SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

ASBM 2013 European Prescriber Survey

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About ASBM

ASBM Composition: Diverse Membership

SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

AfPA Alliance for Patient Access
American Autoimmune Related Diseases Association, Inc.
American Academy of Dermatology
ACRO ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS
COLON CANCER ALLIANCE
GLOBAL COLON CANCER ASSOCIATION
ican international cancer advocacy network
GLOBAL HEALTHY LIVING FOUNDATION
Kidney Cancer Association www.KidneyCancer.org
HealthHIV
ZERO THE END OF PROSTATE CANCER

STEERING COMMITTEE

- Runs day-to-day operations
- Composed exclusively of physician and patient groups

GENERAL MEMBERSHIP

- Composed primarily of patient groups but also includes BIO and EuropaBio, plus biologic manufacturers, some plan on making biosimilars, some do not.

ACSH American Council on Science and Health
AMGEN
AAPD
Bio Biotechnology Industry Organization
ABC Association of Black Cardiologists, Inc. Saving the Hearts & Minds of a Diverse America
Association of Gastrointestinal Motility Disorders, Inc. (AGMD)
FIGHT COLORECTAL CANCER
Genentech A Member of the Roche Group
icps.org International Conference of Physicians and Surgeons
EuropaBio
MANA A National Latina Organization
NAMI National Alliance on Mental Illness
RetireSafe Standing up for America's Seniors!

ASBM's Guiding Principles: "The Four Pillars"

- PRIORITIZING PATIENT SAFETY
- LEVERAGING WHAT WE HAVE LEARNED from the EU's science-based approach
- PROMOTING PHARMACOVIGILANCE: building and maintaining a robust track and trace system
- KEEPING DOCTORS RELEVANT: Physicians and their patients should determine treatment, not a third party

ASBM International Activity Over the Past Year

- April 8, 2013: Whitepaper *"The Future of Biological Therapy: a Pathway Forward for Biosimilars"* published in *Generics and Biosimilars Initiative Journal (GaBI)*
- May 2013: International Alliance of Patient Organizations (IAPO) Workshop on Biosimilar Medicines, Geneva, Switzerland
- June 2013: Regulator Forum on Biologic Naming and Traceability, *Ottawa, Canada*
- September 2013: IAPO Conference*, Mexico City, Mexico*
- October 2013: Presented at World Health Organization's 57th Consultation on WHO International Non-proprietary Names (INN) -*Geneva, Switzerland*
- November 2013: Previewed European Prescriber Survey Results while presenting at DIA Biosimilars Workshop – *Dublin, Ireland*
- Formal Launch of European Prescriber Survey Results – *Brussels, Belgium*
- April 8, 2014: Presenting at WHO 58th Consultation on WHO International Non-proprietary Names (INN) -*Geneva, Switzerland*

2013 ASBM European Prescriber Survey

The First Large-scale Survey on Biosimilars in Europe

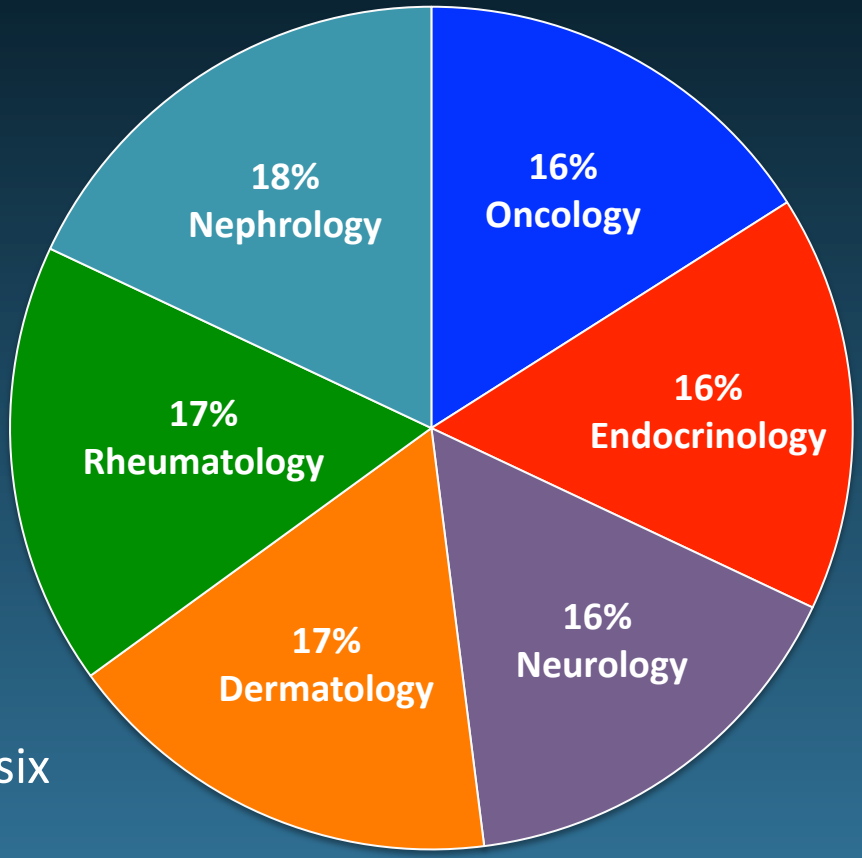
Goals:

