



SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

International Harmonization of Biologic Nomenclature: 2020

Presented at the 70th INN Consultation Open Session for Stakeholders
April 21, 2020

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When we last spoke in
October, we reiterated the
importance of WHO providing
LEADERSHIP with regard to
biologic naming...



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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 (balocco@who.int)"

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The mention of specific companies or of certain manufacturers that are not mentioned in this draft does not imply endorsement or recommendation by the World Health Organization.

The COVID-19 Pandemic demonstrates how the world looks to the WHO on issues of public health.

HEALTH AND SCIENCE

WHO says coronavirus vaccine and treatment research has 'accelerated at incredible speed'

PUBLISHED MON, APR 6 2020-12:34 PM EDT | UPDATED MON, APR 6 2020-3:02 PM EDT

The coronavirus 'will stalk the human race for a long time to come,' WHO envoy says

Isaac Scher Apr 13, 2020, 11:04 AM



COVID-19 STRATEGY UPDATE

14 April 2020

THE CORONAVIRUS CRISIS

WHO Sets 6 Conditions For Ending A Coronavirus Lockdown

April 15, 2020 · 9:24 AM ET

The need for **WHO LEADERSHIP** on Naming has been a key, recurring theme in our presentations over the years...

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 benefits, 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.

OCTOBER 2016

The World Awaits Leadership and Action on Naming

- The BQ is a well-considered and practicable solution to the global problem of naming.
- The WHO has the world's confidence and is unquestionably the best situated to facilitate global harmonization of biologic naming.
- Yet regulators recognize the need for action is immediate, and in frustration, are looking elsewhere. We are witnessing the beginning of the fragmentation the BQ was created precisely to avoid.
- Further delay in BQ implementation risks further fracturing of international naming systems, and additional proliferation of country-specific naming schemes.



World Health Organization

OCTOBER 2017

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.

MAY 2018

The WHO Should Listen to Patients, Physicians, Regulators Who Want This Voluntary Standard Made Available...

- Broad policies should reflect the needs and desires of those whom they affect. A strong majority of patients, physicians, pharmacists, and regulators want the BQ.
- NRAs have relied upon WHO, witnessed its lack of action and then decided they must act in WHO's absence to protect patient safety.
- Countries with advanced pharmacovigilance systems that believe the BQ redundant should not deny it to those that have asked for an international standard, see its value, and continue to support it.
- This especially includes lower- and middle- income countries, which have the most to gain from improved systems for biologics AND from a global pharmacovigilance standard.
- The time for WHO leadership action, more than ever, is now.

OCTOBER 2018

Meetings with FDA and Health Canada:

Over the past year, ASBM has hosted three meetings with FDA and Health Canada to discuss the benefits, and importance of:

- Increasing Biosimilar Uptake
- Building Confidence in safe use of Biosimilars
- Distinct Naming as a tool to address pharmacovigilance challenges, increase confidence
- International Harmonization as a tool to promote safety and collect data
- **WHO Leadership on these issues**

APRIL 2019

Here We Are... Again.

Like the swallows returning to Capistrano... ...or the Monarchs migrating to Mexico...

...ASBM returns to Geneva to urge the WHO to assume Global Leadership on Biologic Nomenclature.



