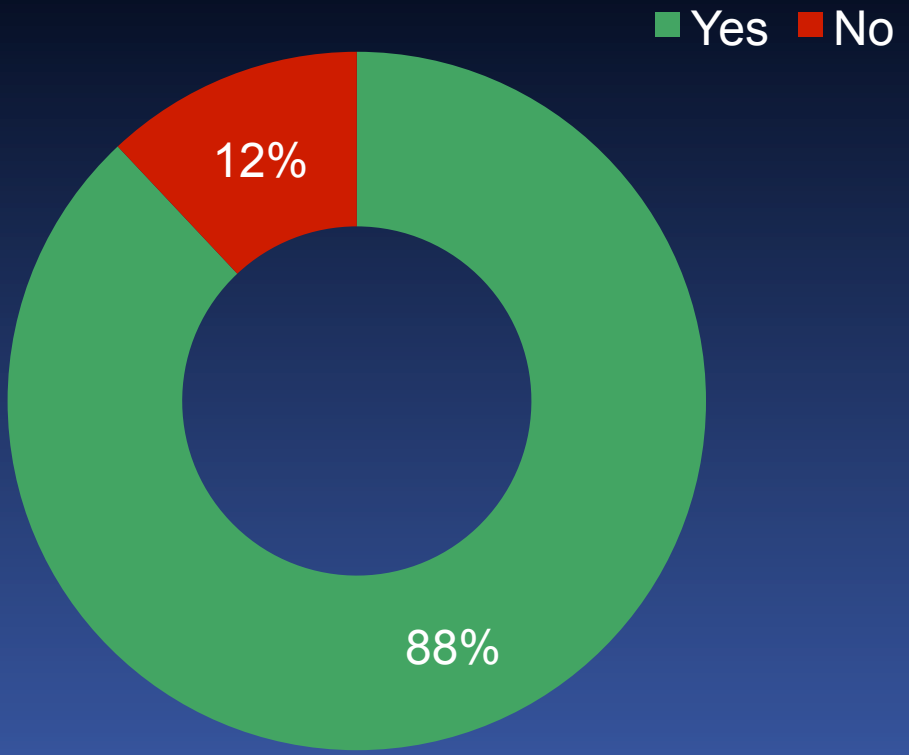


Length of Time in Healthcare Sector

"How long have you been in medical practice?" (N=399)



Do You Prescribe Biologics?



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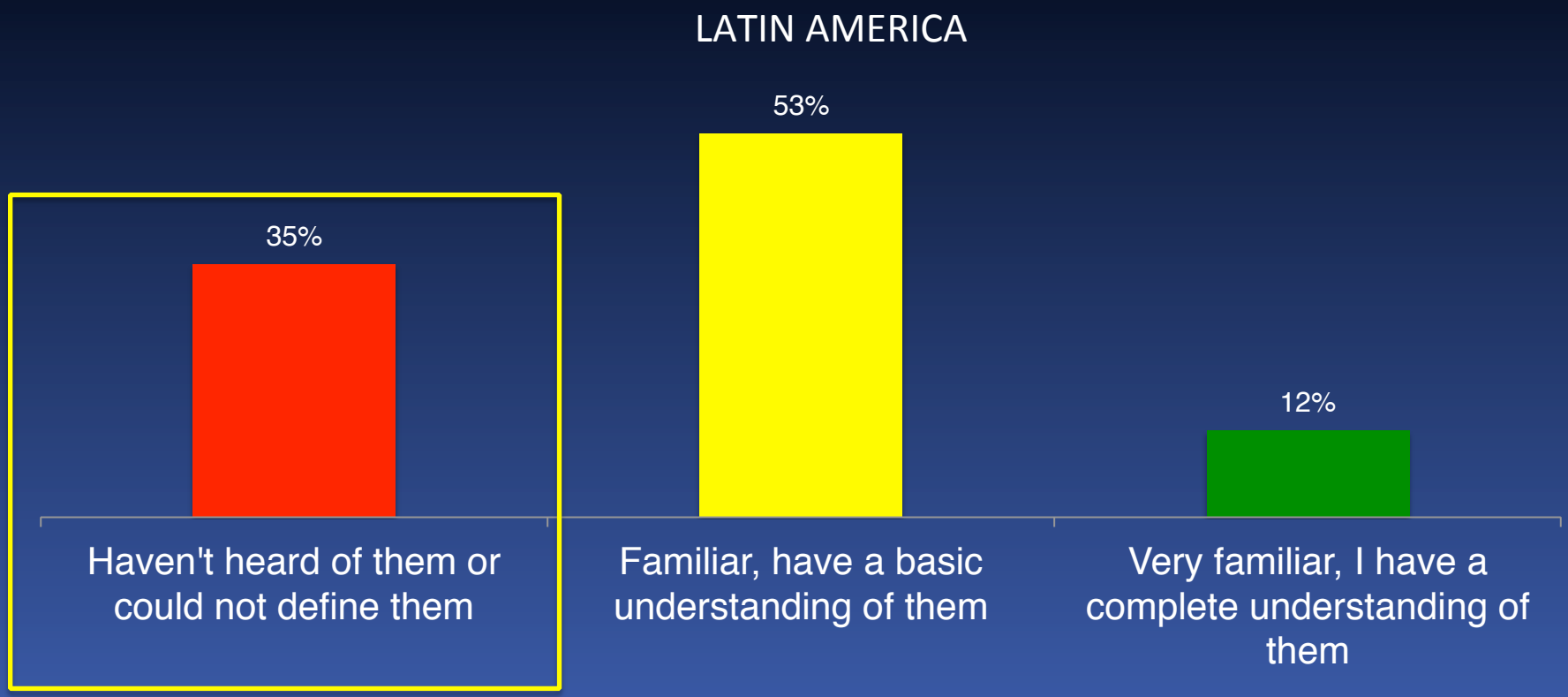
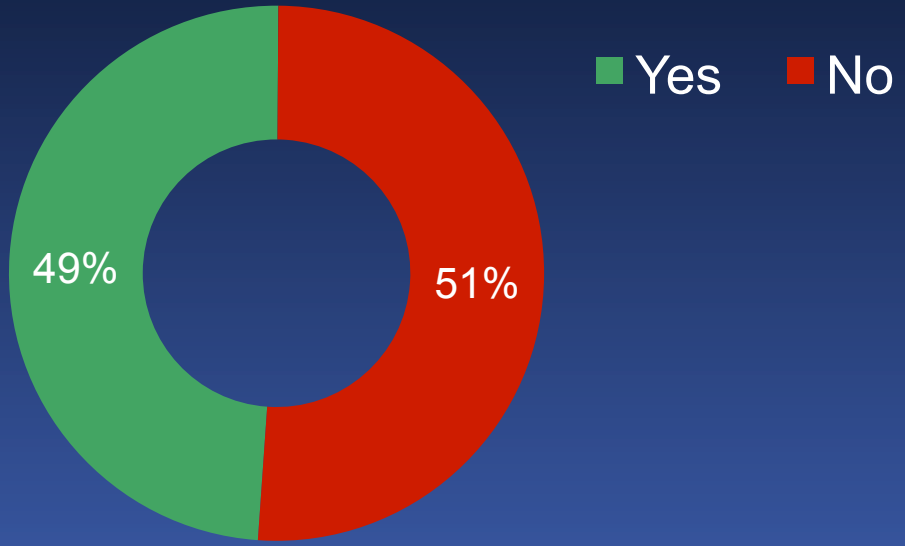
Biologic and Biosimilar Familiarity

