Latin American Physician Perspectives on Biosimilars

Harry L. Gewanter, MD, FAAP, FACR

Presented at the BIO Latin America Conference

October 16, 2015   Rio De Janeiro, Brazil
About The Alliance for Safe Biologic Medicines (ASBM)

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

Philip Schneider, MS:  
Chair, International Medical Advisory Board  
Dean, University of Arizona College of Pharmacy

Michael Reilly, JD:  
Executive Director  
michael@safebiologics.org

- Steering Committee composed of patient and physician groups
- Advisory Board of physician, researcher, pharmacist, and patient groups
March 15, 2015: The week following FDA approval of first U.S. biosimilar, ASBM’s Dr. Gewanter and Dr. Schneider led a five-hour continuing education course for 125 pharmacists.

April 13, 2015: Dr. Gewanter and Dr. Schneider participated in 60th WHO Consultation on International Nonproprietary Names (INN).

May 2015: Conducted CE courses on biosimilars for 180 Pharmacists in NY and CA.

June 2015: Revealed Latin American survey results (399 physicians in 4 countries) at DIA 2015 meeting.

June 2015: Participated in WHO Frontpage Meeting to finalize the Biologic Qualifier (BQ) proposal.

July 2015: Conducted a CE Course for physicians, pharmacists, and nurses in a six-hospital Health System in Oregon employing 3000.

October 13: Participated in the 61st WHO Consultation on International Nonproprietary Names (INN) in Geneva, Switzerland.
ASBM Surveys of Physicians and Pharmacists

U.S. Physician Survey (September 2012): 376 physicians

E.U. Physician Survey (November 2013): 470 physicians

Canadian Physician Survey (November 2014): 427 physicians

U.S. Labeling Survey (February 2015): 400 physicians

Latin American Survey (May 2015): 399 physicians

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

To learn more about ASBM surveys, visit www.SafeBiologics.org
Latin American Survey: Overview

• 399 Prescribers were recruited from 4 countries in Latin America
  • Argentina (N=99)
  • Brazil (N=101)
  • Columbia (N=100)
  • Mexico (N=99)
• 15 minute web-based survey
• All surveys were administered in native languages
  • Argentina, Columbia, Mexico: Spanish
  • Brazil: Portuguese
“Please indicate your primary practice area or therapeutic area in which you practice?” (N=399)

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatology</td>
<td>22%</td>
</tr>
<tr>
<td>Oncology</td>
<td>18%</td>
</tr>
<tr>
<td>Neurology</td>
<td>18%</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>17%</td>
</tr>
<tr>
<td>Rheumatology</td>
<td>13%</td>
</tr>
<tr>
<td>Nephrology</td>
<td>7%</td>
</tr>
<tr>
<td>Hematology oncology</td>
<td>2%</td>
</tr>
<tr>
<td>Transplant</td>
<td>1%</td>
</tr>
<tr>
<td>Metabolism</td>
<td>1%</td>
</tr>
<tr>
<td>Other</td>
<td>2%</td>
</tr>
</tbody>
</table>
Primary Therapeutic Area: Brazil

“Please indicate your primary practice area or therapeutic area in which you practice?” (N=101)

- Endocrinology: 26%
- Dermatology: 21%
- Rheumatology: 19%
- Neurology: 13%
- Oncology: 11%
- Nephrology: 6%
- Hematology oncology: 3%
- Ophthalmology: 1%
- Metabolism: 1%
“Which of the following best describes the type of practice in which you work?” (N=399)

- Hospital: 32%
- University Teaching Hospital: 21%
- Private multi-specialty clinic: 18%
- Traditional, non-government, medical practice: 13%
- Private primary care clinic: 11%
- Government-run Multi-specialty clinic: 2%
- Government-run primary care clinic: 1%
- Other: 3%
“Which of the following best describes the type of practice in which you work?” (N=101)

