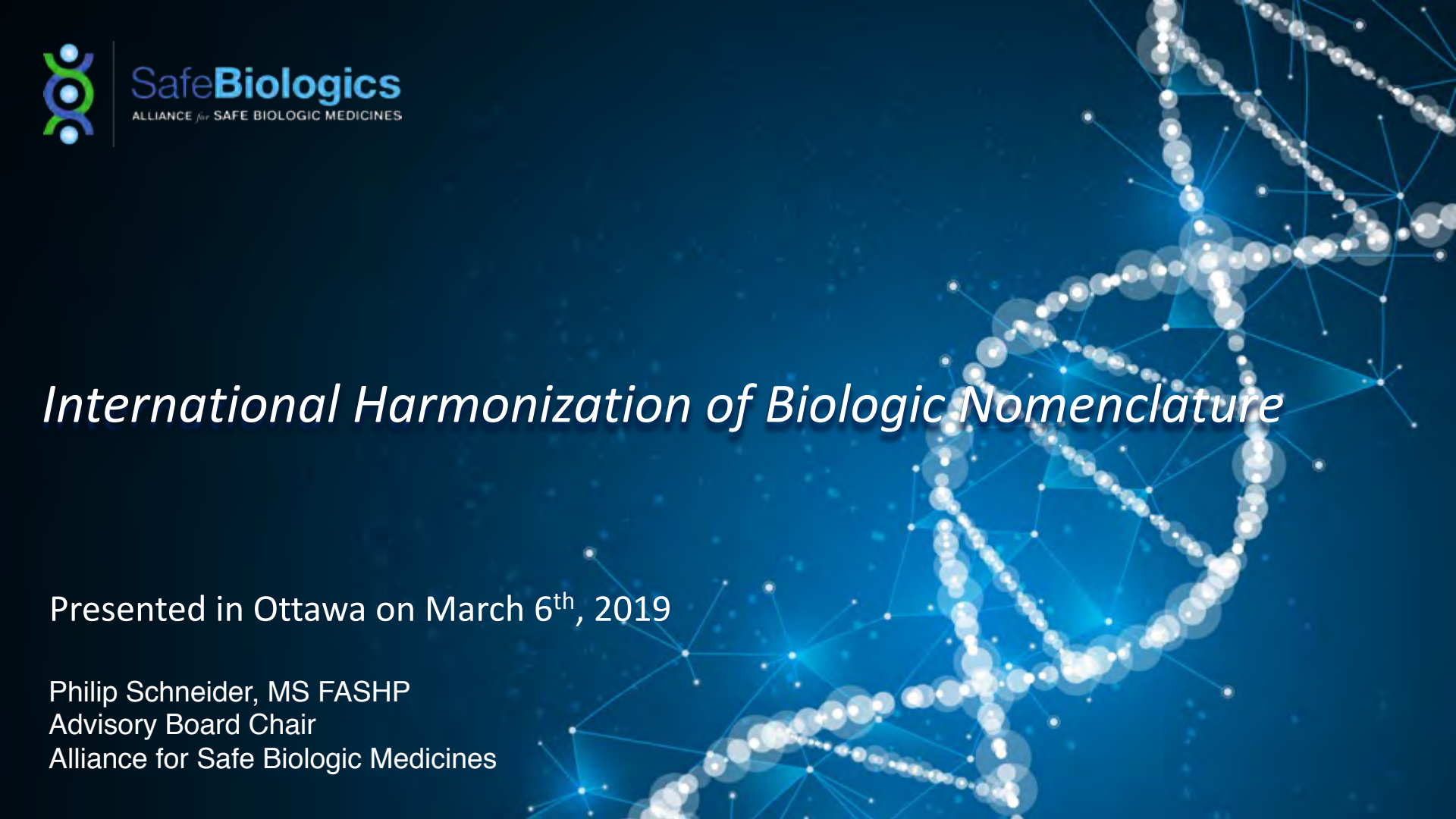


International Harmonization of Biologic Nomenclature

Presented in Ottawa on March 6th, 2019

Philip Schneider, MS FASHP
Advisory Board Chair
Alliance for Safe Biologic Medicines

I. Recap: Takeaways from Previous Meetings

ASBM Forum on International Harmonization of Biologic Nomenclature- April 11, 2018

Key Observations

- Strong agreement that BIOSIMILARS are critical to increasing patient access to biologic therapies and to controlling health costs.
- Also strong agreement that UNIQUE and HARMONIZED NOMENCLATURE is critical to building physician confidence in the safe use of biosimilars by promoting better pharmacovigilance globally.
- Increasing physician confidence in biosimilars, and their safe use, will increase biosimilar uptake.

The Need for Global Leadership on Naming

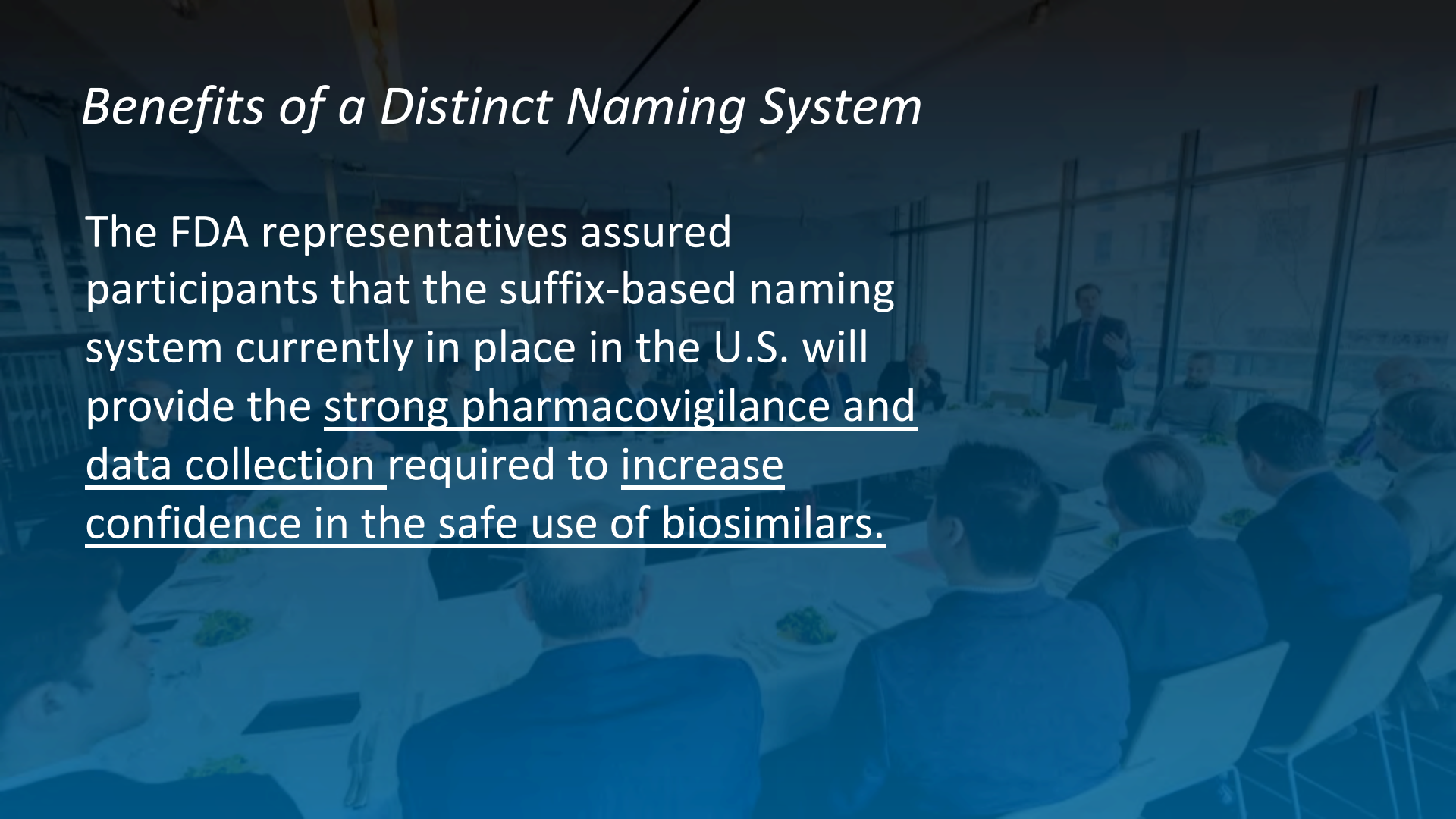
- Clear product identification was thought especially important for countries with less-developed pharmacovigilance systems.

- While regulators are willing to collaborate on the implementation of a distinct naming system, the WHO's leadership is essential to avoid the proliferation of multiple different systems globally.

WHO Leadership is Essential

- In addition, the meeting participants were extremely disappointed that the WHO was not present for this discussion.

- They felt WHO's leadership is essential, not only in the meeting, but for the advancement of a harmonized global nomenclature system broadly.



Benefits of a Distinct Naming System

The FDA representatives assured participants that the suffix-based naming system currently in place in the U.S. will provide the strong pharmacovigilance and data collection required to increase confidence in the safe use of biosimilars.

Benefits of International Harmonization

Anthony Ridgway of Health Canada reiterated the FDA's comments, adding that pharmacovigilance is a global concern, not merely a matter of ensuring safety and efficacy for one's citizens within one's own borders.

If a Canadian travels outside of North America, they should have assurances they can get the correct medicine, and that robust and appropriate pharmacovigilance is present.

Benefits of International Harmonization

Mr. Ridgway also observed that a further benefit of a INTERNATIONAL NAMING SYSTEM vs. country-specific naming systems is the tremendous value of tracking the use of biosimilars in large populations across many countries.

Letters of Support

At the April 11th meeting, Anthony Ridgway of Health Canada proposed drafting letters of support from NRAs, signed by NRAs worldwide, to ask the WHO to provide leadership on establishing a global nomenclature standard.

Second Forum on International Harmonization of Biologic Nomenclature- July 12, 2018

Second Forum on International Harmonization of Biologic Nomenclature- July 12, 2018

APhA's Thomas Menighan:

"[pharmacists} keep it by NDC (National Drug Code), we have a way already. If a pharmacovigilance system needs to know which product it is, we can tell you.