Familiarity With Biosimilars



Awareness of Different Classes of Biologics

"Are you aware of the difference between biologics, biosimilars and non-comparable biologics? " (N=399)



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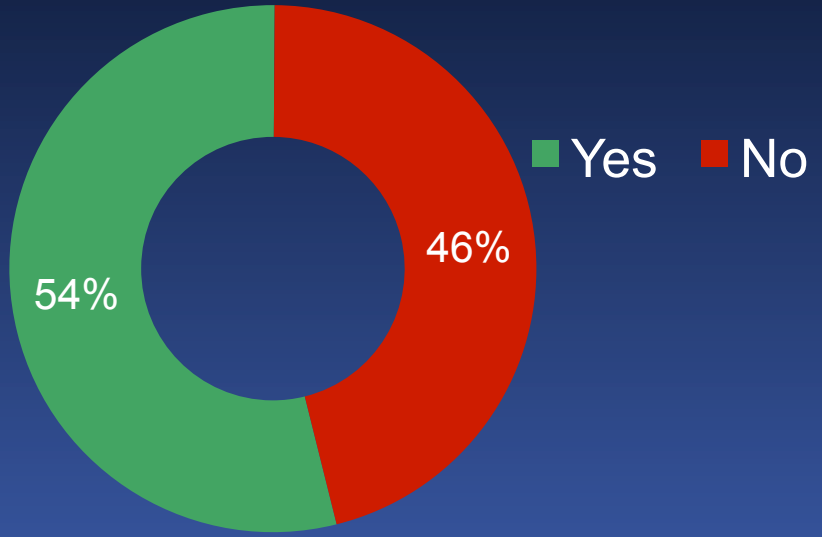
Awareness of Approval Process

"Do you assume that all biosimilars go through the same regulatory process for approval as the original biologic products?" (N=399)



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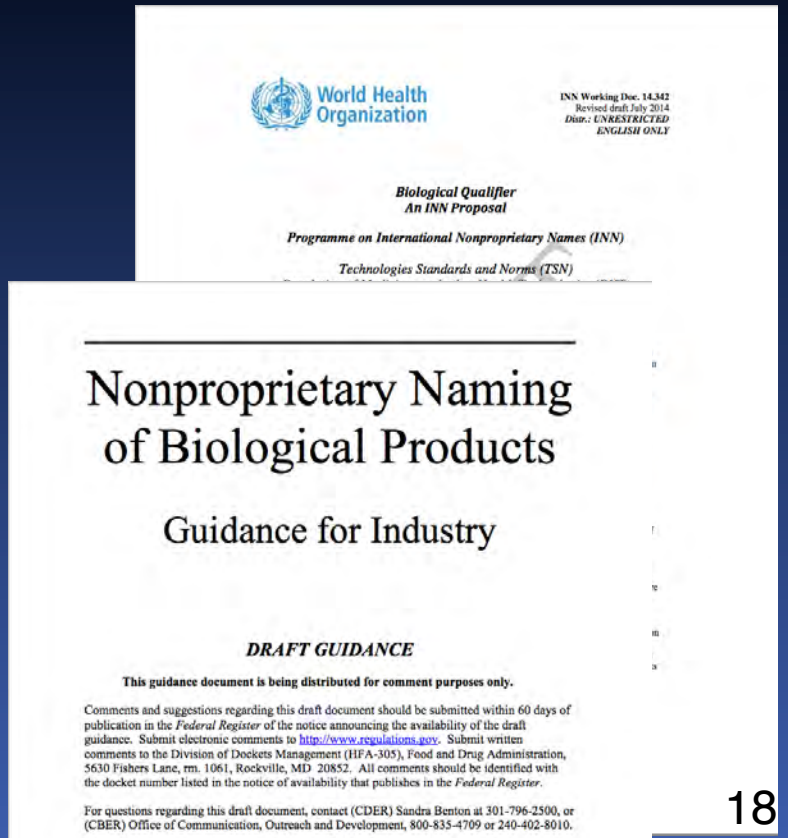
Naming of Biologics and Biosimilars

WHO and FDA: Distinguishable Naming Proposals

- Both regulators are updating their naming systems for biosimilars.
- Distinguishability aids in clear communication throughout treatment, improves tracking of safety and efficacy, and promotes manufacturer accountability.
- Both call for similar biologics (including biosimilars) to have a shared root name (International Nonproprietary Name/ INN) followed by a four-letter suffix.
- The WHO calls this a "Biological Qualifier"


World Health Organization

INN Working Doc. 14.342
Revised draft July 2014
Distr.: UNRESTRICTED
ENGLISH ONLY

Biological Qualifier
An INN Proposal

Programme on International Nonproprietary Names (INN)

Technologies Standards and Norms (TSN)

Nonproprietary Naming of Biological Products

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Sandra Benton at 301-796-2500, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

What's In A Name?

Suffix Formats: Random or Meaningful?

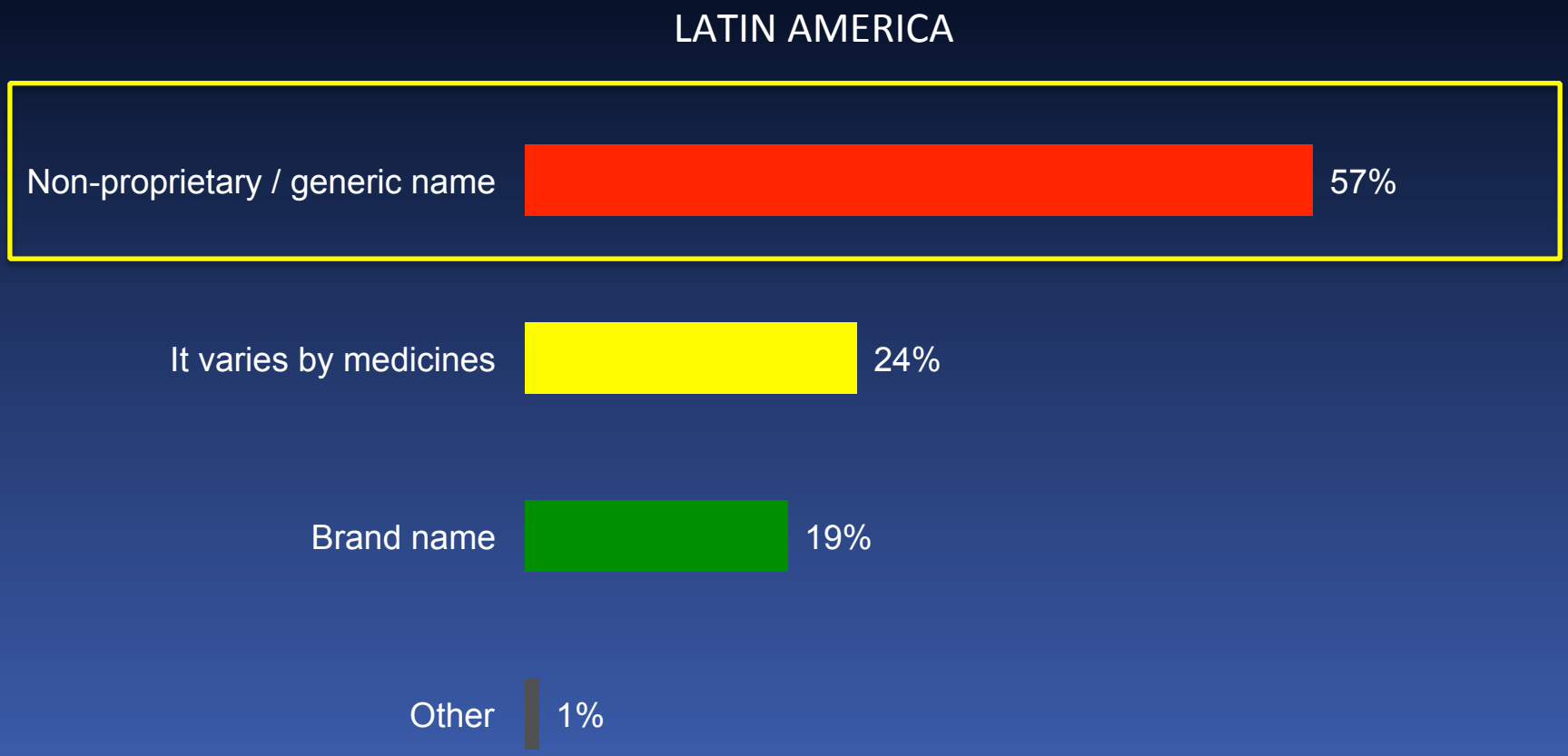
EMA: No suffix, uses trade name. Example: infliximab (REMICADE®) vs. infliximab (INFLECTRA®) vs. infliximab (REMSIMA®) vs. infliximab (FLIXABI®)