- Private multi-specialty clinic: 36%
- University Teaching Hospital: 20%
- Hospital: 20%
- Private primary care clinic: 9%
- Traditional, non-government, medical practice: 8%
- Government-run Multi-specialty clinic: 4%
- Government-run primary care clinic: 2%
- Other: 2%
**Length of Time in Healthcare Sector**

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

- 1-5 years: 10%
- 6-10 years: 34%
- 11-20 years: 36%
- 21-30 years: 14%
- More than 30 years: 7%

Mean = 14.3 years
“How long have you been in medical practice?” (N=101)

- 1-5 years: 10%
- 6-10 years: 34%
- 11-20 years: 36%
- 21-30 years: 14%
- More than 30 years: 7%

Mean = 11.7 years
Do You Prescribe Biologics?

LATIN AMERICA
- Yes: 88%
- No: 12%

BRAZIL
- Yes: 84%
- No: 16%
Familiarity With Biosimilars

LATIN AMERICA

- Haven't heard of them or could not define them: 35%
- Familiar, have a basic understanding of them: 53%
- Very familiar, I have a complete understanding of them: 12%

BRAZIL

- Haven't heard of them or could not define them: 28%
- Familiar, have a basic understanding of them: 52%
- Very familiar, I have a complete understanding of them: 20%
Awareness of Different Classes of Biologics

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

LATIN AMERICA

- Yes: 49%
- No: 51%

BRAZIL

- Yes: 45%
- No: 55%
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)

LATIN AMERICA

- Yes: 54%
- No: 46%

BRAZIL

- Yes: 62%
- No: 38%
## Identifying Medicine in Patient Record

<table>
<thead>
<tr>
<th></th>
<th>LATIN AMERICA</th>
<th>BRAZIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-proprietary / generic name</td>
<td>57%</td>
<td>32%</td>
</tr>
<tr>
<td>It varies by medicines</td>
<td>24%</td>
<td>39%</td>
</tr>
<tr>
<td>Brand name</td>
<td>19%</td>
<td>28%</td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Percent of Physicians Using **INN Only** when Identifying Medicine in Patient Record

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

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>17%</td>
</tr>
<tr>
<td>EU</td>
<td>24%</td>
</tr>
<tr>
<td>CAN</td>
<td>17%</td>
</tr>
<tr>
<td>LAT.AM</td>
<td>57%</td>
</tr>
</tbody>
</table>
### Identifying Medicine When Reporting Adverse Events

<table>
<thead>
<tr>
<th>Product Name</th>
<th>LATIN AMERICA</th>
<th>41%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both equally</td>
<td>32%</td>
<td></td>
</tr>
<tr>
<td>Non-proprietary / generic name</td>
<td>28%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Name</th>
<th>BRAZIL</th>
<th>47%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both equally</td>
<td>37%</td>
<td></td>
</tr>
<tr>
<td>Non-proprietary / generic name</td>
<td>17%</td>
<td></td>
</tr>
</tbody>
</table>
Percent of Physicians Using **INN Only** when Reporting Adverse Events.

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

**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”
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)

(Structural identicality is not possible with biologics.)
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?”

<table>
<thead>
<tr>
<th>Region</th>
<th>YES</th>
<th>NO</th>
<th>NO OPINION</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>76%</td>
<td>14%</td>
<td>10%</td>
</tr>
<tr>
<td>EU</td>
<td>53%</td>
<td>32%</td>
<td>15%</td>
</tr>
<tr>
<td>CAN</td>
<td>64%</td>
<td>30%</td>
<td>6%</td>
</tr>
<tr>
<td>LAT.AM</td>
<td>54%</td>
<td>41%</td>
<td>5%</td>
</tr>
</tbody>
</table>
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)

LATIN AMERICA

- Yes: 74%
- No: 26%

BRAZIL

- Yes: 79%
- No: 21%
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...)
“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)
Automatic Pharmacy Substitution around the World

• Australia poised to allow pharmacy-level substitution of a biosimilar without physician involvement, over opposition of the Australian Rheumatology Association.