"to us it's a systems issue- adding a suffix can be a challenge, not insurmountable"

"I like the idea of a global solution, absolutely"

Second Forum on International Harmonization of Biologic Nomenclature- July 12, 2018

The FDA's Deputy Director for Medication Error at CDER, Kellie Taylor, PhD, replied:

"Just to make it clear, a pharmacovigilance system can't work by going back for every report, following up with pharmacists to identify which product was taken when. It's inoperable in passive pharmacovigilance, and it's absolutely disastrous in active pharmacovigilance."

"we don't have those NDC codes in the billing systems in active pharmacovigilance…the most expert analysis within FDA [has determined] *product specific identification is dependent upon the nonproprietary name having a suffix"*

Second Forum on International Harmonization of Biologic Nomenclature- July 12, 2018

Representatives from FDA and Health Canada ***again agreed*** with the physicians, pharmacists, and patient advocates present that:

- The need to act is urgent
- Distinct nonproprietary naming is critical to strong pharmacovigilance and increasing confidence.
- The WHO is the body best situated to operationalize a harmonized naming standard.

What We Learned

- We know from survey data and their own position statements that the global physician and patient communities strongly support distinct naming and international harmonization.

- We know from our meetings in April and July that U.S. and Canadian regulators agree.

What We Learned

- We know that in the absence of WHO action, these regulators were working on creating a harmonized regional standard for North America.

WHO Leadership Remains Critical

- We know that supporters of the BQ have changed course repeatedly, as a result of WHO delay.
- We know that still others have failed to act, while waiting for WHO action.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Australia doubles back on biosimilar naming conventions to follow WHO move

By Zachary Brennan

23-Jan-2015 - Last updated on 23-Jan-2015 at 09:09 GMT

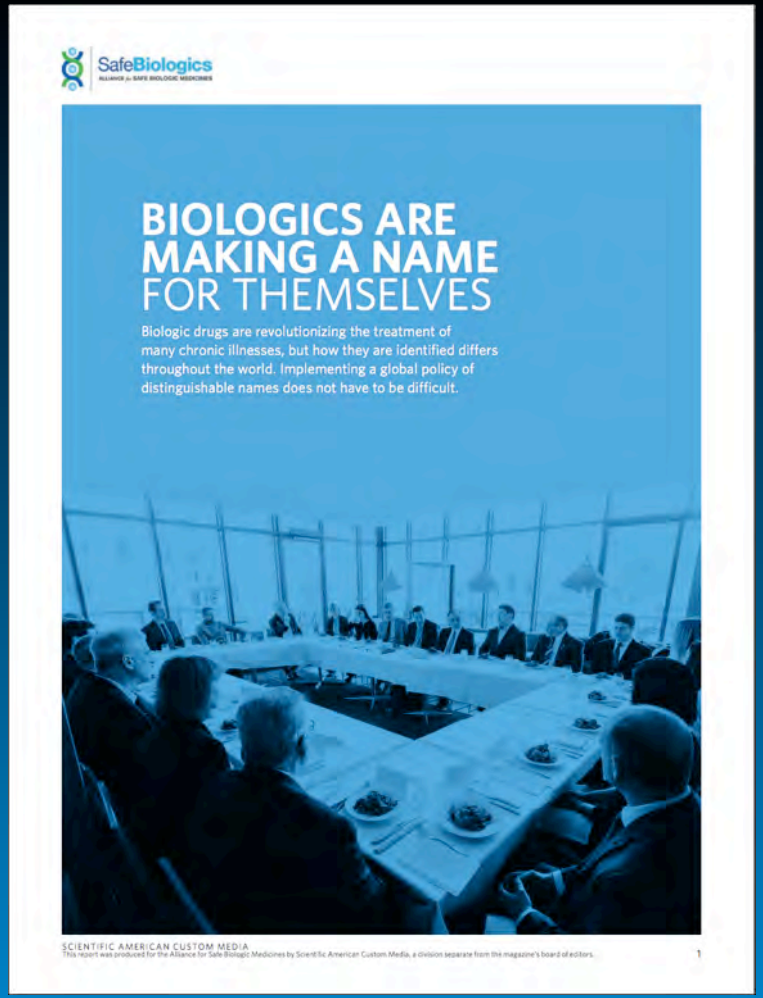
Australia is following the WHO's lead

Australia's TGA (Therapeutic Goods Administration) is shifting its stance on the way it plans to name biosimilars to keep the country more in line with the WHO's (World Health Organization) proposed policies

II. Developments Since the July Meeting

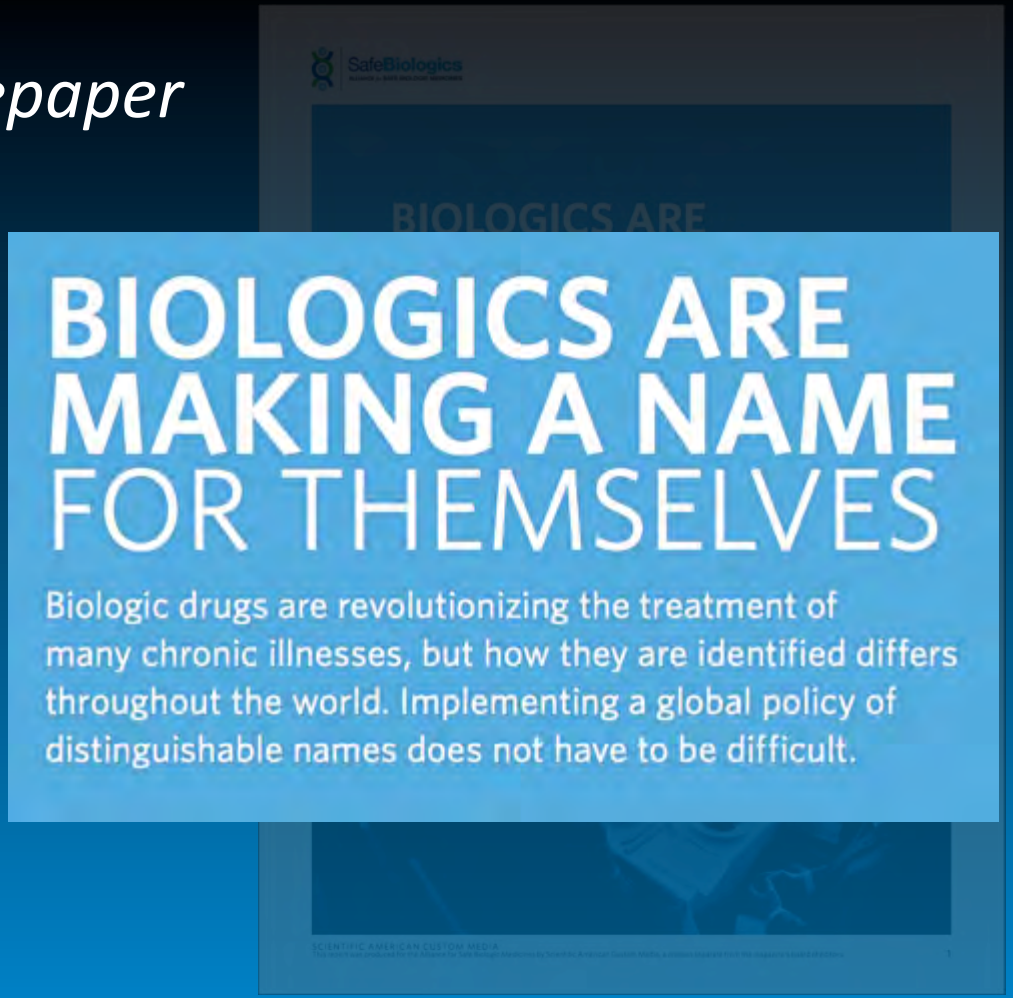
Scientific American Whitepaper

- A Whitepaper capturing the April Meeting was released in October.
- It was prepared by the *Scientific American* and *Nature: Biotechnology* reporters who moderated the Forum.



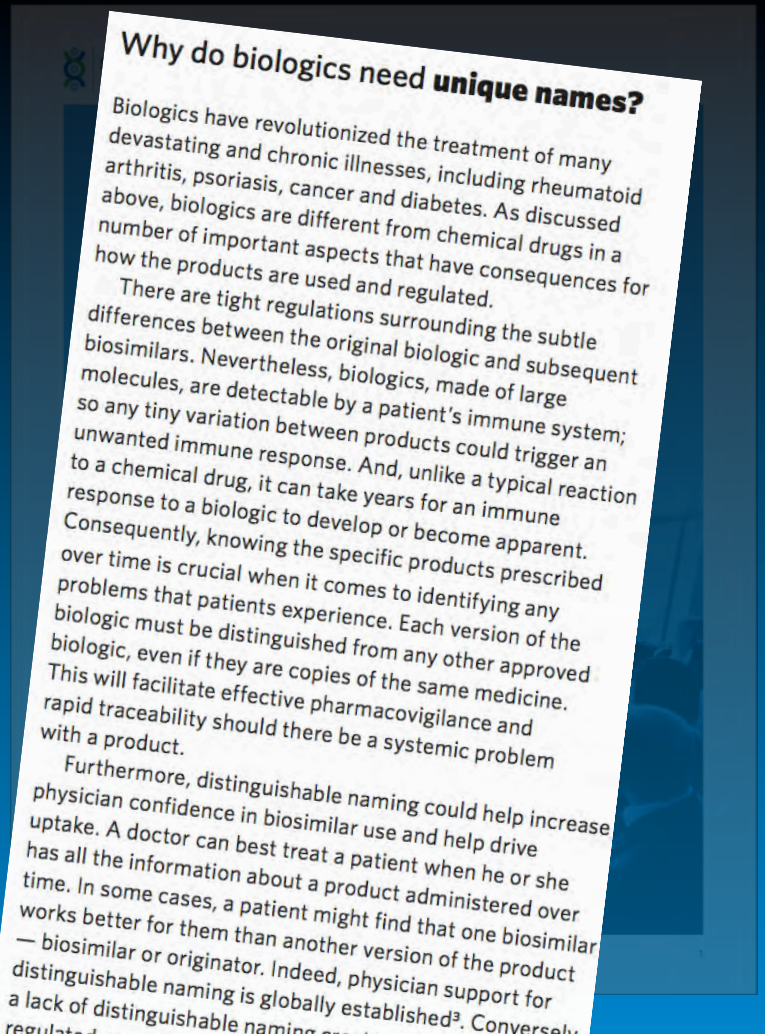
Scientific American Whitepaper

- As the subhead states, “implementing a global policy of distinguishable names for biologics doesn’t have to be as difficult as it has thus far proven to be.”