WHO: Biological Qualifier will be random four-letter suffix.

FDA: has used both meaningful and random suffixes:

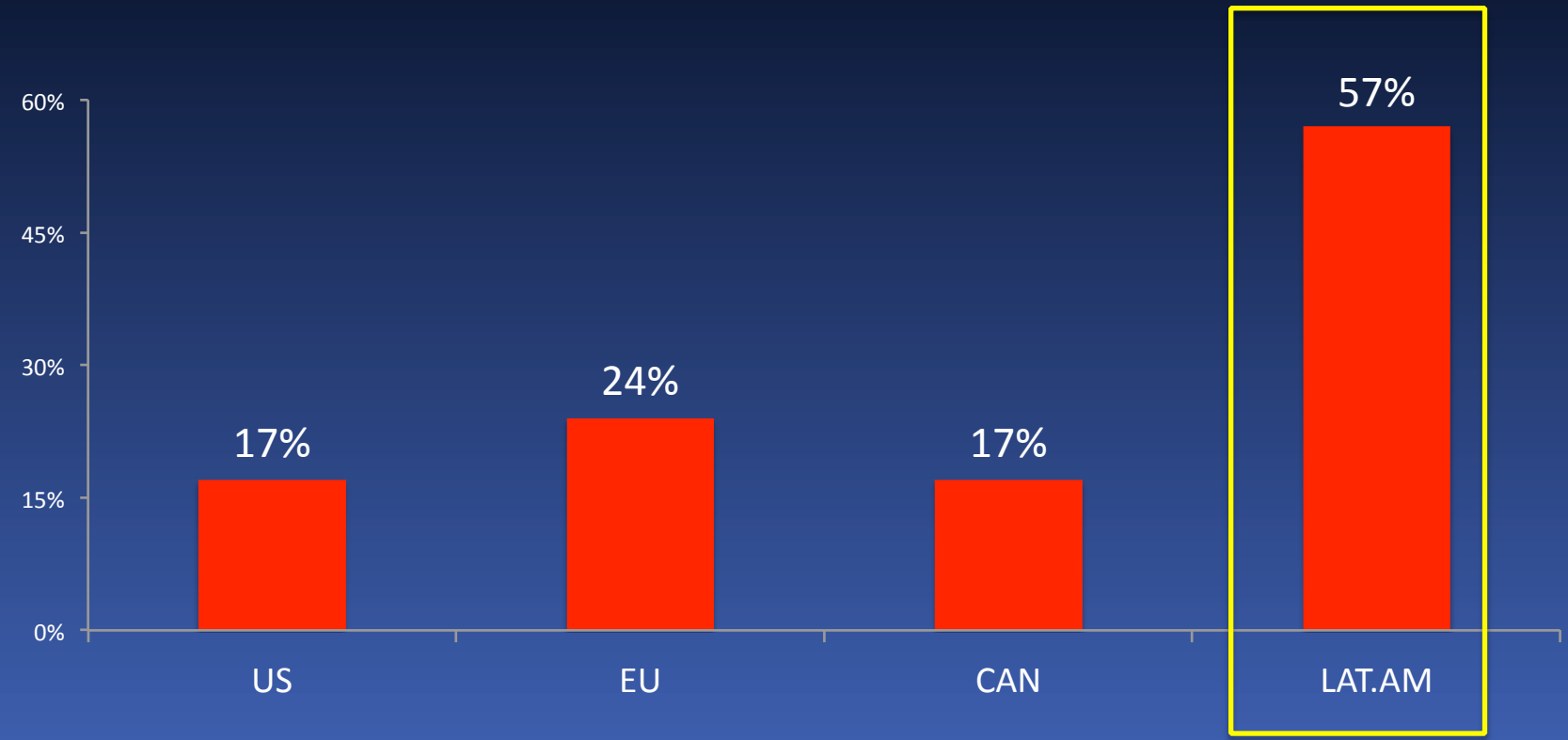
- March 2015: ZARXIO (filgrastim-sndz) provisional name, suffix based on its manufacturer, “Sandoz”.
- August 2015: Draft Naming Guidance proposes to shift to random suffixes; proposes to rename “filgrastim-sndz” to “filgrastim-blfm”.
- April 2016: Second biosimilar approved, Inflectra (infliximab-dyyb), with random suffix.

