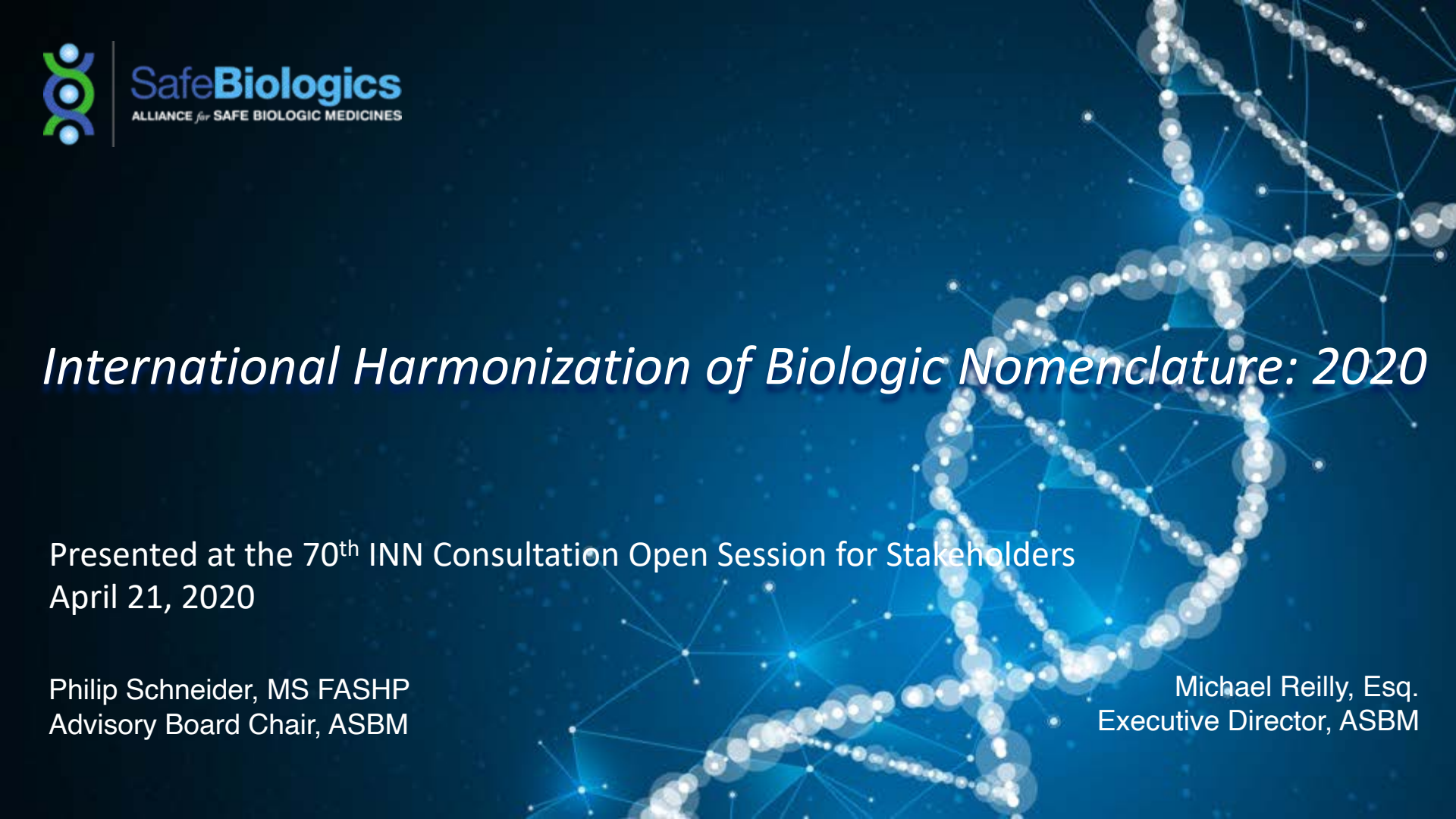


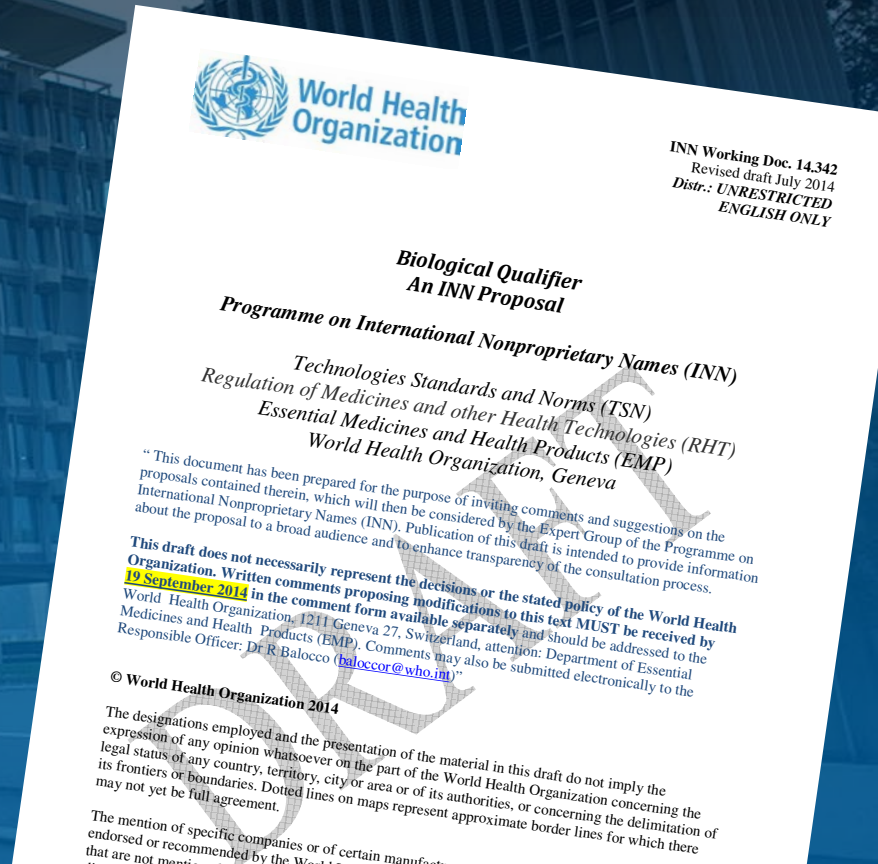
International Harmonization of Biologic Nomenclature: 2020

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

Philip Schneider, MS FASHP
Advisory Board Chair, ASBM

Michael Reilly, Esq.
Executive Director, ASBM

When we last spoke in October, we reiterated the importance of WHO providing LEADERSHIP <u>with regard to biologic naming…</u>



