Differences in Physicians' Understanding of

# Biologics AND Biosimilars

in the U.S. and Europe

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## INTRODUCTION

### STUDY OBJECTIVE

To evaluate differences in physicians' understanding of biologic and biosimilar medicines in the U.S. & Europe.

Biologic medicines, such as botulinum toxins and monoclonal antibodies, are important therapies in many different medical specialties.

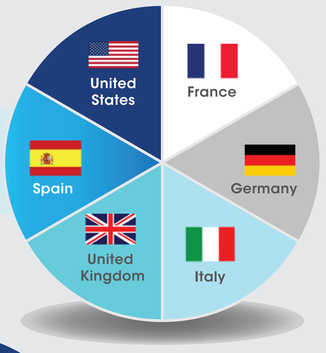
Biosimilar medicines, which are similar, but not identical, to original innovator biologics, have been approved in many countries. Inflectra, a biosimilar of infliximab, and Zarxio, a biosimilar of filgrastim, are the only two biosimilars approved by the Food and Drug Administration in the United States. In Europe, a total of 20 biosimilars are currently approved by the European Medicines Agency (EMA).

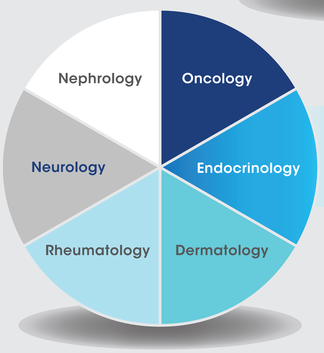
Although biosimilars offer important treatment alternatives at potentially lower costs, their structural differences compared to innovator biologics may produce significantly different dosing, adverse events, and immunogenicity. Thus, it is important that physicians understand that biosimilar medicines are not simply generic alternatives for innovator biologics.

## METHODS

Physicians in the U.S. and in Europe completed a web-based survey.

Survey Participants' HOME COUNTRIES



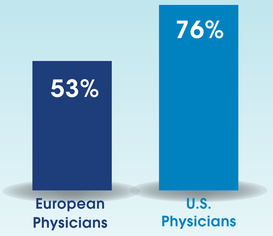




Survey Participants' MEDICAL SPECIALTIES

## RESULTS

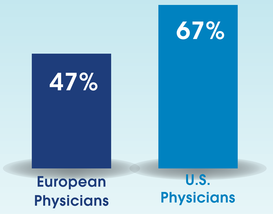
"If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that...

...the medicines are structurally identical?"



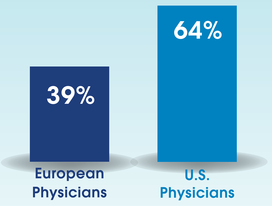

"If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that...

...a patient could be safely switched between the products during a course of treatment and expect the same result as treatment with only one of the products?"




"If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that...

...a patient could safely receive either product and expect the same result?"




## ABOUT

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

The Alliance for Safe Biologic Medicines (ASBM) is an organization composed of diverse healthcare groups and individuals—from patients to physicians, biotechnology companies that develop innovative and biosimilar medicines and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion. Our membership list and steering committee reflect the wide range of voices within the healthcare community. Our coalition ultimately strives to position itself to be an authoritative resource center of information for the healthcare and policy communities.
**ww.safebiologics.org**

GAfPA
Global Alliance for Patient Access

The Global Alliance for Patient Access (GafPA) is an international network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. GAfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access.
**www.gafpa.org**

## CONCLUSIONS

A significant portion of physicians in the U.S. and Europe do not understand important differences between innovator biologics and biosimilars.

This lack of knowledge is particularly evident in the U.S.

Clinical trials of biosimilars for each medical indication are needed to define safety and efficacy and inform physicians and patients about the implications of switching medications.

Furthermore, educational initiatives should seek to educate physicians, patients, and pharmacists on the differences between biologics and biosimilars.

**Unique names for each biosimilar medication is an essential step toward reducing physician confusion and risks to patients.**

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