OCTOBER 2019

*Biologic naming
remains another issue
where WHO's
leadership is needed.*



World Health
Organization

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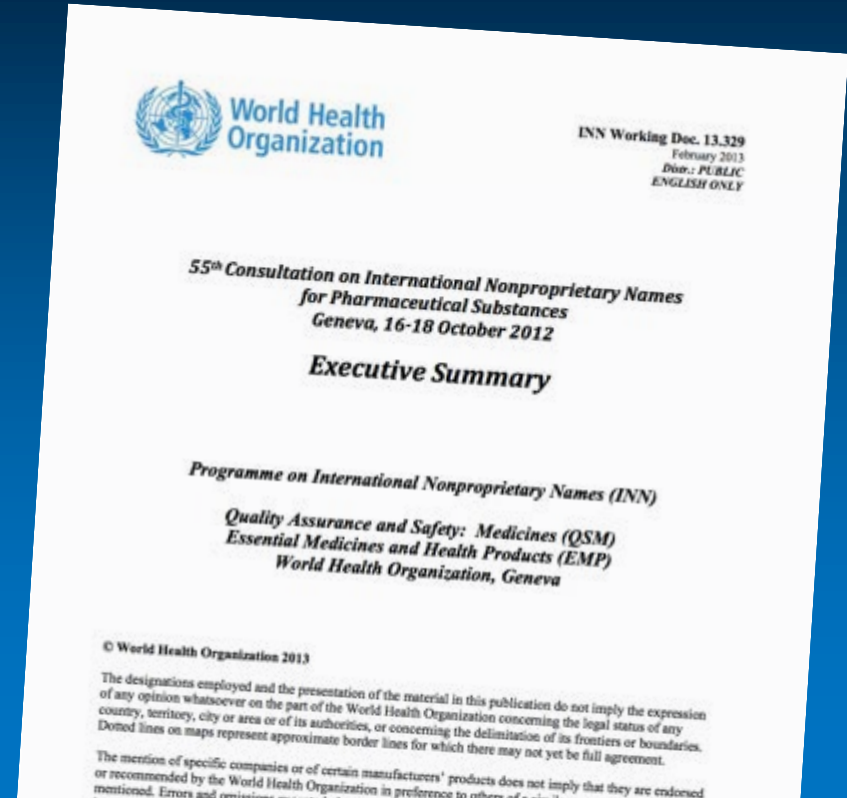
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It Remains an “Urgent Need”.

“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



The INN Expert Group Recommendation Remains Valid.

- During the previous Open Session in October, we were informed by the Secretariat that the INN Expert Group Recommendation still remains valid.
- **A harmonized system of distinct biologic naming will still improve biologic pharmacovigilance.**



Broad Support for WHO Proposal Still Exists:

FDA: **SUPPORT**

Health Canada: *Past supporter willing to harmonize*

TGA: *Early strong supporter, may be willing to harmonize*

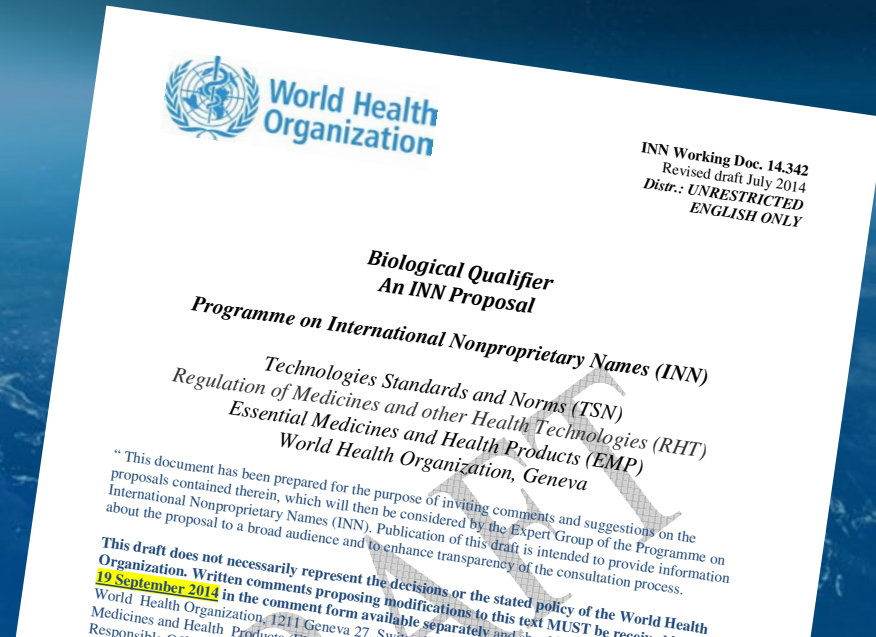
Japan: **SUPPORT**

Denmark: **SUPPORT**

UAE: **SUPPORT**

Jordan: **SUPPORT**

Most Physicians: **SUPPORT**

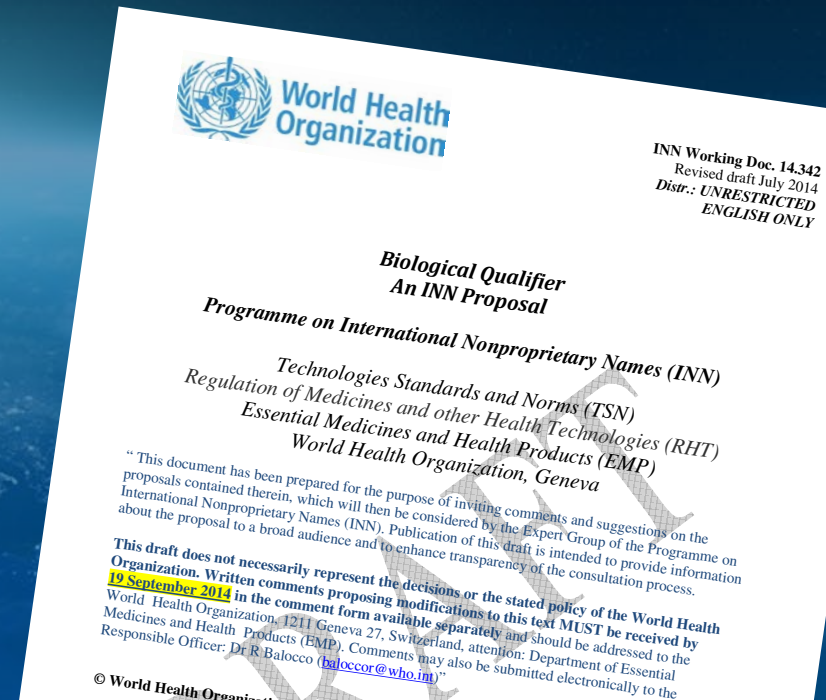


Yet the slow pace of response by WHO has led to countries going their own way...

Had WHO moved to implement the BQ recommendation after it was made, we can say with a high degree of certainty that FDA, Health Canada, and TGA would ALREADY have implemented.

Other regulators have expressed support as well.

Who can say how many other countries would have joined after them?