Identifying Medicine in Patient Record

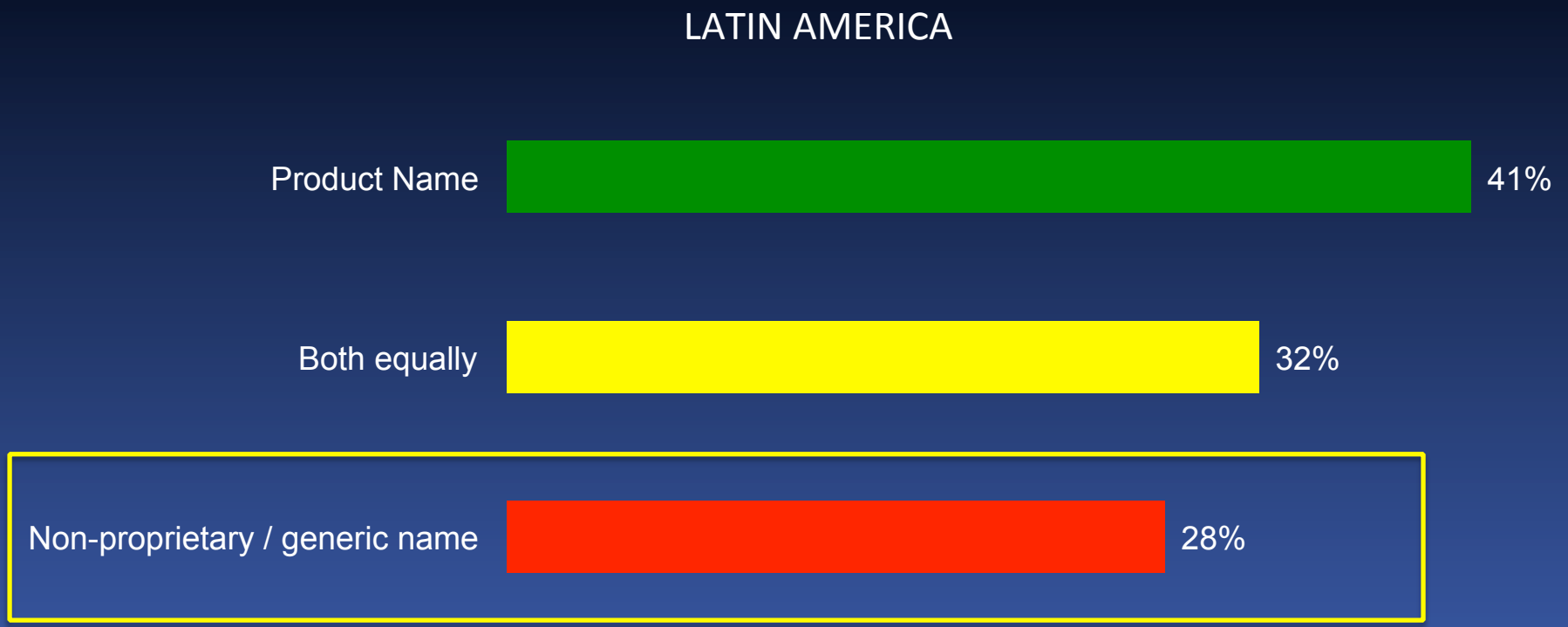


Percent of Physicians Using INN Only when Identifying Medicine in Patient Record

(This could result in patient receiving the wrong medicine.)

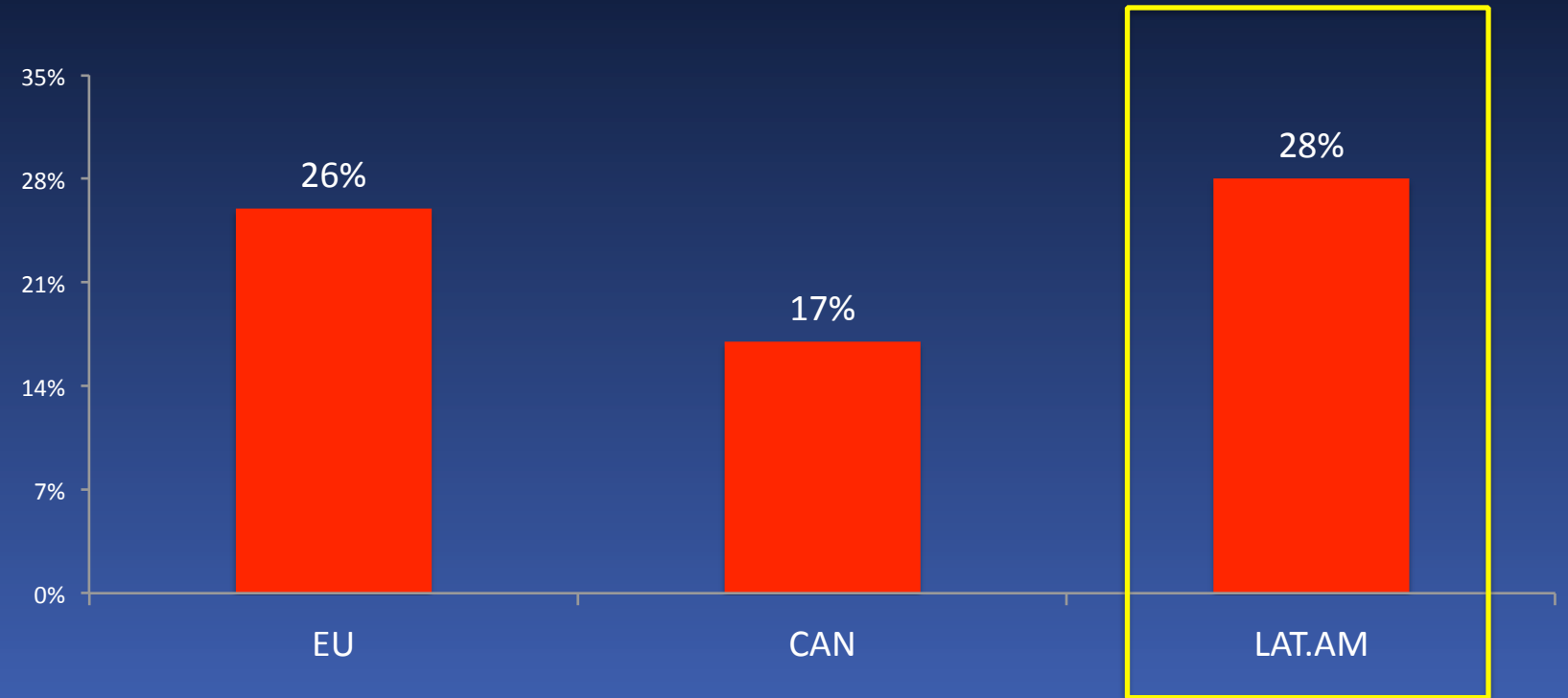


Identifying Medicine When Reporting Adverse Events.



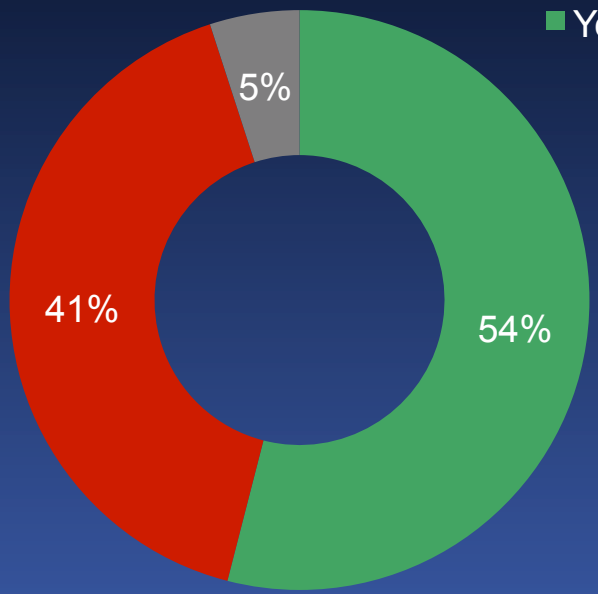
Percent of Physicians Using INN Only when Reporting Adverse Events.

(This could result in improper attribution or pooling of adverse events.)



Implications of Shared INN: Structurally Identical?

"If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that the medicines are structurally identical?" (N=399)



(It is not possible to create structurally identical molecules with biologic medicines.)