• Practice is opposed by European Medicines Agency and Health Canada.

• Banned in many countries including the UK, Germany, Ireland, Spain, Sweden, Norway, and Finland. While France statutorily permits it in limited cases (bio-naïve patients), this policy has never been implemented.

• U.S. policy is evolving, but 18 of 20 states that allow substitution, passed laws requiring pharmacists communicate to physicians in the event of a substitution.

• Only Venezuela currently permits the practice.
Pharmacy Substitution: Automatic 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)
Acceptability of Pharmacist Determination 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)

<table>
<thead>
<tr>
<th>LATIN AMERICA</th>
<th>BRAZIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not acceptable – only the prescriber should make this determination</td>
<td>85%</td>
</tr>
<tr>
<td>Acceptable, provided such exchange has been agreed with clinicians for these…</td>
<td>13%</td>
</tr>
<tr>
<td>Totally acceptable</td>
<td>2%</td>
</tr>
</tbody>
</table>
Importance of Substitution Notification

- **Very important or critical**
  - **LATIN AMERICA**: 87%
  - **BRAZIL**: 93%

- **Somewhat important**
  - **LATIN AMERICA**: 10%
  - **BRAZIL**: 5%

- **Slightly or not important**
  - **LATIN AMERICA**: 3%
  - **BRAZIL**: 2%
Percentage of Physicians saying NOTIFICATION in the case of a biosimilar substitution is “Very Important or Critical”

- US: 80%
- EU: 77%
- CAN: 85%
- LAT.AM: 87%
Importance of Dispense as Written (DAW) Authority

<table>
<thead>
<tr>
<th>Category</th>
<th>LATIN AMERICA</th>
<th>BRAZIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very important or Critical</td>
<td>85%</td>
<td>85%</td>
</tr>
<tr>
<td>Somewhat important</td>
<td>12%</td>
<td>11%</td>
</tr>
<tr>
<td>Slightly or not important</td>
<td>4%</td>
<td>4%</td>
</tr>
</tbody>
</table>
Percentage of Physicians saying “Dispense as Written” (DAW) Authority is “Very Important or Critical”

- US: 82%
- EU: 74%
- CAN: 80%
- LAT.AM: 85%
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)

<table>
<thead>
<tr>
<th>Option</th>
<th>LATIN AMERICA</th>
<th>BRAZIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not acceptable – only the prescriber should make this determination</td>
<td>85%</td>
<td>75%</td>
</tr>
<tr>
<td>Acceptable, provided such exchange has been agreed with clinicians for these…</td>
<td>13%</td>
<td>25%</td>
</tr>
<tr>
<td>Totally acceptable</td>
<td>2%</td>
<td>0%</td>
</tr>
</tbody>
</table>
Percentage of Physicians who consider a pharmacist determination of which biologic their patient receives at initiation of treatment “unacceptable”:

- EU: 62%
- CAN: 71%
- LAT.AM: 85%
Summary

• Where is still a need for education about biosimilars in Latin America, ASBM’s surveys demonstrate that this is a global need.

• Physician practices (use of INN in patient record and adverse event reporting, inconsistent use of batch number) in Latin America, as elsewhere, show the value of distinguishable naming.

• Physicians in Latin America overwhelmingly support (94%) the World Health Organization’s BQ Proposal (Brazil: 97%) to help ensure their patients receive the correct medicine.

• A strong majority of Latin American physicians do not find a pharmacist determination of which biologic to dispense acceptable, even at initiation of treatment.
Summary

• Patient safety must remain paramount in any/all identification scheme. That means patients, prescribers, pharmacists, manufacturers and regulators must know which specific medication is prescribed and dispensed.

• We are in a critical time to have global harmonization of identifying biosimilars and future biologic medicines. The window of opportunity is closing.

• While there is much discussion regarding if/how to identify each product, we need to create a global solution soon to prevent a “Tower of Babel” environment for these miracle medications.
Thank You For Your Attention