***A Major Objection to Distinct Naming has been that it
IMPLIES INFERIORITY and thus would IMPEDE ACCESS...***

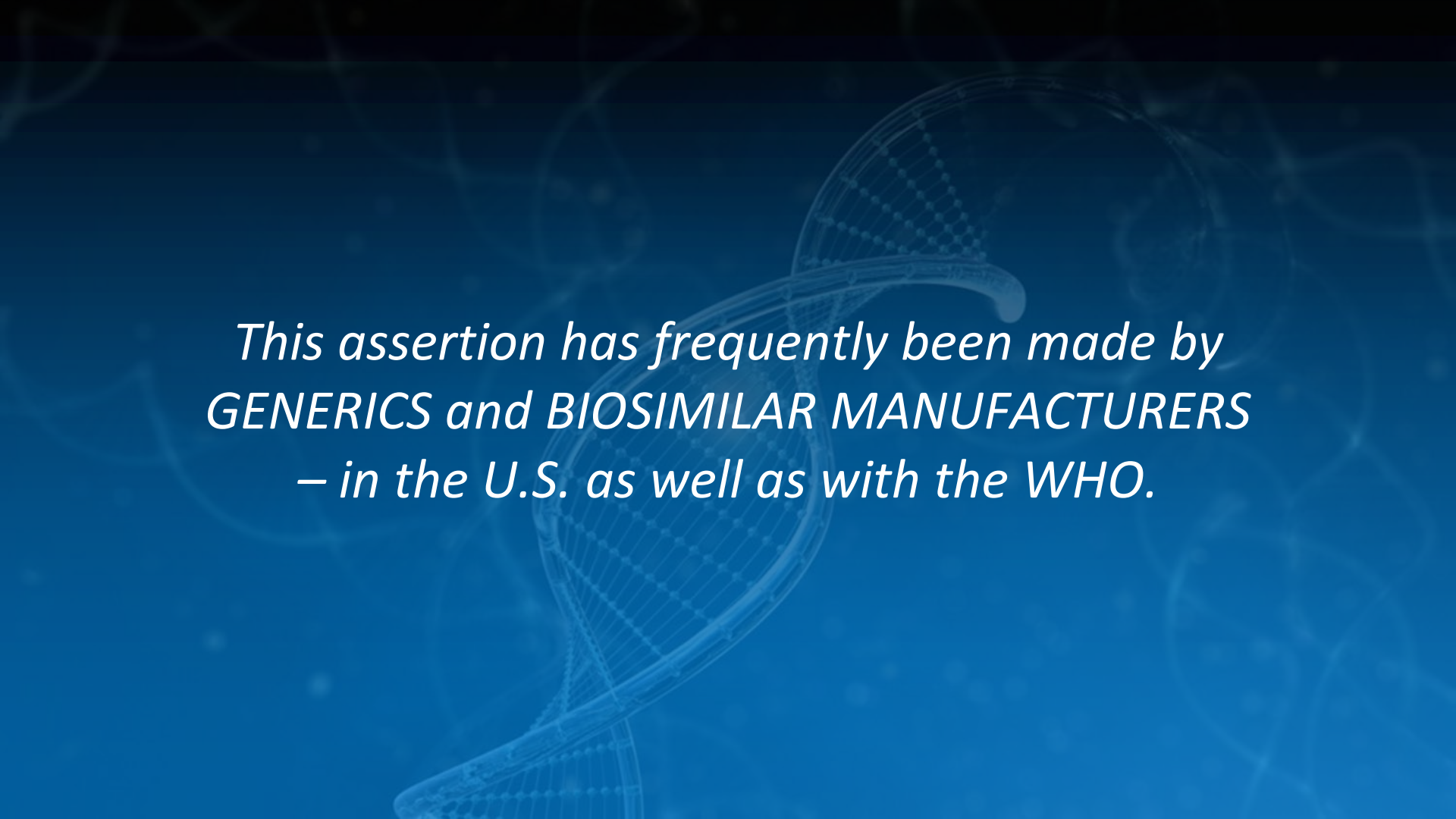
“FTC staff is concerned that FDA’s proposal—to assign different suffixes to the drug substance names of biosimilars and their reference biologics—could result in physicians incorrectly believing that biosimilars’ drug substances differ in clinically meaningful ways from their reference biologics’ drug substances...**A misperception that the drug substance in a biosimilar differs in clinically meaningful ways from that in the reference biologic could deter physicians from prescribing biosimilars, thus impeding the development of biosimilar markets and competition.**”



Comment of the Staff of the Federal Trade Commission on FDA Guidance for Industry on the “Nonproprietary Naming of Biological Products; Draft Guidance for Industry; Availability”; October 27, 2015

The establishment of a **unique suffix for biological reference products and biosimilar products** may be interpreted to indicate that biosimilar products have substantially different safety and efficacy profiles and therefore may not be substituted or interchanged. These perceived differences **may cause patients and health care providers to not use, prescribe, or dispense these products** because of concerns over safety and efficacy.





*This assertion has frequently been made by
GENERICs and BIOSIMILAR MANUFACTURERS
– in the U.S. as well as with the WHO.*

“Finally, we are concerned about the lack of clarity surrounding the nonproprietary naming convention that will apply to interchangeable biological products, particularly since **the current approach of requiring different suffixes could mislead doctors and pharmacists to conclude that a product that FDA has deemed to be interchangeable is not.**”



February 13, 2017; Comments of the Generic Pharmaceutical Association and the Biosimilars Council re: “Nonproprietary Naming of Biological Products”

Cited by Health Canada When it Decided to Abandon Distinct Naming.

“other respondents commented that the suffix may be more confusing than helpful as drugs with different suffixes may have the same indications and clinicians and patients **could assume that different suffixes indicate clinically meaningful differences between a biosimilar and its reference product.**”

*Health Canada “What We Heard” Report; Stakeholder Consultation on the Naming of Biologic Drugs; “Option 3: **Implement a 4-Letter Suffix Appended to the Non-Proprietary Name**”. February 14, 2019*