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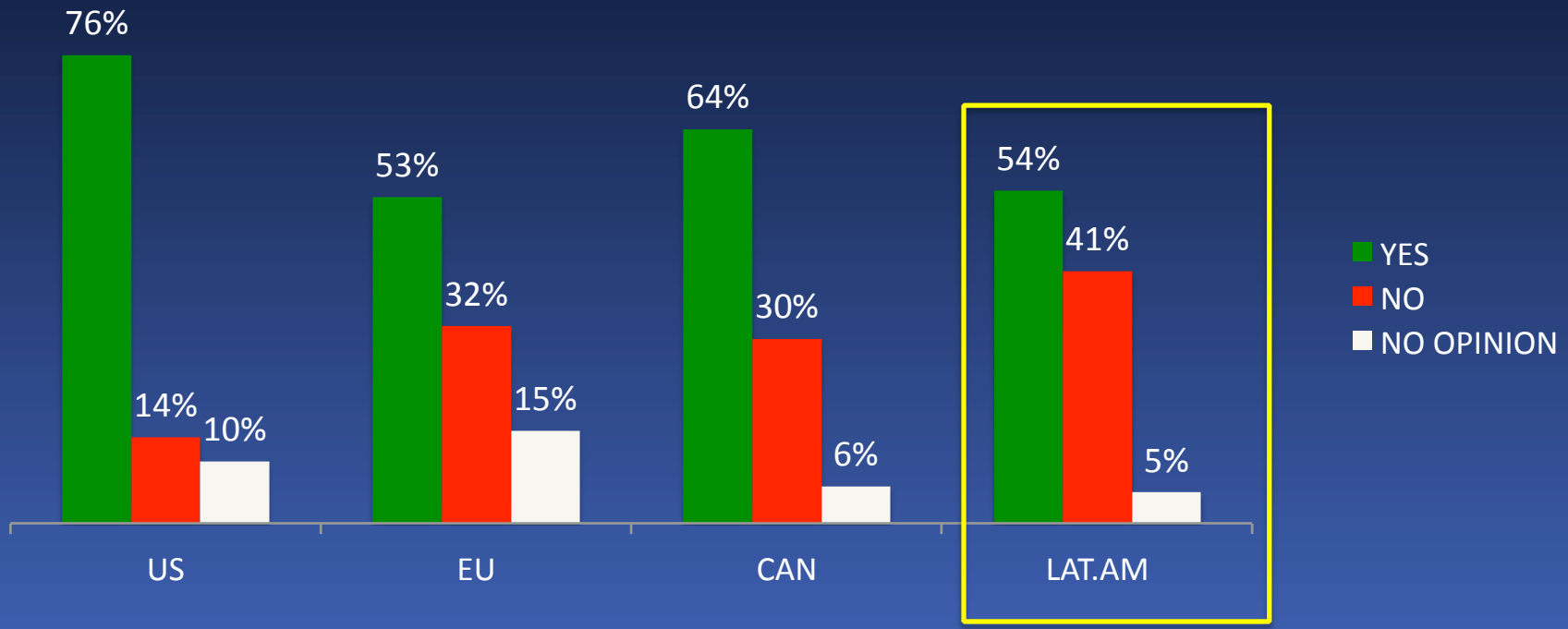
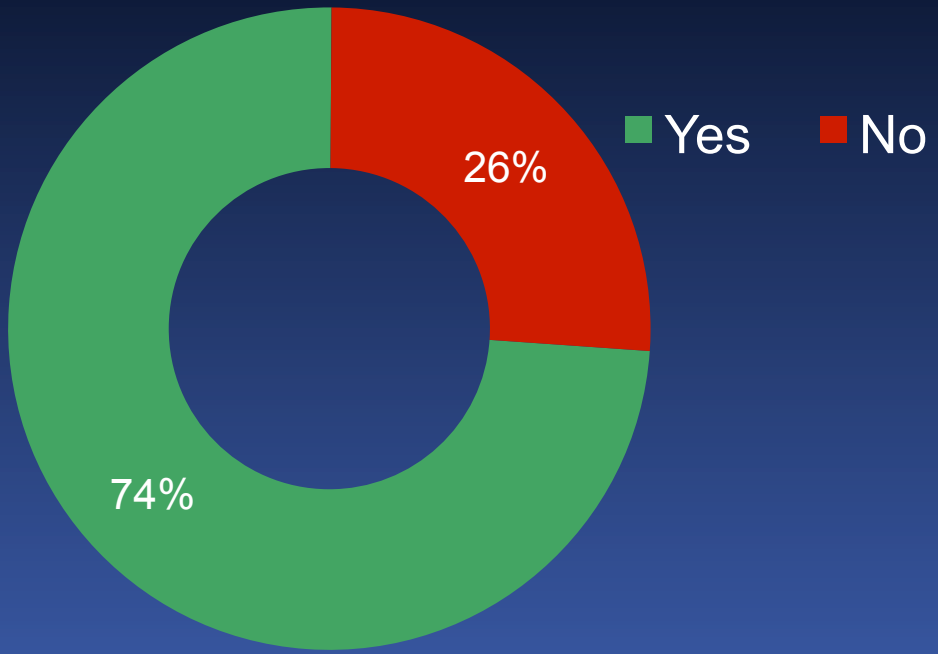
Globally, ASBM Physician Surveys Show Potential for Confusion in Absence of Distinguishable Names

"Is a Biosimilar With The Same Non-Proprietary Name STRUCTURALLY IDENTICAL to its Reference Product?"



Implications of Shared INN: Approved Indications

"Would you assume that a follow-on product which has the same non-proprietary name (e.g., infliximab, trastuzumab) as the innovator product, is approved for all the same indications as the innovator product?" (N=399)



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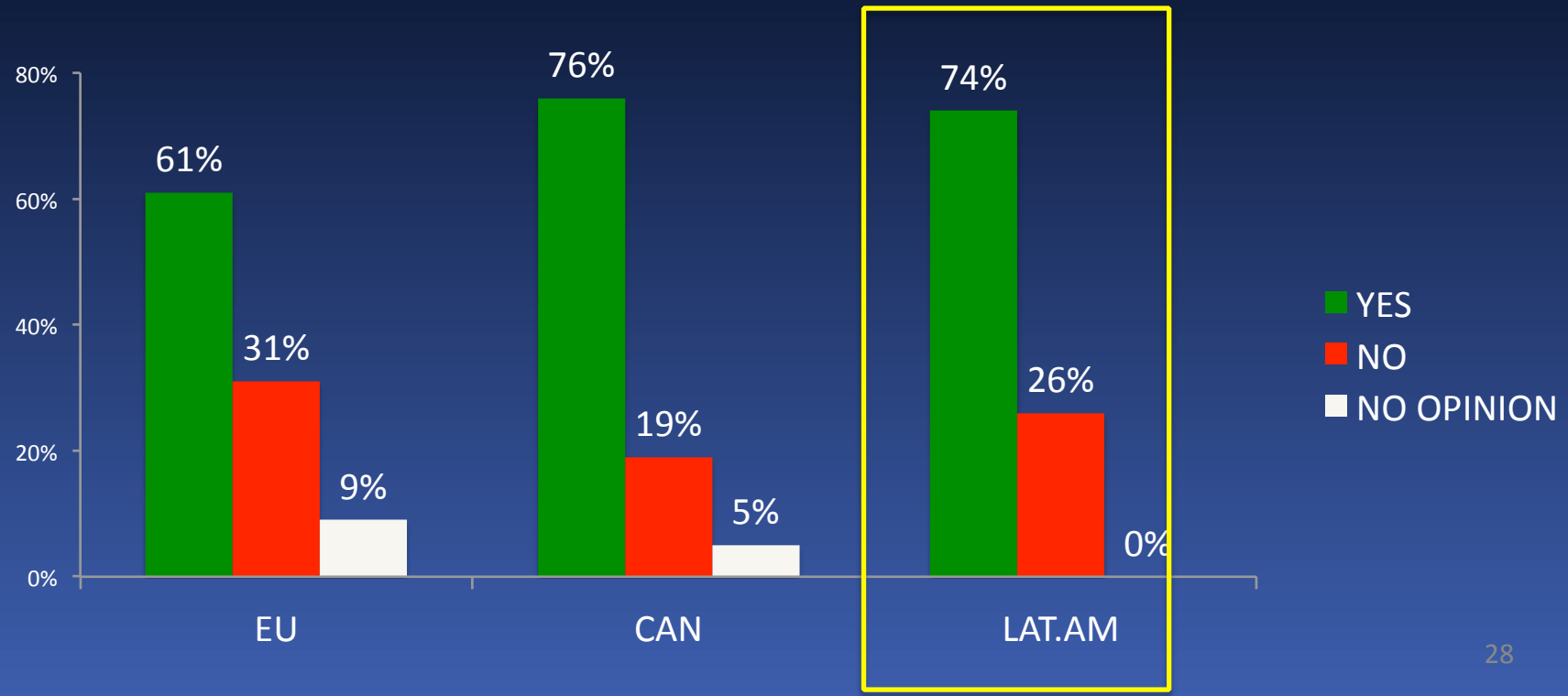
Percentage of Physicians Saying A Biosimilar Sharing an INN with its Reference Product Implies Approval for the Same Indications:

