Position Statements [1]

Sandoz position on the naming of biosimilars

Biosimilars must have the same International Non-Proprietary Name (INN) as the reference products. A modified INN for biosimilars would impede their ability to compete fairly in the marketplace, create confusion and limit patient access to these critical medicines.

Tab:

Biosimilars naming [2]

Understanding INN

INN stands for “International Nonproprietary name,” a recognized naming system that has been administered by the World Health Organization (WHO) since 1953. It is used to identify the active pharmaceutical ingredient in all medicines for healthcare providers.

According to the WHO, “[t]he 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.”[1]

This includes biologics. Many independently developed biologics on the market in the US and Europe today share INNs and no safety issues have arisen because of that. In fact, INN was never meant to track and trace adverse events, as some people and organizations now claim. Rather, the current pharmacovigilance system includes redundant means of biologic identification. This consists of brand names, INN (USAN in US), manufacturer, national drug code in the US (NDC), and lot number.

How INN is used successfully today

European regulators have shown that the same INN system can be successfully used for all biologics including biosimilars, in the same way as it does for all other biologics as well as for small-molecule products. A 2013 study of the identification of biosimilars in the EU pharmacovigilance system found that the naming convention for biosimilars has a highly successful product identification rate of 96.2% across all three marketed biosimilar classes – the same rate as for originator biologics. In the US, the FDA already allows different recombinant and naturally-occurring proteins from different manufacturers to share the same non-proprietary name even though they have been approved under different Biologics License Applications (BLA) or New Drug Applications (NDAs) and have never demonstrated

comparability. To date, there is no documented evidence of any safety issues resulting from these different products sharing the same INN.

Established drug safety system exists

There is a robust drug safety system in use today for tracking and tracing individual finished products. The key identifiers used in this system are the Brand name, Manufacturer name, INN (also called USAN in the US) and several elements including the national drug code (NDC) in the US that can identify medicines down to the specific batch of drug manufactured. Unfortunately, healthcare personnel and patients do not often identify the drug by all these specific identifiers when reporting adverse events. Therefore, adding a any new nonproprietary name could further complicate the situation - no system can compensate for poor record keeping. However, most people include the brand name because it is designed to be recognizable and it is specific to the product. (According to the EMA [3], in the period from December 1, 2001 to June 30, 2012, 81% of biologics-related adverse events reports included the brand name.) Indeed, each brand name has been carefully vetted for distinctiveness and clarity by FDA. INNs are not vetted by FDA for distinctiveness and clarity because medicines in the U.S. are not routinely prescribed by INN.

Impact of deviating from INN system

A few groups are proposing changes to the well-established INN system that would apply only to biosimilars claiming to do so on grounds of undefined risks to patient safety. However, it is important to note that introducing separate and different “names” for what the FDA has agreed is essentially the same active pharmaceutical ingredient is what poses the real threat to patient safety.

- If naming conventions are changed then the existing safety alerts that depend on identifying products that share active ingredients will be disrupted. Each process will have to be individually rebuilt to ensure patient safety and restore functionality to the prescription tracking systems. Additionally, participants will need to be trained in the new requirements. Any transition will take time and resources, and the impact of such a move on currently approved products is not well understood.
- Demanding unique INNs for biosimilars, if applied appropriately to all biologics that have undergone manufacturing changes, would require health authorities to rename virtually every licensed biologic medicine currently on the market. This is entirely inappropriate as it would lead to widespread confusion and a significant administrative burden for the system.

The fact is that mandating a different INN for biosimilars will simply create another barrier to more affordable alternatives for physicians and patients. Much better that we recognize biosimilars as containing the same approved, high-quality active ingredients as their reference and thus foster fair competition and better patient access.

Unique brand names, not unique INNs

A few groups are proposing changes to the well-established INN system that would apply only to biosimilars in the U.S., claiming to do so on grounds of undefined risks to patient safety. Yet we know that any differentiator in nonproprietary names will reduce competition in the healthcare market and patients may have to pay more. Much better that we recognize

biosimilars in the U.S. market as containing the same FDA-approved, high-quality active ingredients as their reference and thus foster fair competition and better patient access, just as we saw when generic drugs first became available.

The fact is that mandating a different INN for biosimilars will simply create another barrier to more affordable alternatives for physicians and patients.

1.http://www.who.int/medicines/services/inn/innquidance/en/ [4]

Stakeholder views [5]

- AARP
  Letter to US FDA (Food and Drug Administration) (PDF 50.2 KB) [6]

- Pharmacies, Labor Unions, State Retirement Systems, Payors Call on FDA to Protect Patient Safety and Patient Access by Preserving Accepted International Nonproprietary Name (INN) Conventions for Biosimilar Medicines
  Thirty-two groups lodge concerns with agency on consequences of lack of continuity, including patient safety risks and increased costs (PDF 49.2 KB) [7]

- Council for Citizens Against Government Waste (CCAGW)
  National Council for Prescription Drug Programs (NCPDP)
  Taxpayers for Common Sense
  Freedom Works
  Joint letter to FDA (PDF 191 KB) [8]

- American Pharmacists Association (APhA)
  National Association of Chain Drug Stores (NACDS)
  National Community Pharmacists Association (NCPA)
  Joint letter to US Department of Health & Human Services (HHS) (PDF 136 KB) [9]

- American Pharmacists Association (APhA)
  National Association of Chain Drug Stores (NACDS)
  National Community Pharmacists Association (NCPA)
  Joint letter to US FDA

- Generic Pharmaceuticals Association (GPhA)
  European Generic Medicines Association (EGA)
  Joint letter to World Health Organization (WHO) (PDF 197 KB) [10]

- Senator John D. Rockefeller IV
  Senator John McCain
  Senator Charles E. Schumer
  Senator Tom Harkin
  Senator Bill Nelson
  Senator Ron Wyden
  Bipartisan letter to US FDA (PDF 496 KB) [11]

Additional reading [12]

- RPM Report: Biosimilar by Name and Biosimilar by Nature (PDF 445 KB) [13]
  This article in the July/August 2013 issue of the RPM Report explains that requiring biosimilars to have unique INNs is unnecessary and will neither protect nor promote the public health. Co-written by Mark McCamish, MD PhD, Global Head of Development, Sandoz Biopharmaceuticals & Oncology.

- Novartis Citizen Petition (PDF 9.06 MB) [14]
  On October 30, 2013, Novartis announced that it had filed a Citizens Petition with the

US Food and Drug Administration (FDA), urging the agency to require that a biosimilar share the same INN as the reference product.

- Effect of Naming on Competition and Innovation (PDF 1.3 MB) [15]
  Presentation to US Federal Trade Commission (FTC) by Mark McCamish, MD, PhD, Global Head of Development, Sandoz Biopharmaceuticals & Oncology Injectables. December 10, 2013

Links
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