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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

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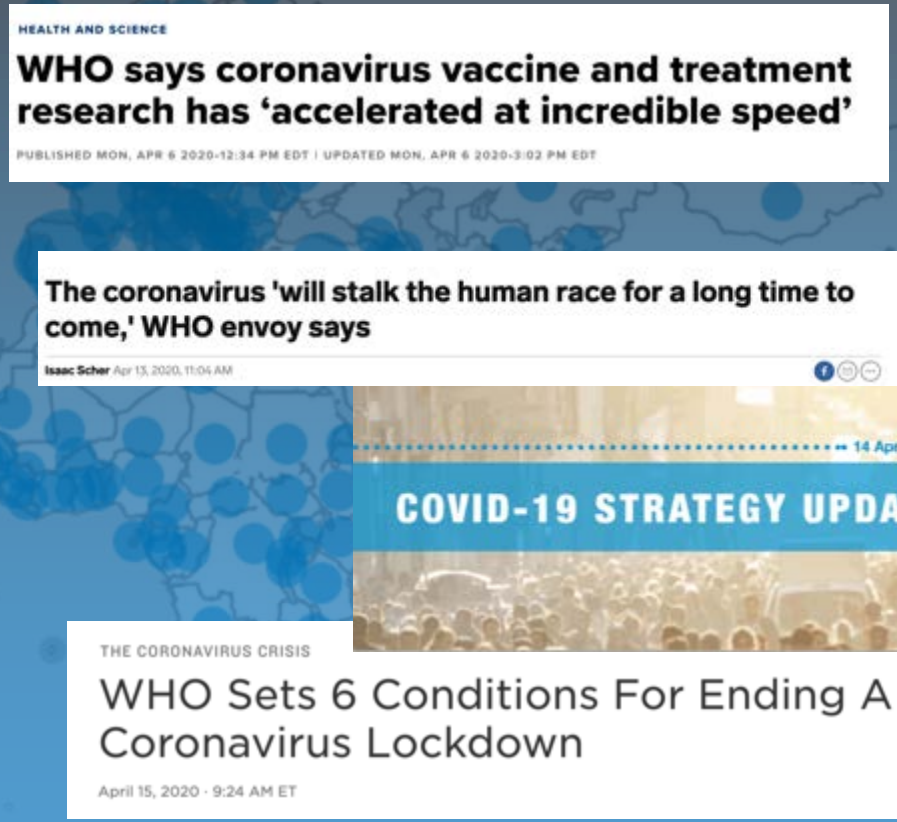
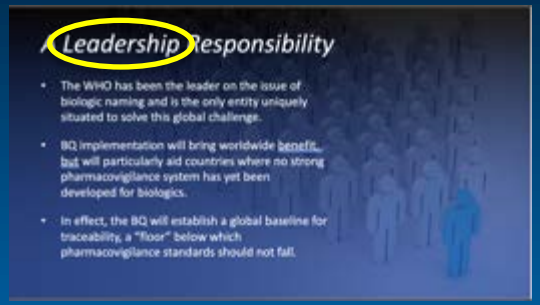
The mention of specific companies or of certain manufact
endorsed or recommended by the
that are not