(This may or may not be the case…)



ASBM Global Physician Surveys Show Potential for Confusion in Absence of Distinguishable Names

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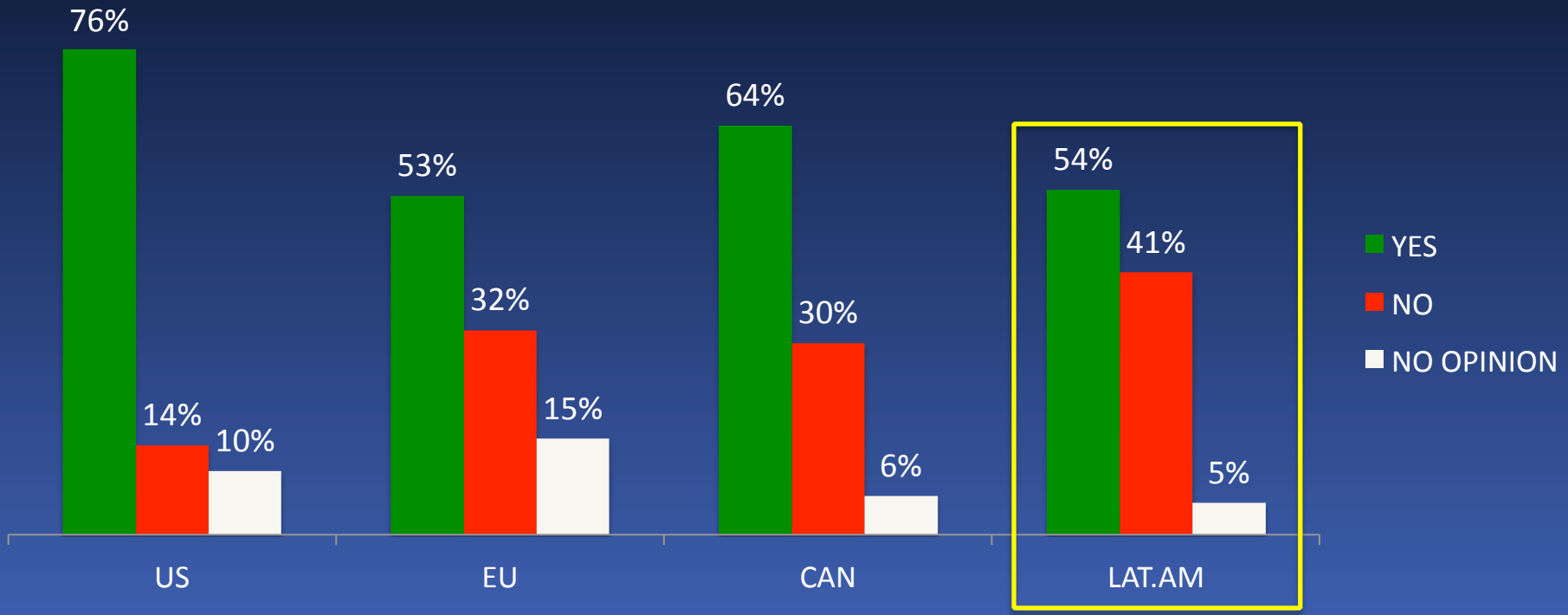

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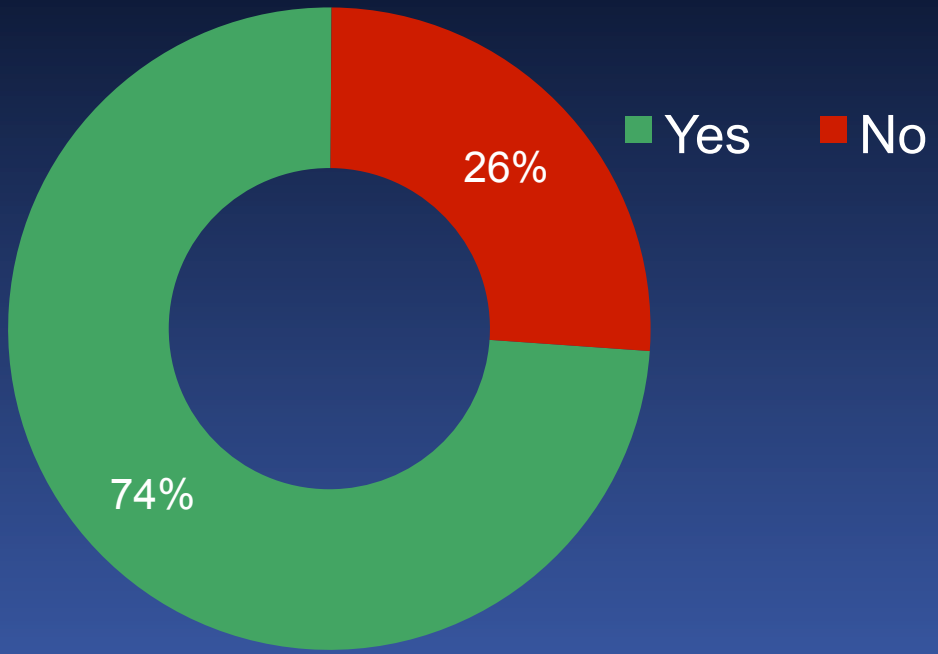