Scientific American Whitepaper

- The paper examines need for and benefits of distinct names:
  - clear differentiation between originator vs. biosimilar A vs. biosimilar B, C, D…
  - Improved traceability of problems to enable prompt resolving.
  - Accurate tracking of effects over time
  - Increased physician confidence/physician support
  - Increased manufacturer accountability



Why do biologics need **unique names?**

Biologics have revolutionized the treatment of many devastating and chronic illnesses, including rheumatoid arthritis, psoriasis, cancer and diabetes. As discussed above, biologics are different from chemical drugs in a number of important aspects that have consequences for how the products are used and regulated.

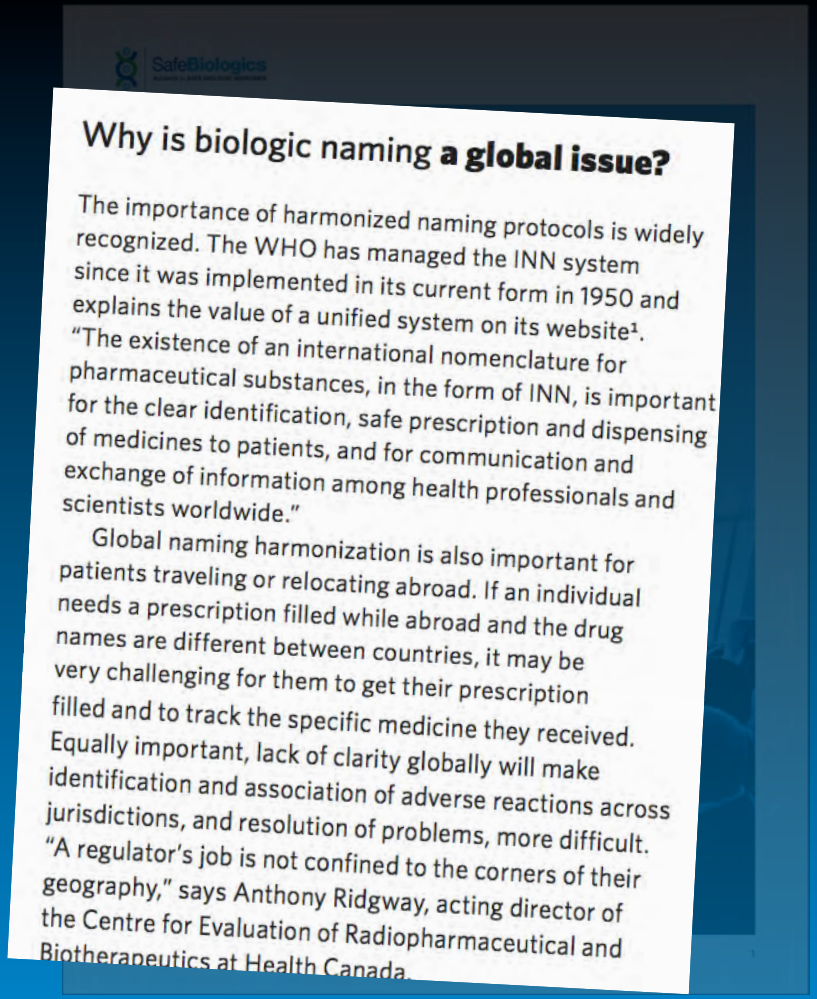
There are tight regulations surrounding the subtle differences between the original biologic and subsequent biosimilars. Nevertheless, biologics, made of large molecules, are detectable by a patient's immune system; so any tiny variation between products could trigger an unwanted immune response. And, unlike a typical reaction to a chemical drug, it can take years for an immune response to a biologic to develop or become apparent. Consequently, knowing the specific products prescribed over time is crucial when it comes to identifying any problems that patients experience. Each version of the biologic must be distinguished from any other approved biologic, even if they are copies of the same medicine. This will facilitate effective pharmacovigilance and rapid traceability should there be a systemic problem with a product.

Furthermore, distinguishable naming could help increase physician confidence in biosimilar use and help drive uptake. A doctor can best treat a patient when he or she has all the information about a product administered over time. In some cases, a patient might find that one biosimilar works better for them than another version of the product — biosimilar or originator. Indeed, physician support for distinguishable naming is globally established[3]. Conversely, a lack of distinguishable naming

Scientific American Whitepaper

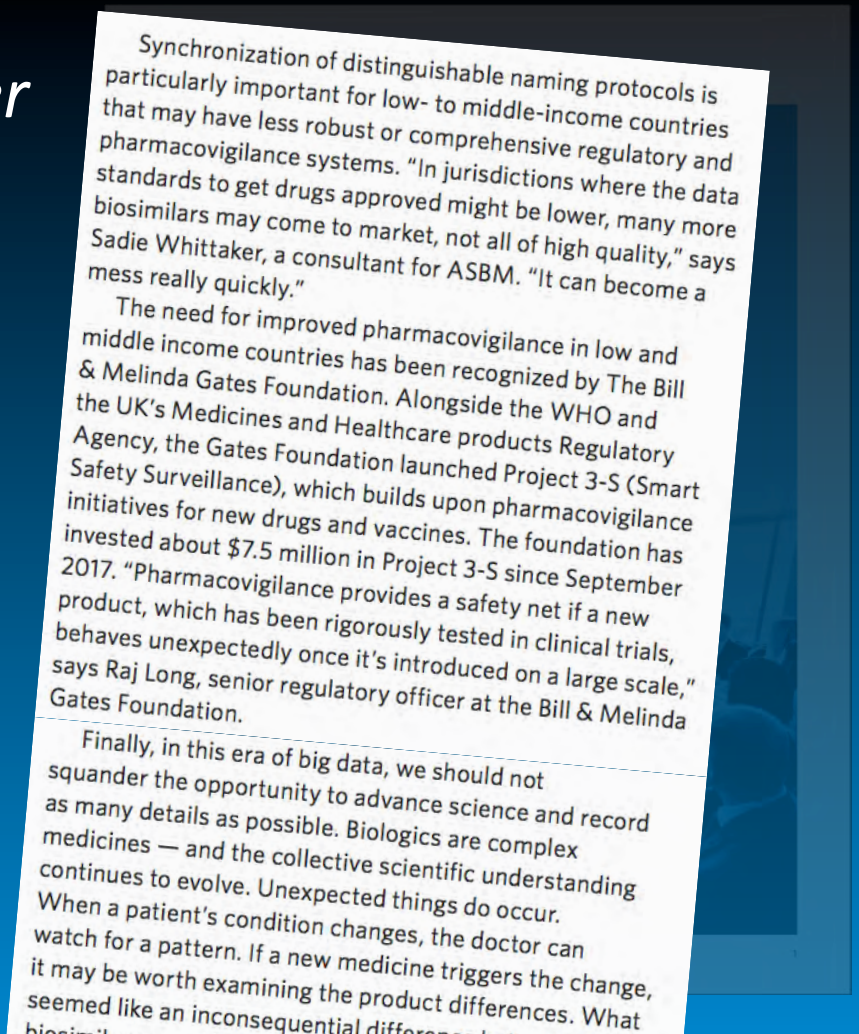
- It also lays out the value of a unified naming system, citing the WHO's own rationale for the INN program:
- "The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide."

-WHO INN Programme Website



Scientific American Whitepaper

- Other benefits of harmonization include:
  - **Improved pharmacovigilance in lower- and middle-income countries** who lack robust pharmacovigilance systems of their own.
  - **The ability to aggregate data** showing safe use, or to detect any safety/efficacy issues- at large scales over international populations.



Synchronization of distinguishable naming protocols is particularly important for low- to middle-income countries that may have less robust or comprehensive regulatory and pharmacovigilance systems. "In jurisdictions where the data standards to get drugs approved might be lower, many more biosimilars may come to market, not all of high quality," says Sadie Whittaker, a consultant for ASBM. "It can become a mess really quickly."

The need for improved pharmacovigilance in low and middle income countries has been recognized by The Bill & Melinda Gates Foundation. Alongside the WHO and the UK's Medicines and Healthcare products Regulatory Agency, the Gates Foundation launched Project 3-S (Smart Safety Surveillance), which builds upon pharmacovigilance initiatives for new drugs and vaccines. The foundation has invested about $7.5 million in Project 3-S since September 2017. "Pharmacovigilance provides a safety net if a new product, which has been rigorously tested in clinical trials, behaves unexpectedly once it's introduced on a large scale," says Raj Long, senior regulatory officer at the Bill & Melinda Gates Foundation.

Finally, in this era of big data, we should not squander the opportunity to advance science and record as many details as possible. Biologics are complex medicines — and the collective scientific understanding continues to evolve. Unexpected things do occur. When a patient's condition changes, the doctor can watch for a pattern. If a new medicine triggers the change, it may be worth examining the product differences. What seemed like an inconsequential

Scientific American Whitepaper

- This quote from the whitepaper captured the consensus among the regulators, physicians, and patients, assembled in the room.

World Health Organization 67th INN Consultation
October 23, 2018

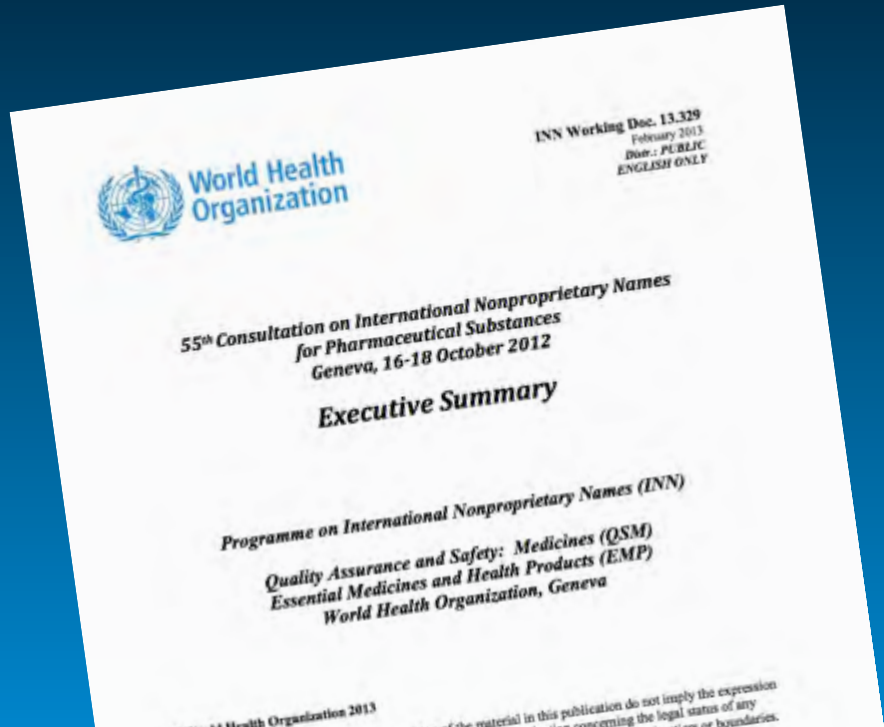
- While we are not allowed to reveal the discussion that took place at the meeting, we do think it is important to address key objections to the BQ which ASBM has consistently encountered, which have contributed to the delay of its implementation.