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

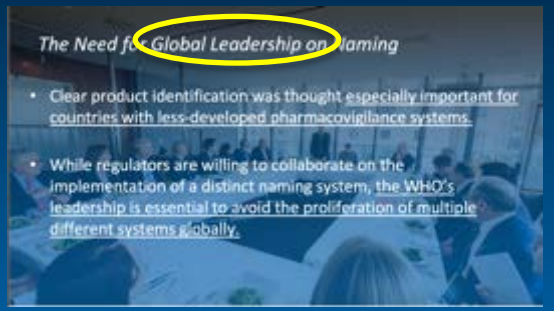


The need for WHO LEADERSHIP on Naming has been a key, recurring theme in our presentations over the years…

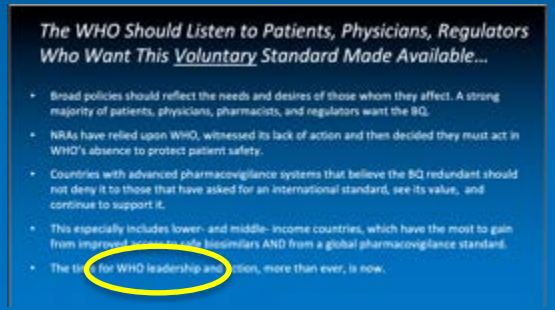


OCTOBER 2016

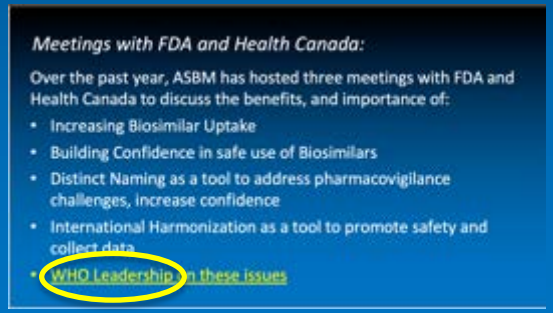
OCTOBER 2017



MAY 2018



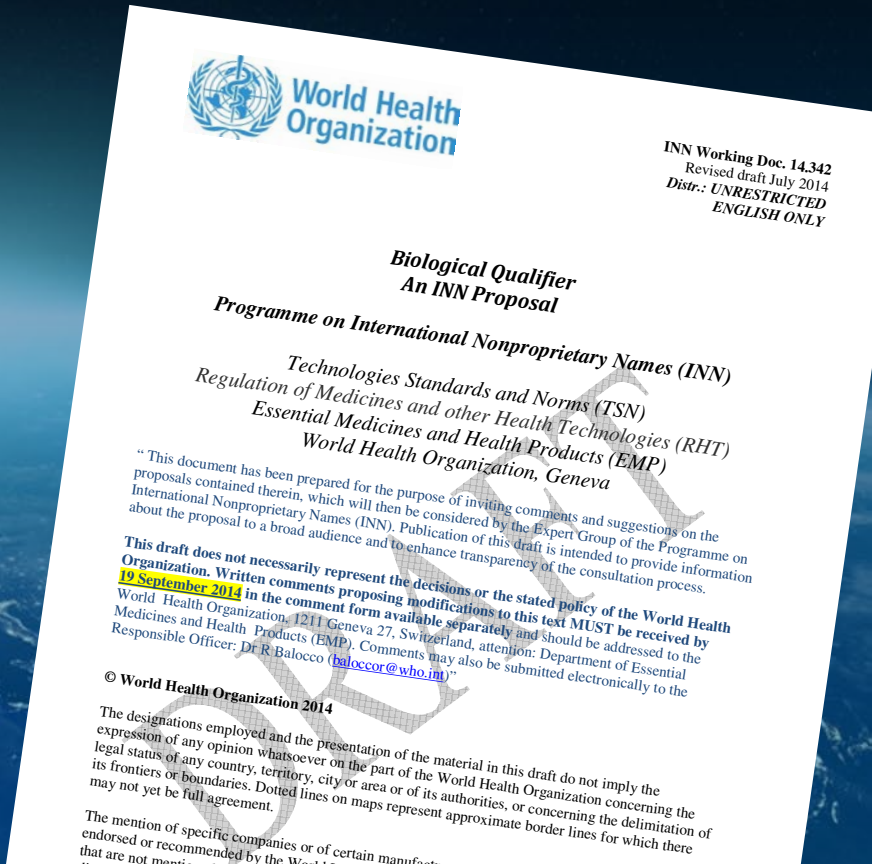
OCTOBER 2018



APRIL 2019

OCTOBER 2019