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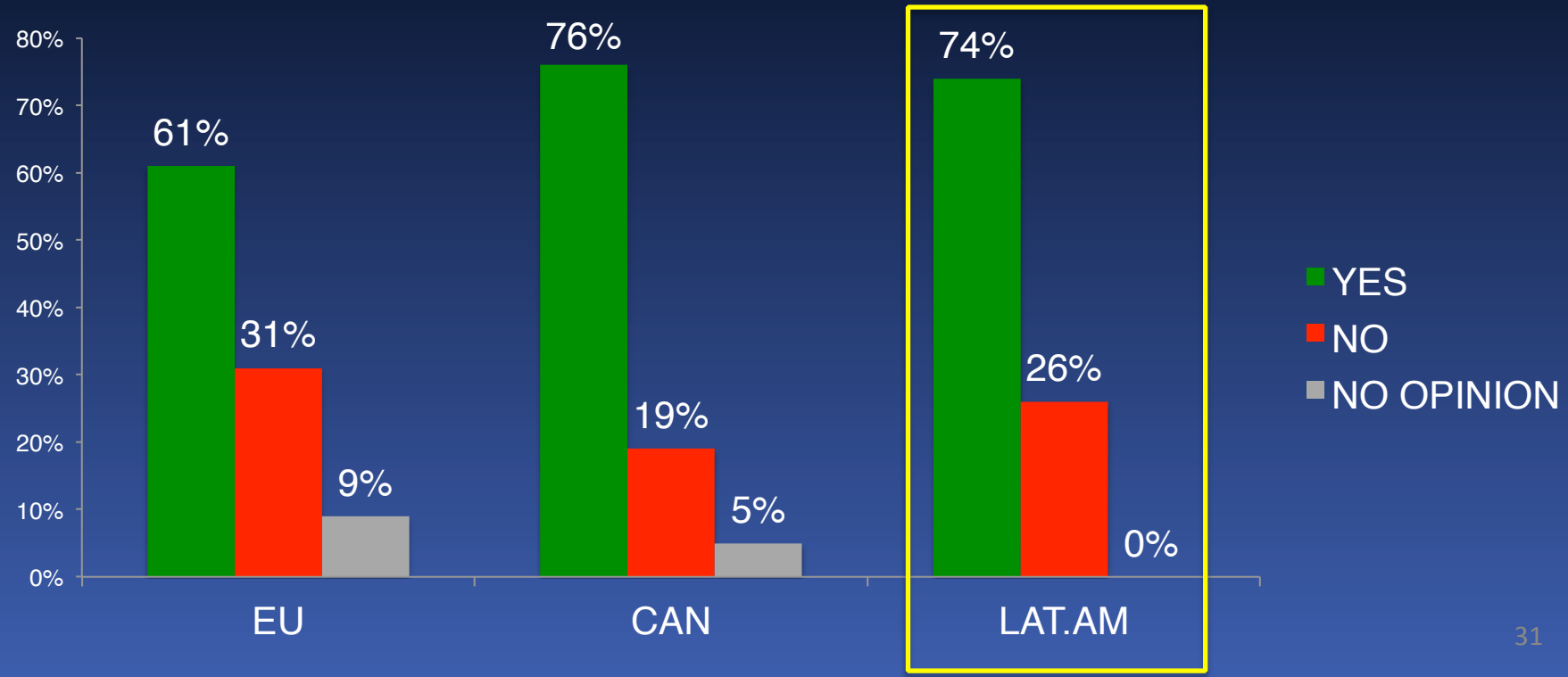
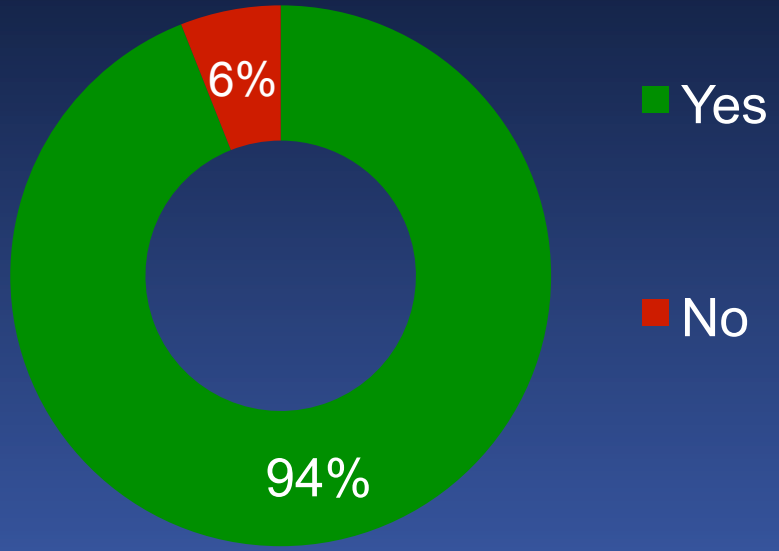
Global Percentage of Physicians Saying A Biosimilar Sharing an INN with its Reference Product Implies Approval for the Same Indications:

(This may or may not be the case…)



Latin American Physicians Overwhelmingly Consider WHO's Biological Qualifier Proposal Useful…

"Do you think [The WHO's proposed] "biologic qualifier" would be useful to you to help you ensure that your patients receive the right medicine that you have prescribed for them?" (N=399)



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Global Surveys Demonstrate Broad Physician Support for Distinguishable Naming

79% of Canadian physicians support Health Canada 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)

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

Pharmacy-Level Substitution

What is "Automatic Substitution"?

1) Physician writes a prescription

2) Pharmacist is allowed, or required, to provide a different medicine to the patient <u>without communication with prescribing doctor beforehand</u>

Automatic Pharmacy Substitution around the World

- Opposed by European Medicines Agency and Health Canada.
- *Banned in many countries including the UK, Germany, Ireland, Spain, Sweden, Norway, and Finland.*
- France statutorily permits it in limited cases (bio-naïve patients), this policy has never been implemented.
- Australia about to allow pharmacy-level substitution of a biosimilar without physician involvement, over opposition of the Australian Rheumatology Association.

Automatic Pharmacy Substitution around the World

- U.S. policy is evolving, but 19 states and Puerto Rico have passed laws which allow substitution, requiring pharmacists to communicate to physicians which product was dispensed.

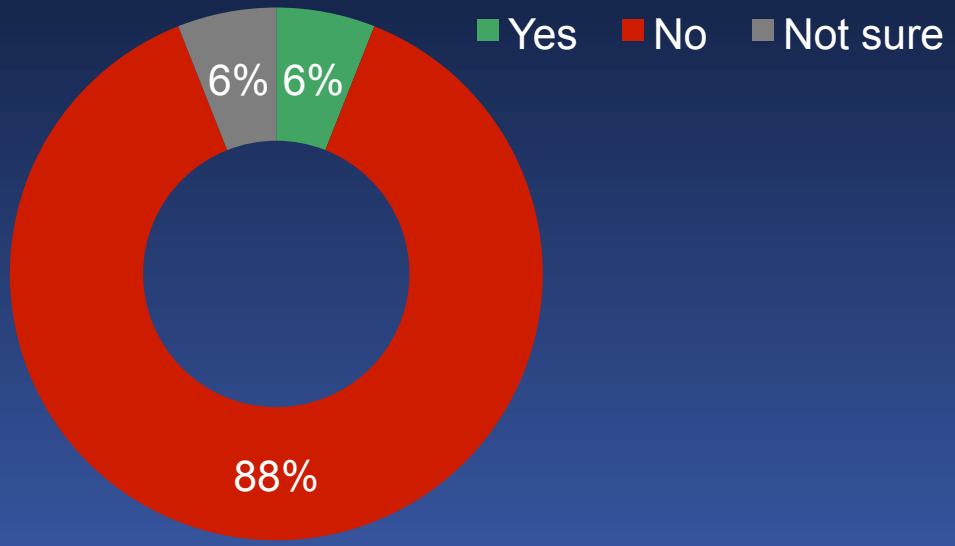
- Latin America - Range from substitution policies that afford physician prescribing autonomy to non-existent policies. In those instances where physicians have "DAW" protections, enforcement is not always consistent.