International Harmonization of Biologic Nomenclature: An Urgent Need… back in 2012.

That year, the WHO's Executive Summary of the INN Consultation said:

"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



World Health Organization

INN Working Doc. 13.329
February 2013
Distr.: 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

Health Organization 2013

material in this publication do not imply the expression
concerning the legal status of any
or boundaries.

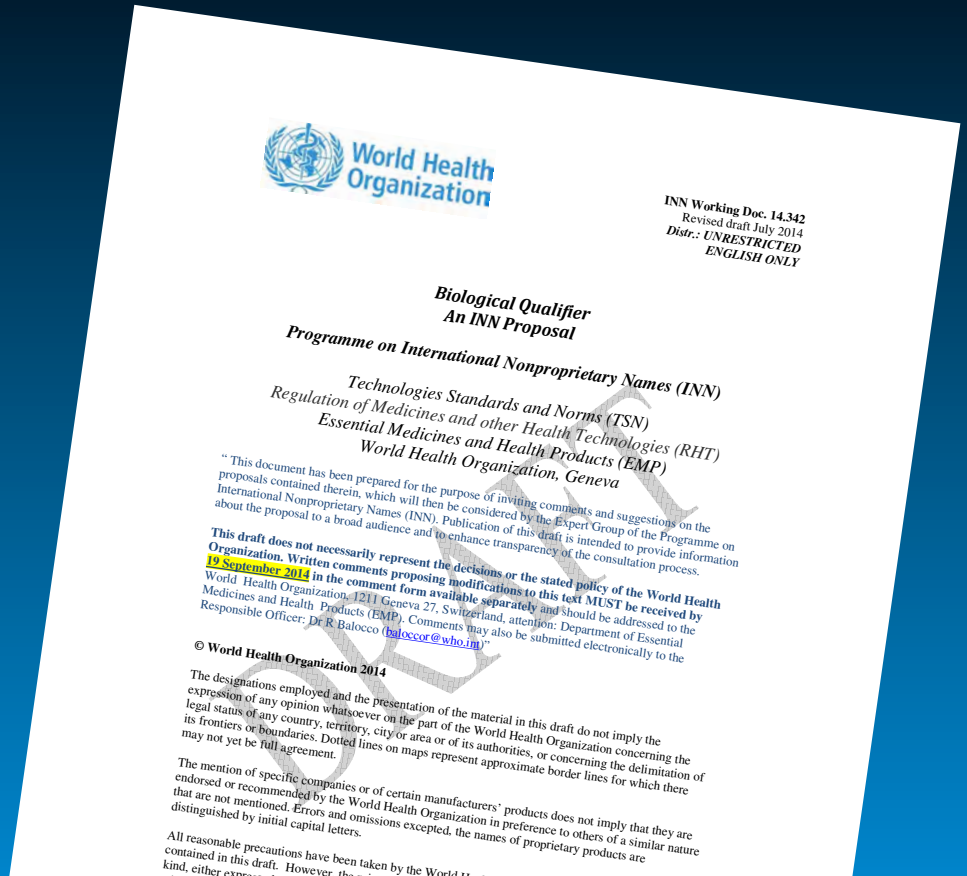
Six Years Later, the Need is Even More Urgent.

The number of approved biosimilars has grown tremendously since 2012:

- 24 in Europe (multiple license holders)
- 20 in Australia
- 16 in U.S.
- 10 in Canada
- 23 in Latin America

The INN Expert Group Made its Recommendation in 2014…

- Requested by regulators "to avoid proliferation of separate and distinct national qualifier systems".
- After years of research on the problem; and after consultation with regulators and other stakeholders; **the INN Expert Group Recommendation remains unimplemented.**



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)
Regulation of Medicines and other Health Technologies (RHT)
Essential Medicines and Health Products (EMP)
World Health Organization, Geneva

" This document has been prepared for the purpose of inviting comments and suggestions on the proposals contained therein, which will then be considered by the Expert Group of the Programme on International Nonproprietary Names (INN). Publication of this draft is intended to provide information about the proposal to a broad audience and to enhance transparency of the consultation process.

This draft does not necessarily represent the decisions or the stated policy of the World Health Organization. Written comments proposing modifications to this text MUST be received by 19 September 2014 in the comment form available separately and should be addressed to the World Health Organization, 1211 Geneva 27, Switzerland, attention: Department of Essential Medicines and Health Products (EMP). Comments may also be submitted electronically to the Responsible Officer: Dr R Balocco (baloccor@who.int)"

After the expert committee recommendation, reasons for inaction and disregarding the experts were suggested:

Redundancy?

Concerns with suffix design?

Cost of implementation?

Implementation not feasible?

Impedes access?

Impedes uptake?

Lack of physician support?

Lack of support from regulators?

WHO process issues?

These objections lack a basis in fact and were addressed by the expert committee

Redundancy? ***NONE***

- "The use of the BQ offers an alternate and acceptable means (a) which uniquely identifies the drug substance even if used alone and/or (b) of crosschecking other information supplied in a prescription/dispensing or pharmacovigilance setting**, in the absence of other sophisticated tracking systems**."

- The BQ can help ensure safety and promote acceptance of biologics and biosimilars **in countries without pre-existing robust pharmacovigilance systems.**

> Some regulatory authorities have made the decision that the use of trade name and INN are adequate for prescription and dispensing and that trade name, INN, MAH name and batch number are adequate for pharmacovigilance in conjunction with other tracking systems such as 2D barcoding. The use of the BQ offers an alternate and acceptable means (a) which uniquely identifies the drug substance even if used alone and/or (b) of crosschecking other information supplied in a prescription/dispensing or pharmacovigilance setting, in the absence of other sophisticated tracking systems.

Biological Qualifier
Frequently Asked Questions
INN Working Doc. 15.382
Final October 2015

Concerns with Suffix Design? ***DEBUNKED***

"[the BQ] has been **developed in consultation with national regulatory authorities and stakeholders over several years** and, while the form is not the most memorable, **it is the most robust and versatile. "**

"The use of four consonants means there are 160,000 (204) possible codes, providing sufficient capacity to provide codes for all biological medicines for the foreseeable future."

What form will the BQ take?

The code will consist of four random consonants and an optional two digits as a checksum. The WHO INN will issue the BQ letters with the corresponding checksum, but it is at the discretion of the individual regulatory authority whether the checksum is used as part of the BQ. The form of the BQ may take:

- four letters;
- four letters followed by the checksum; or
- two letters, two digits and two letters, thus mimicking car registration plates to be more memorable.

The following fictitious example is worked out in the three possible ways:

TRADENAME	INN	BQ
GROKINO	anonutropin alfa	bxsh
GROKINO	anonutropin alfa	bxsh08
GROKINO	anonutropin alfa	bx08sh

This form has been developed in consultation with national regulatory authorities and stakeholders over several years and, while the form is not the most memorable, it is the most robust and versatile. The use of four consonants means there are 160 000 (20^4) possible codes, providing sufficient capacity to provide codes for all biological medicines for the foreseeable future.

Biological Qualifier Frequently Asked Questions
INN Working Doc. 15.382 Final October 2015

Impedes Access? ***NO***

Since 2014, the BQ was always "intended to apply to all biological medicines…where possible retrospectively. The impact of the BQ on access to biosimilars (and price savings…) is therefore likely to be **"minimal".**

Will the BQ affect access to similar biotherapeutic products?
Because the initial requests made to establish the BQ were by NRA's intending to use it for similar biotherapeutic products (or biosimilars), the perception was built up that the BQ would distinguish biosimilars from other biological medicines. This is not the case. From the first published version of the BQ Proposal in Jul 2014, the BQ Scheme has always been intended to apply to all biological medicines with no distinction, where possible retrospectively. The impact of the BQ on access to biosimilars (and price savings through their use) is therefore likely to be minimal.

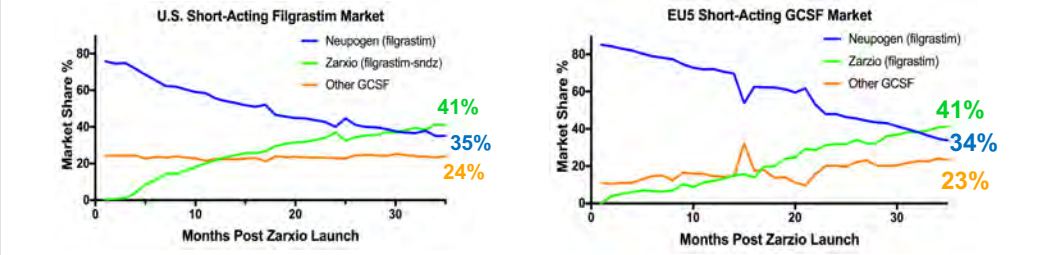
Biological Qualifier Frequently Asked Questions
INN Working Doc. 15.382 Final October 2015

Impedes Uptake? ***NO***

- Biosimilar filgrastim-sndz has achieved **the same market share (41%) 36 months post-launch**, compared to the EU biosimilar without a distinct name.

U.S. BIOSIMILAR COMPETITION IS JUST BEGINNING

- **Four products currently have competition:**
  - **Filgrastim biosimilar quickly gained majority share in U.S.**
  - **Two infliximab biosimilars have struggled early after launch**
- **The current competitive landscape enables successful launch of biosimilars**



Source: Market share calculated from units sold. Data obtained by Amgen from IQVIA, National Sales Perspectives/MIDAS, <2010-2018>.