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



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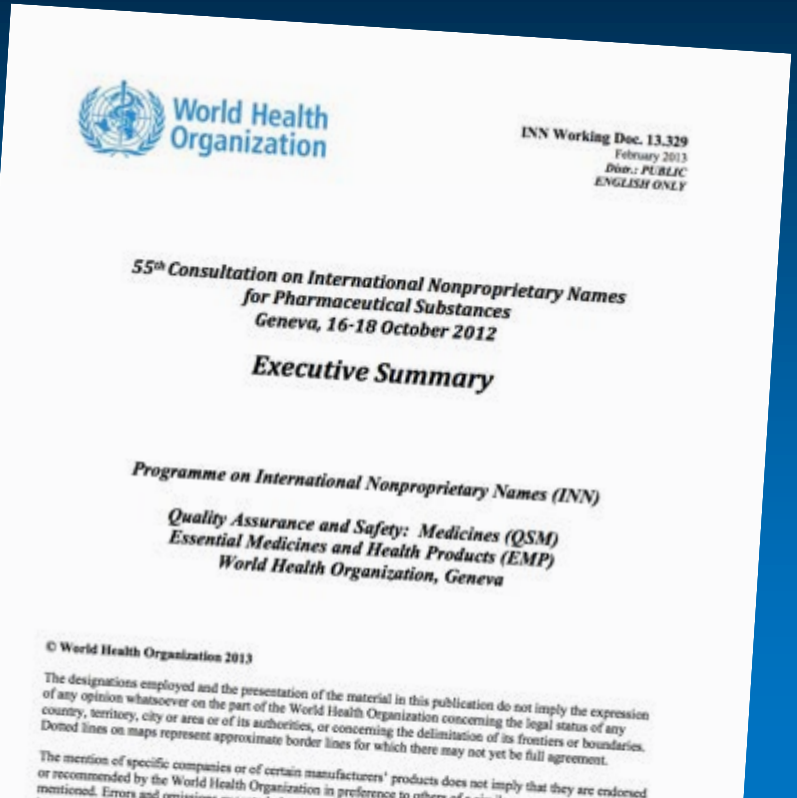
that are not

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



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INN Working Doc. 13.329
February 2013
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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