Physician Concerns With Automatic Substitution

- Physicians absolutely need to know which medicine the patient is actually receiving to make informed treatment decisions.
- Knowing this helps us assess the patient's response to a particular treatment. For example, if a patient were to stop responding, we need to know if it is potentially due to a switch, or some other factor.
- There is often variability in patient response. The best treatment for one patient is not the best choice for all.
- Physicians and patients, not a third party, should always have the final say on which medicine is the appropriate choice.

Automatic Pharmacy Switching

"Should the pharmacist have the authority to automatically switch a patient to a biosimilar without certainty that the switch would not cause an unwanted immune response or that small differences between products would not have clinical implications for patients?" (N=399)



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How Important is Notification of Which Medication Is Dispensed?

85% of Canadian physicians consider it "very important" or "critical"

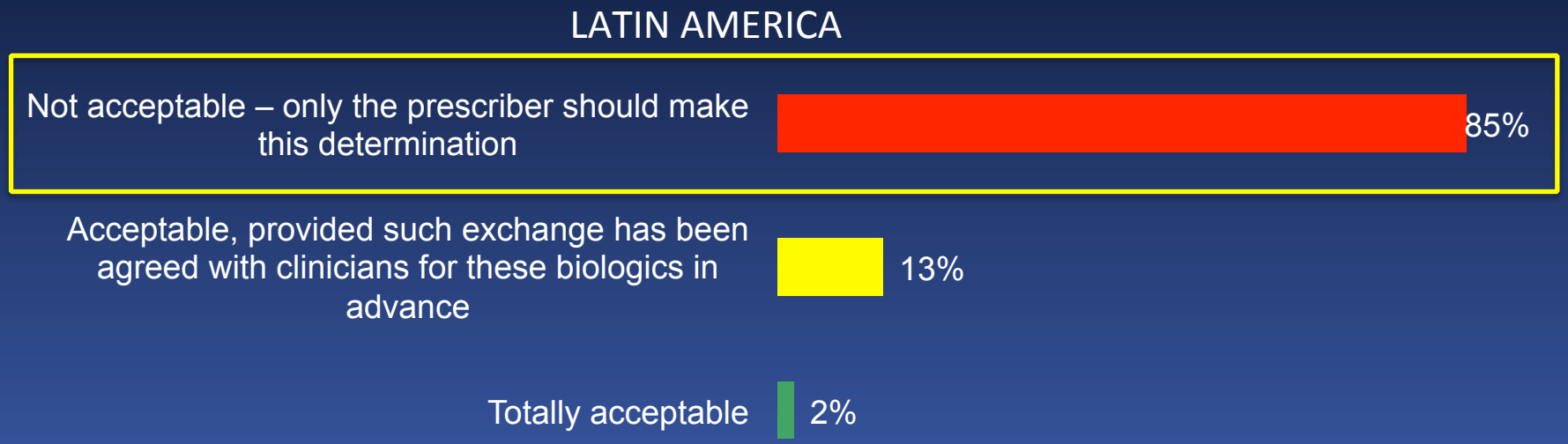
77% of EU Physicians consider it "very important" or "critical"

80% of US physicians consider it "very important" or "critical"

87% of Latin American Physicians consider it "very important" or "critical"

Pharmacist Determination: Acceptable at Initiation of Treatment?

"How acceptable would it be for you if the pharmacist made the determination which biologic (innovator or biosimilar) to dispense to your patient on initiation of treatment?" (N=399)



How Important is "Dispense as Written" (DAW) Authority?

80% *of Canadian physicians consider it "very important" or "critical" (2014)*

74% *of EU physicians consider it "very important" or "critical" (2013)*

82% *of US physicians consider it "very important" or "critical" (2012)*

85% *of Latin American physicians consider it "very important" or "critical" (2015)*

Physician Opinions of a Pharmacist Determining Which Biologic is Dispensed at Initiation of Treatment:

71% *of Canadian physicians consider it "not acceptable" (2014)*

62% *of EU physicians consider it "not acceptable'" (2013)*

85% *of Latin American physicians consider it "not acceptable" (2015)*

Physician/Pharmacist Collaboration is Key

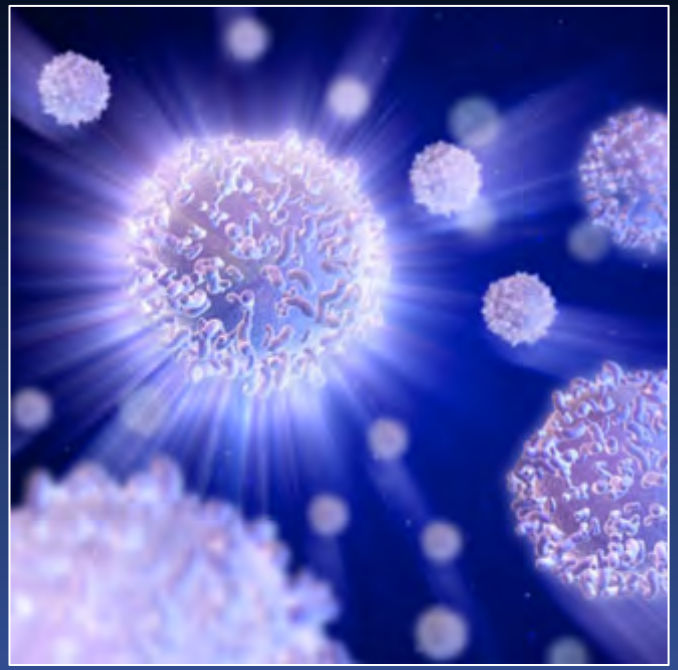
Physicians and pharmacists should **work collaboratively** to ensure that the treating physician is aware of the exact biologic – by manufacturer – given to a patient in order to facilitate patient care and accurate attribution of any adverse events that may occurs.

Summary

There is a SIGNIFICANT EDUCATIONAL NEED about biosimilars for physicians, patients and regulators in Latin America and globally.

Summary

Physician prescribing and record-keeping practices in Latin America, as elsewhere, show the VALUE OF AND NEED FOR DISTINGUISHABLE NAMING.



Summary

Latin American physicians overwhelmingly support (94%) the World Health Organization's BQ Proposal for DISTINGUISHABLE BIOLOGIC NAMING to help ensure appropriate dispensing and tracking of their prescribed medications.

Summary

A strong majority of Latin American physicians do not support having a pharmacist determine which biologic to dispense acceptable, even at initiation of treatment.

Summary

Global regulatory CONVERGENCE is critical to ensuring that all patients have access to and use of these “miracle” medications.

Summary

As the regulators of the world craft biosimilar policy, it is critical that the PHYSICIAN AND PATIENT PERSPECTIVES inform that policy.

SCIENCE AND SAFETY, not economics, should drive these decisions.

Summary

ULTIMATELY …

It IS all about the patient!

And ALL of us are patients

SafeBiologics

ALLIANCE *for* SAFE BIOLOGIC MEDICINES

Thank You For Your Attention