1

AMGEN

Amgen presentation at FDA Part 15 Hearing on Biosimilars, September 4, 2018

Cost of Implementation? ***ADDRESSED***

- Obstruction to implementation is penny-wise and pound foolish.
- The cost of inaction is significant financially and in terms of patient safety.
- Prompt implementation is most cost effective; efforts to delay are creating expense.

Feasibility of Implementation? ***DEMONSTRATED***

- "Technically, a complete BQ system and database would take approximately **two months to establish** although **random BQ codes could be generated within a few days."** – *62nd INN Exec. Summary*
- ASBM developed a web-based method of pre-defining compliance for FDA or BQ suffixes.
- Web solution shared with WHO and FDA as an example of one potential BQ implementation.
- ASBM tool has been used successfully to generate FDA- and BQ- compliant suffixes.

Lack of Physician Support? ***ROBUST SUPPORT***

68% of Canadian physicians support Health Canada issuing distinct names. (2017)

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)

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

Lack of Support From Regulators? ***ROBUST SUPPORT***

- The INN Group recommendation was made after consultations with, and at the request of regulators.
- "Overall, approximately two-thirds of commentators were in partial or full agreement with the proposal"– *61st INN Exec. Summary*
- We've also seen regulators who had developed their own distinct naming systems **abandon their system when the BQ was proposed-** only to alter course again due to WHO inaction. This indicates support for harmonization.
- **ASBM has observed this support from regulators worldwide-** in various meetings and discussions.

WHO Process Issues? ***DELAY MECHANISM***

Phased implementation programs embraced by WHO have not come to pass, <u>suggesting their purpose was delay, not implementation:</u>

- 2016: provisional implementation of the BQ scheme, 3-year TOR/ prospective impact study.

– "This also would have the benefit of not spending a further six months conducting an interim impact study during which time national schemes may get implemented." *62nd INN Exec. Summary* - Status of this?

- 2017: BQ Pilot Program – Memoranda of Understanding with Regulators- Status of this? Withdrawn?

- 2018: BQ on hold for "Data Gathering"? – Status of this?

GaBI Journal Whitepaper: Distinct Naming in MENA Region

Emphasized Themes Explored in Our Meetings:

"Differential nomenclature helps enable national health authorities to collect and compare real-world data that measure the clinical effects of biologicals including biosimilars. Insights from such data, over time, will enable us to better measure a drug's effectiveness in delivering successful health outcomes for patients.

The World Health Organization (WHO) must finalize their Biologic Qualifier guidance. It is this organization that has the responsibility to ensure that developing nations of the world have access to affordable, quality medicines. Safety is mission critical and the Biological Qualifier is a potent tool on behalf of global public health."

GaBi Journal
Generics and Biosimilars Initiative

GENERICS AND BIOSIMILARS INITIATIVE JOURNAL
Building trust in cost-effective treatments

Medicines regulation in the MENA region and the importance of the World Health Organization's INN proposal of Biological Qualifier

Abstract:
The World Health Organization should finalize its Biological Qualifier guidance. Distinguishable naming will allow quick and accurate tracing of the manufacturer, should adverse events occur and improve patient safety by reducing confusion and mishaps. This will ensure that developing nations, including those in the MENA region, have access to high quality, affordable medicines.

Submitted: *1 June 2018;* ***Revised:*** *29 October 2018;* ***Accepted:*** *30 October 2018;* ***Published online first:*** *2 November 2018*

Introduction

When it comes to monitoring the quality, safety and efficacy of biological medicines, distinguishable naming is imperative because biosimilar therapies are similar to, but not exactly the same as, existing biological medicines. Since no biosimilar is perfectly identical to its innovator parent, every biological – whether reference product or biosimilar – must be fully distinguishable from other biologicals to permit quick and accurate tracing of its manufacturer, should an adverse event be observed. Precise naming of all biologicals will improve patient safety by reducing confusion and mishaps in prescribing and holding manufacturers accountable. Also, differential nomenclature helps enable national health authorities to collect and compare real-world data that measure the clinical effects of biologicals including biosimilars. Insights from such data, over time, will enable us to better measure a drug's effectiveness in delivering successful health outcomes for patients.

The World Health Organization (WHO) must finalize their Biologic Qualifier guidance. It is this organization that has the responsibility to ensure that developing nations of the world have access to affordable, quality medicines. Safety is mission critical and the Biological Qualifier is a potent tool on behalf of global public health.

The primacy of medicines quality

Over the last few years we have travelled to many countries around the
Australia, Europe, Latin America and the Mi
regulators

Following publication we received a response from the United Arab Emirates offering their support for the WHO BQ and for our international harmonization efforts.

"The UAE MOHAP are supporting the WHO moving forward on a distinguishable naming policy ('BQ- Biologic Qualifier')."

- Dr. Ola Al Ahdab
UAE Ministry of Health and Prevention

UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

February 14th: Health Canada Announces Its Naming Policy

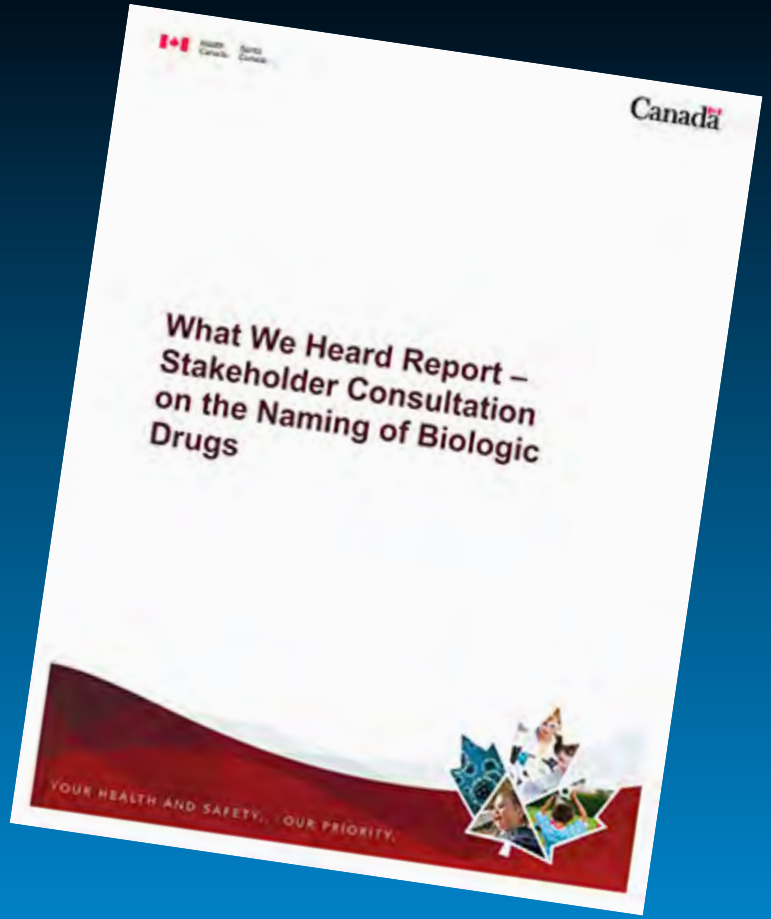
- No distinct nonproprietary names or suffix
- No harmonization with FDA/"North American approach"
- Shared INNs covering multiple products
- Reliance on Drug Information Number (DIN) used by pharmacists
- **Identifies lack of WHO implementation of an international standard** as a factor:
  - "There is no internationally adopted naming scheme to distinguish among biologics that, based on active ingredient, will be assigned the same International Nonproprietary Name (INN) by the World Health Organization"

We will assess the Health Canada naming decision in the following ways:

1. Concerns with Process

2. Concerns with Policy

Health Canada published a report on its consultation process that provides some insight into this surprising reversal.

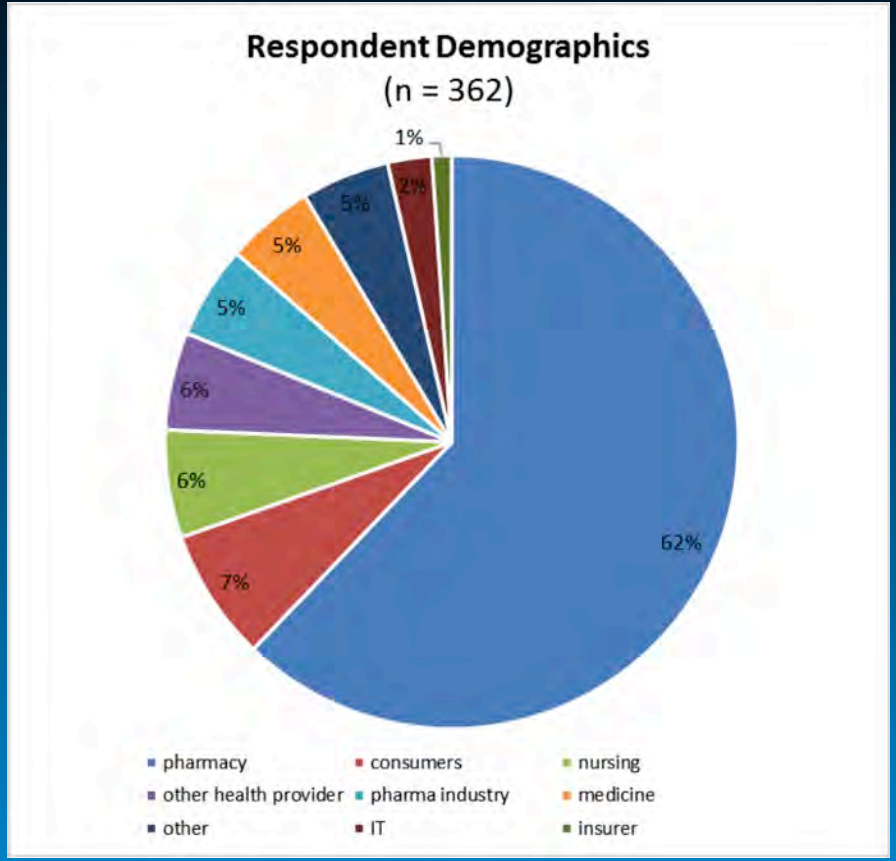


A Disproportionate Responses from Pharmacists

- **62% of responses were from pharmacists or pharmacy organizations (n=224)**

Compared to:

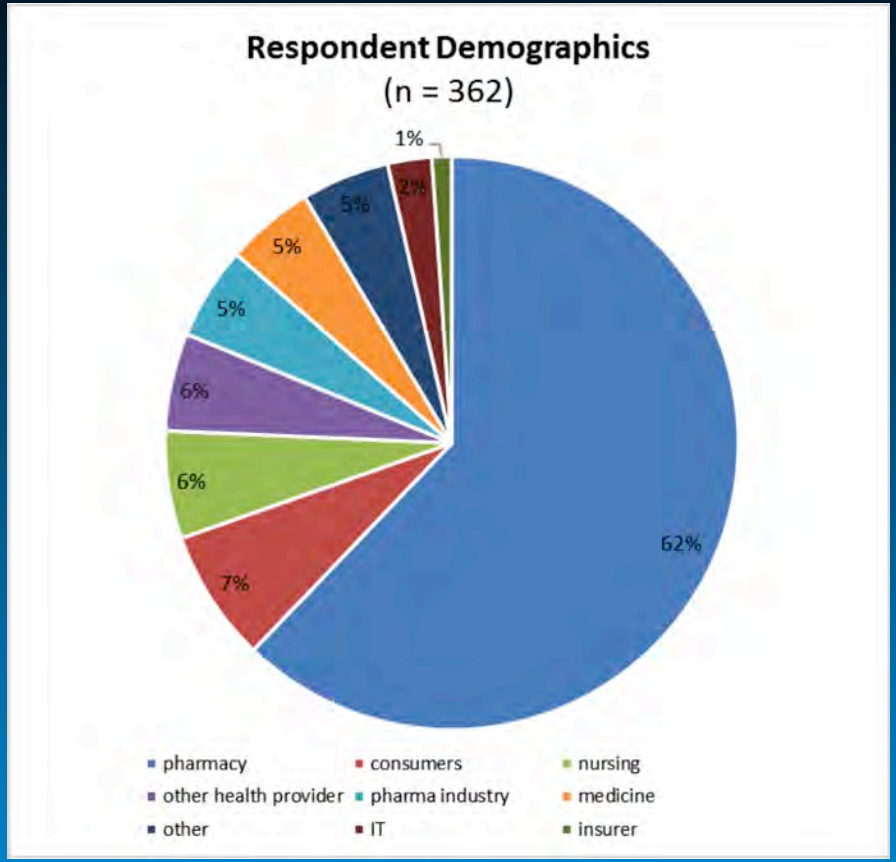
- 5% from the field of medicine (n=18)
- 6% from nursing (n=22)
- 7% from consumers (n=25)



Concerns with Process

- Patient and Physicians are the “customers” of biologics and biosimilars.

  This process did not appropriately reflect the importance of their views.



Concerns with Process

Table 1: Respondent preferences

Option	Preferred	Acceptable	Total Preferred + Acceptable	Not Acceptable
1. Status quo	9%	21%	30%	70%
2. Brand + non-proprietary names	48%	27%	75%	25%
3. Suffix	34%	17%	51%	49%

- Differences in responses among the different disciplines (medicine, nursing, pharmacist, etc.) could have affected the decision had one discipline not been disproportionately represented.

Concerns with Process

- In Canada, where only infusion biosimilars are approved, these are dispensed at infusion clinics rather than through a pharmacy.
- Pharmacist perspectives on naming are not more relevant than of those who are present during the prescribing, dispensing and tracking of adverse events (nurses, physicians, patients).

Concerns with Process

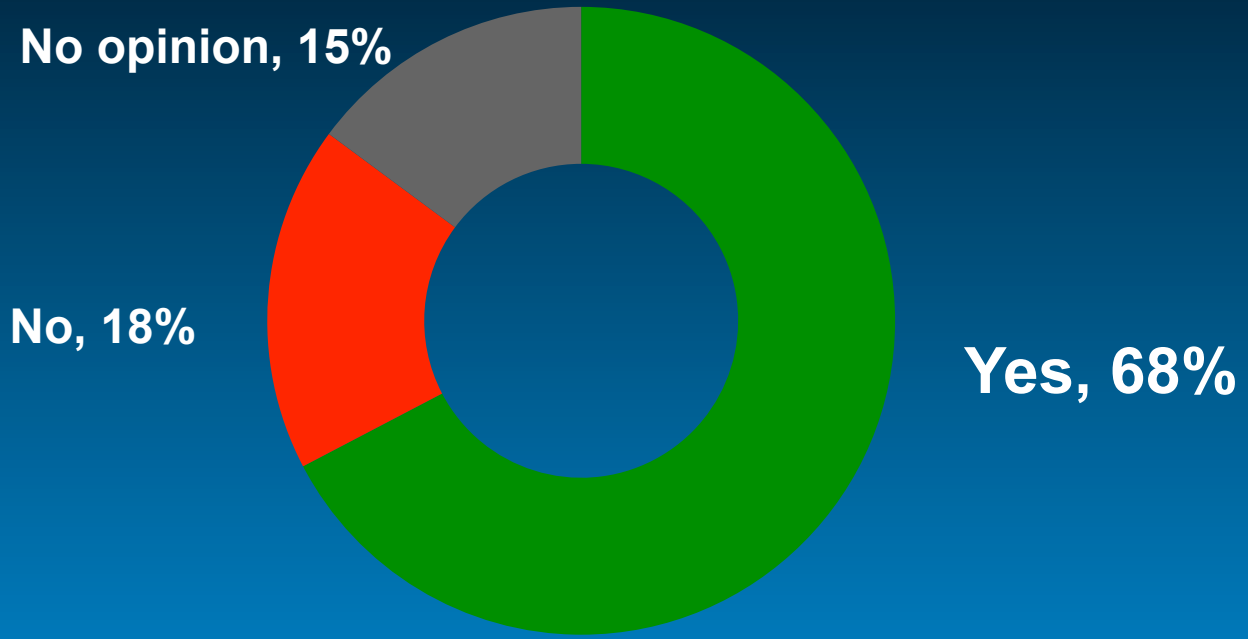
Option 3 – Implement a 4-Letter Suffix Appended to the Non-Proprietary Name:

This was the second-ranked naming option, with 51% of respondents rating it as preferred or acceptable. 61% of respondents indicated that this naming option is compatible with their current practice or environment.

This option was preferred by organizations representing consumers/patients, private insurers, and educational and advocacy groups, as well as some pharmaceutical companies. A minority of pharmacists, physicians, nurses, individual patients, and information technology providers preferred this approach. About half of the respondents who preferred option 3 also rated option 2 as acceptable.

- A minority of the 18 (5% of 362) physician response? Not a representative sample size.
- Perhaps physicians and patients concerned with this issue were less vocal because they were detrimentally relying on Health Canada's previous record of strong leadership on distinct naming and support for international harmonization.

2017 Survey of 403 Canadian Physicians (all biologic prescribers) Shows Strong Support for Distinct Naming…

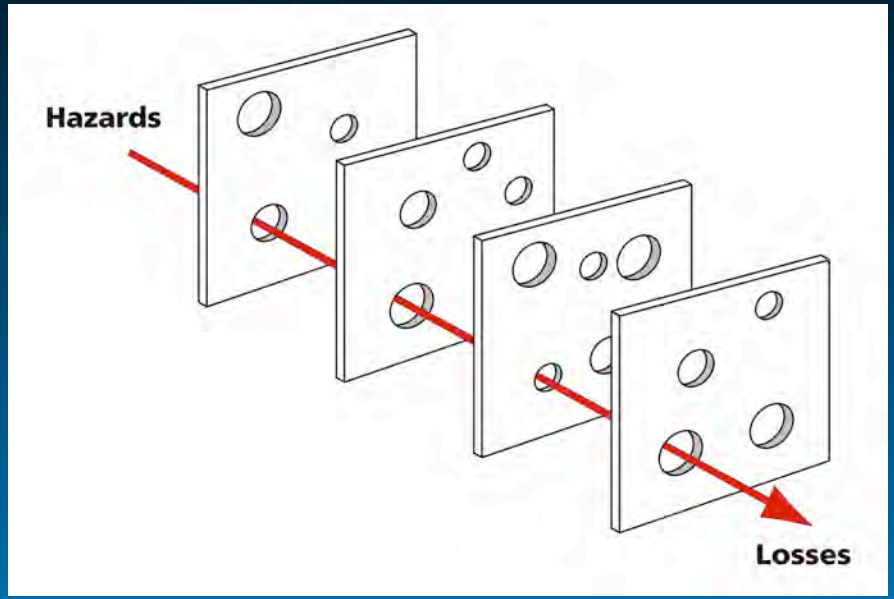


Concerns with Process

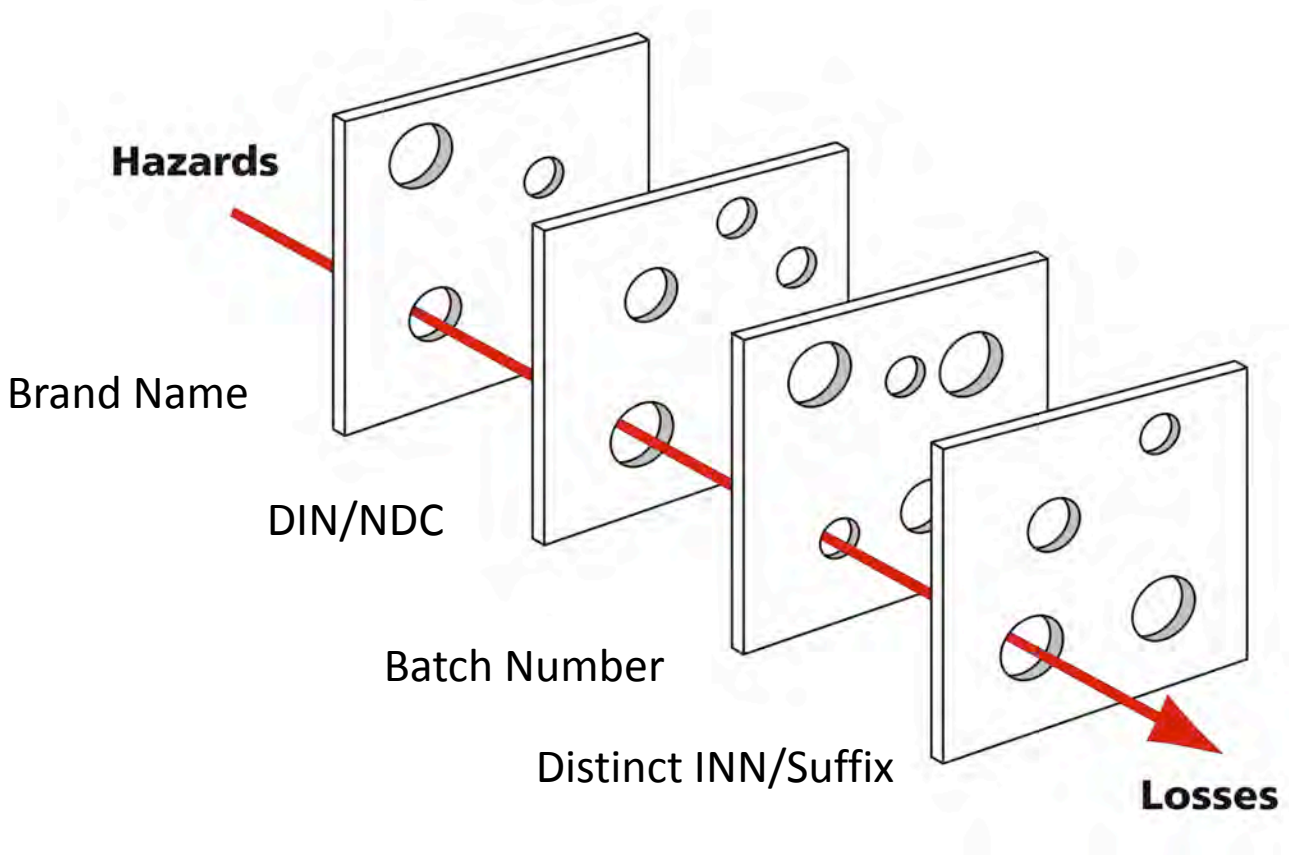
- Finally, the announced Health Canada policy does not adequately address the safety and pharmacovigilance issues inherent in biologic and biosimilar medicine use.