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*

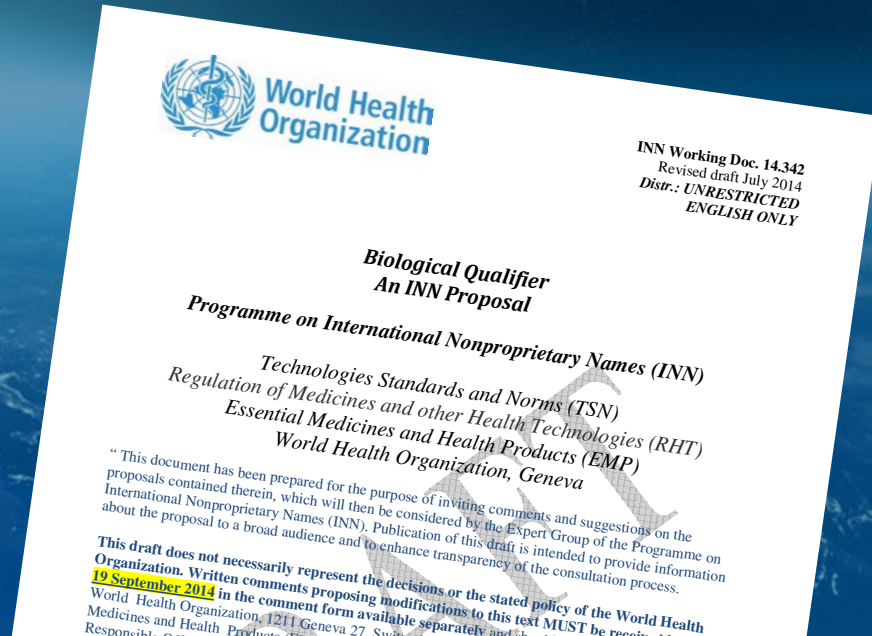
Japan: ***SUPPORT***

Denmark: ***SUPPORT***

UAE: ***SUPPORT***

Jordan: ***SUPPORT***

Most Physicians: ***SUPPORT***



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World Health Organization, 1211 Geneva 27, Switzerland

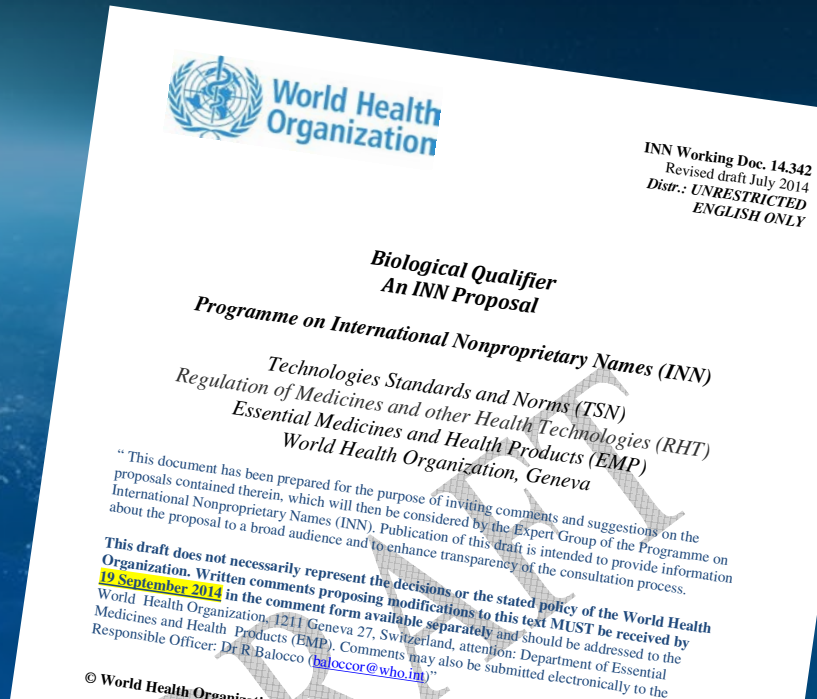
Medicines and Health Products

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?



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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.

AMCP Academy of Managed Care Pharmacy®

October 26, 2015 Comments Re: Nonproprietary Naming of Biological Products

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***