Safety Science: High Reliability Systems

- High-reliability systems need multiple checks: Airlines, Healthcare, Medication systems.
- The “Swiss Cheese Model” from Industrial psychologist Jim Reasons is used worldwide to design high reliability safety systems.
- Each “slice” (“defense”) is a protection against hazardous conditions becoming an accident.



“Defenses” in Identification of Biologic Medicines

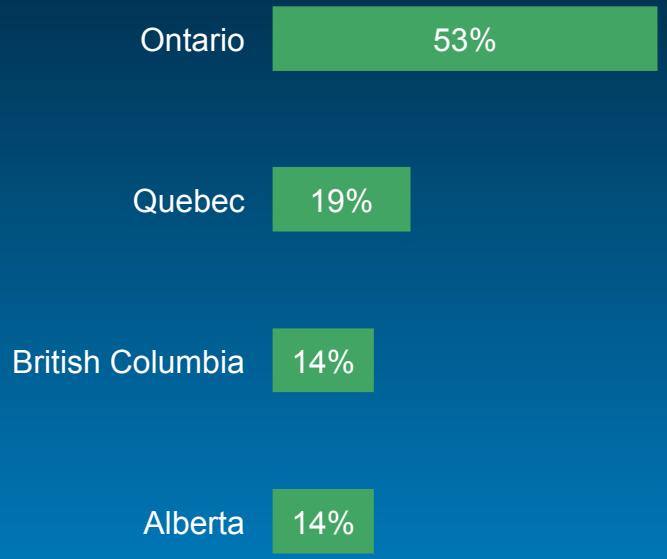


ASBM Has Empirical Data on How These Defense Work in Practice with Canadian Prescribers

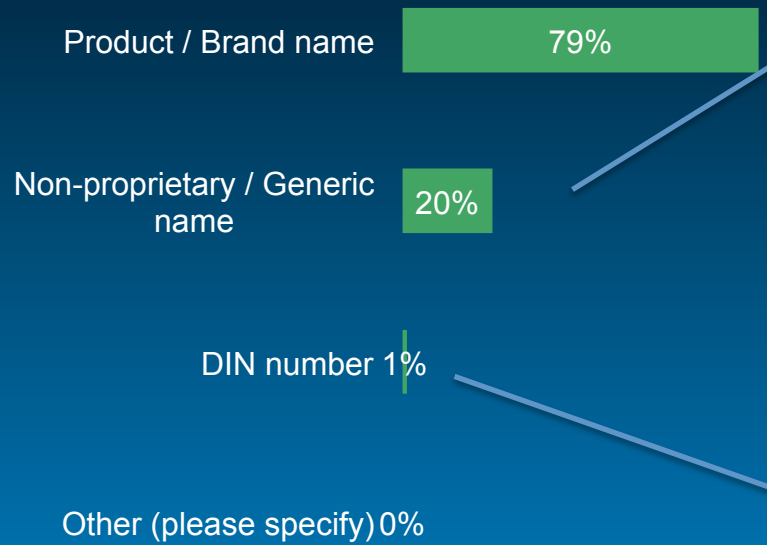
- **2017 Survey of 403 Canadian physicians- all prescribe biologics.**

- Broad cross section from Allergy / Immunology, Dermatology, Endocrinology, Gastrointestinal, Hematology oncology, Infectious Diseases, Internal Medicine, Nephrology, Neurology, Oncology, Respiratory / Pulmonology, Rheumatology, Urology

- Respondent distribution by province roughly reflects Canadian population distribution, with a slight oversampling of Ontario.



Identification of Medicine in Patient Record

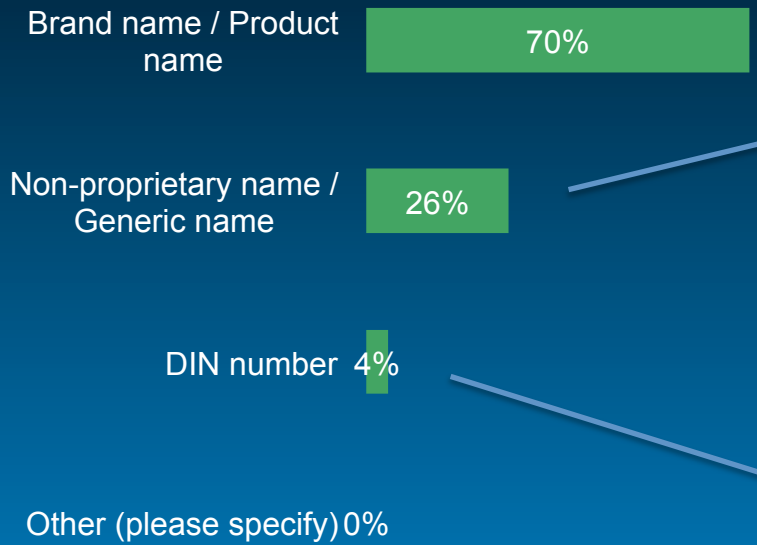


- 20% record *only the product's non-proprietary name in the patient record*, not the brand name.

This can result in inadvertent or inappropriate substitutions, as well as the physician not being aware of which among a number of products the patient will be dispensed at the pharmacy.

- Only 1% of these physicians said they identify the medicine in the patient record using the DIN.

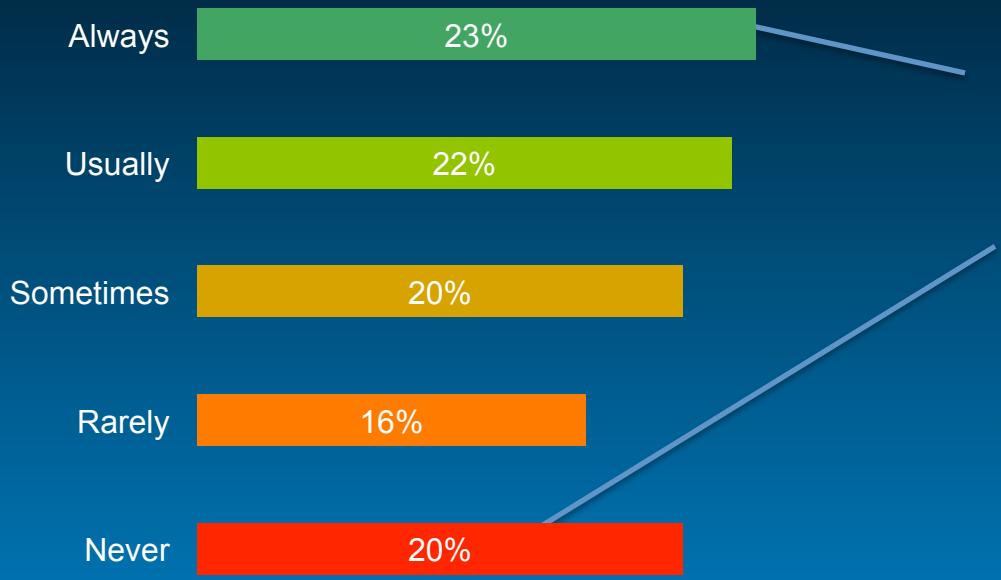
Identification of Medicine in Adverse Event Reporting



- When reporting adverse events, only 70% use the brand name. 26% record *only the product's non-proprietary name*.
- This can result in misattribution of the adverse event to the wrong product, or pooling of adverse events to a class of products.
- When reporting adverse events, only 4% of physicians use the DIN.

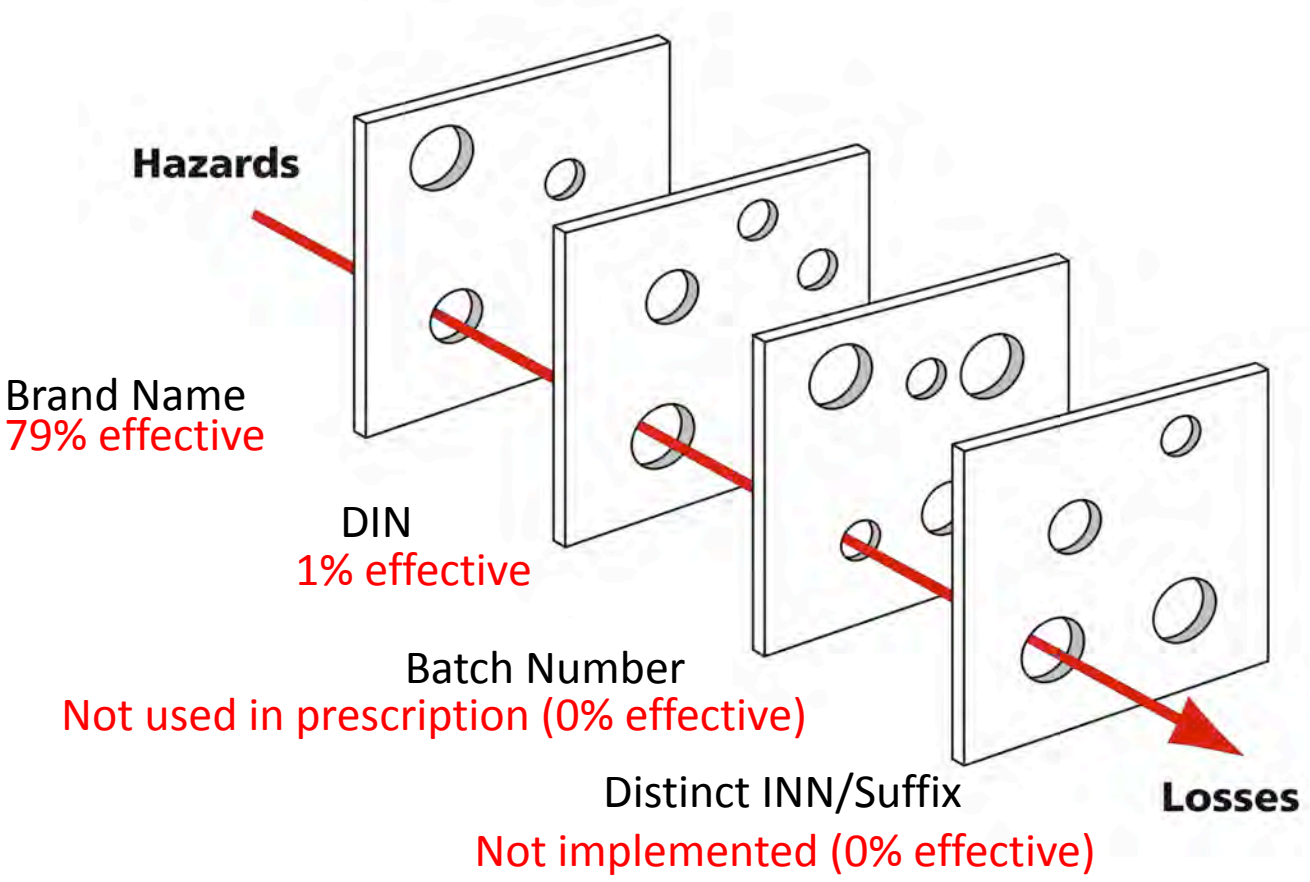
Batch Number

Question:“How often do you include the batch number when reporting adverse events?” (n=403)

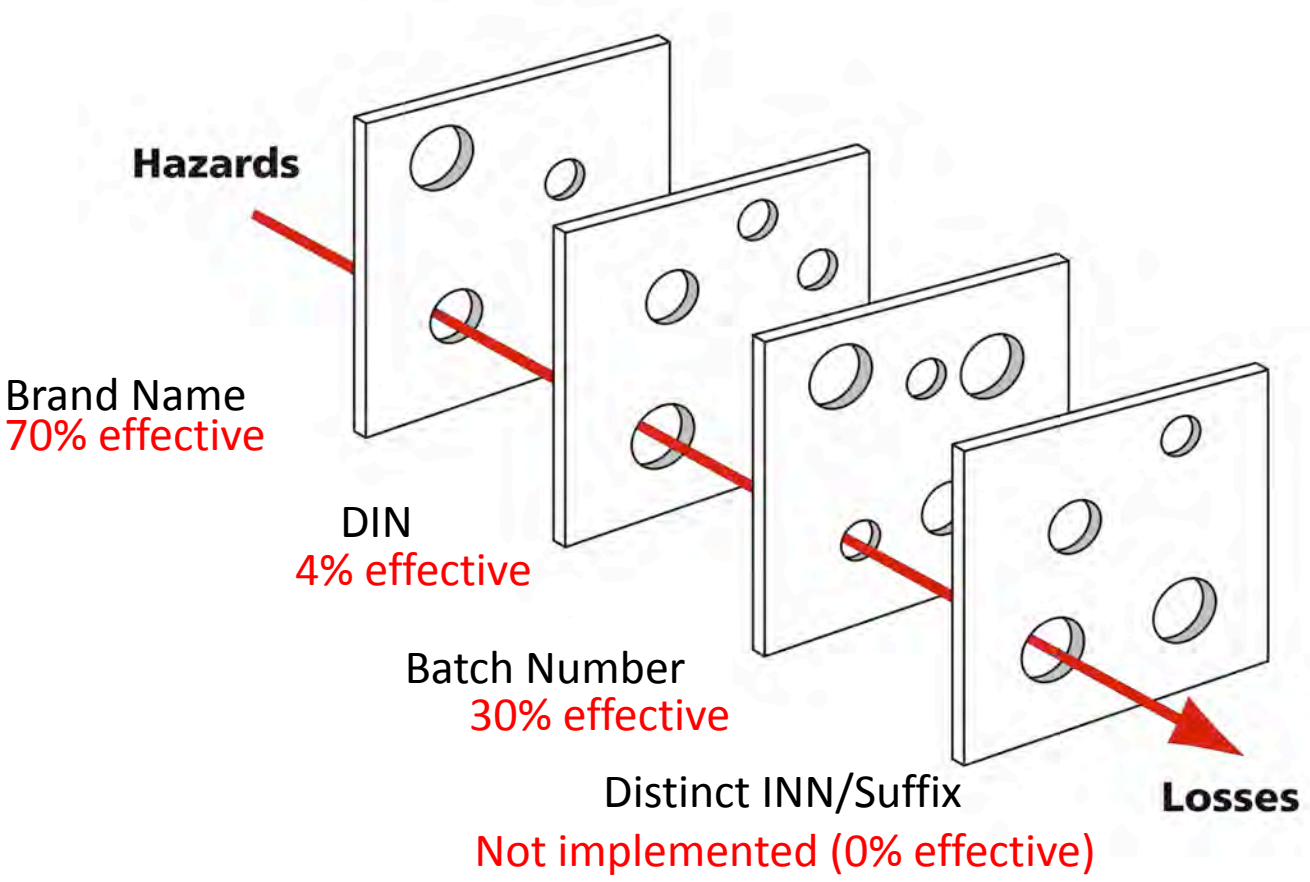


- Only 23% consistently include batch number.
- 20% never include it.

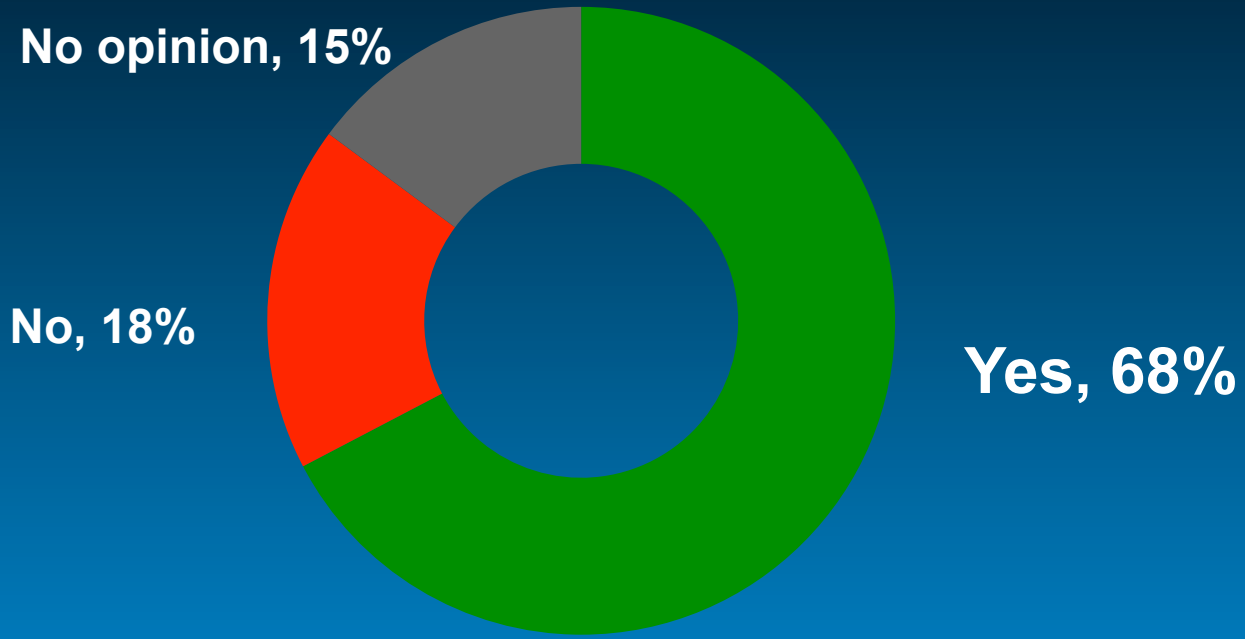
Effectiveness of "Defenses" in Product Identification (Patient Record)



Effectiveness of "Defenses" in Product Identification (Adverse Event Reporting)



For These Reasons, Canadian Physicians Strongly Support Distinct Naming…



Conclusions

- It is clear from the makeup of the respondents that the perspectives of one group of stakeholders, pharmacists, disproportionately influenced the outcome.
- Conversely, the perspectives of other groups - most critically those of patient and physicians - were not adequately taken into account.
- This is especially egregious given the fact that biosimilars are currently dispensed in infusion clinics by nurses and physicians. They are the healthcare providers responsible for biosimilar prescription, dispensing and adverse event reporting. The overwhelming majority of pharmacists do not dispense biologics.
- Patients and physicians have long been supportive of distinct naming as a way to increase confidence in biosimilar use. Enacting a policy which weakens rather than strengthens pharmacovigilance may undermine rather than build their confidence, and thus harm biosimilar uptake.

Conclusions

- In our view Health Canada policy as announced does not adequately address the pharmacovigilance challenges of biologics and biosimilars.
- The policy relies upon use of brand name, yet data show that many Canadian physicians identify products only by a shared nonproprietary name (INN) that will cover multiple different products.
- The policy also relies on a pharmacist-specific, country-specific identifier (DIN) which data show is not used by physicians either in prescription or in adverse event reporting; a batch/lot number not consistently used by physicians.
- While we are appreciative of Health Canada's continuing support for the WHO attempts to provide a global standard, unfortunately this decision is counterproductive to these efforts.

SafeBiologics

ALLIANCE *for* SAFE BIOLOGIC MEDICINES

Thank You For Your Attention