- Examine attitudes of European physicians on biosimilar naming and substitution
- Assess physician knowledge, sources of information and need for further education on biosimilars
- Provide data to put policy developments at EU and national level into perspective and inform policy recommendations

Conducted by Industry Standard Research, October-November 2013

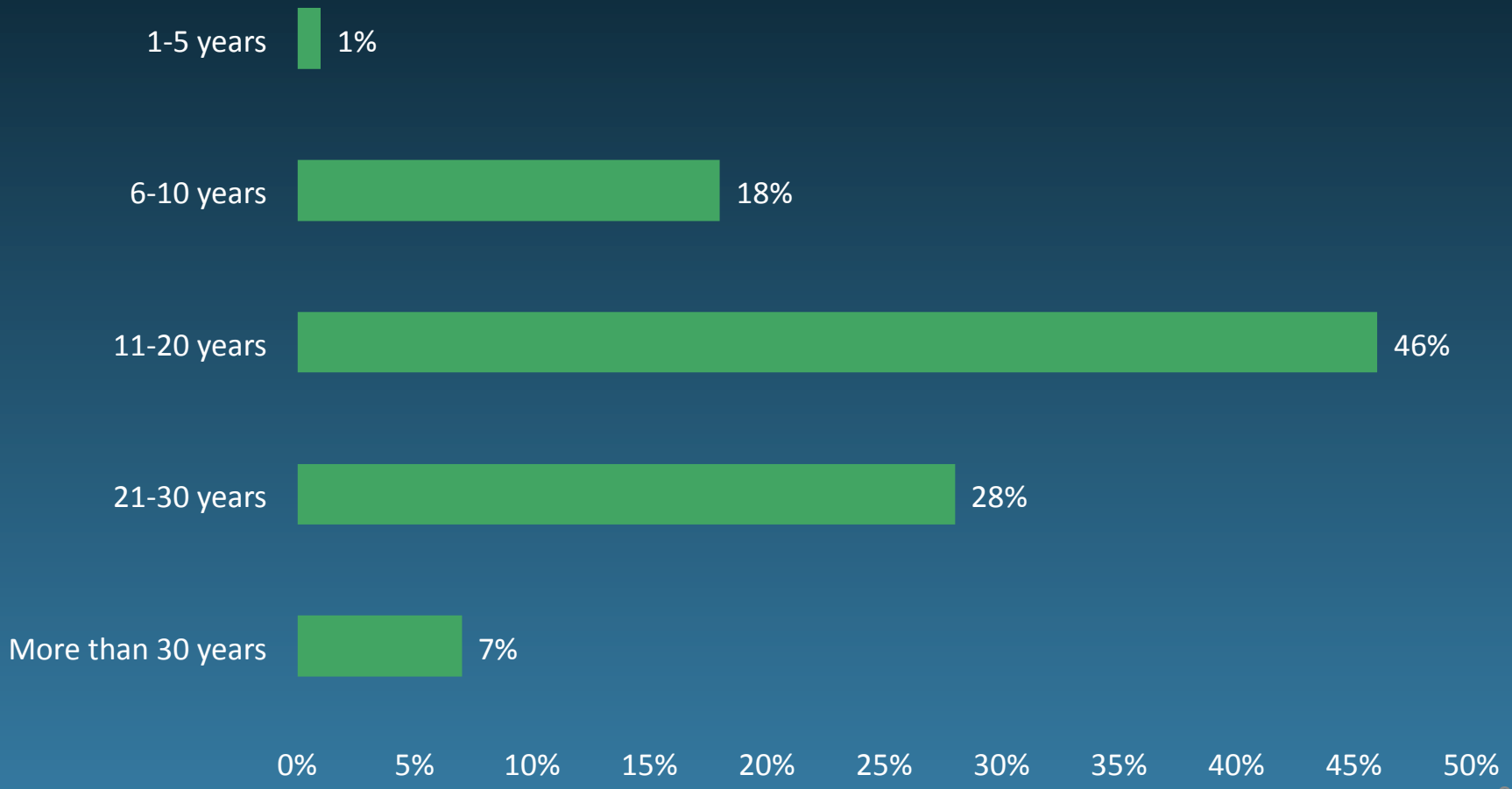
Survey Methodology

- 15-Minute Web-based Survey
- 470 Prescribers distributed equally between 5 countries in Western Europe:
  - France
  - Germany
  - Italy
  - Spain
  - United Kingdom
- Roughly equal distribution between six specialties in which biologics are frequently prescribed.



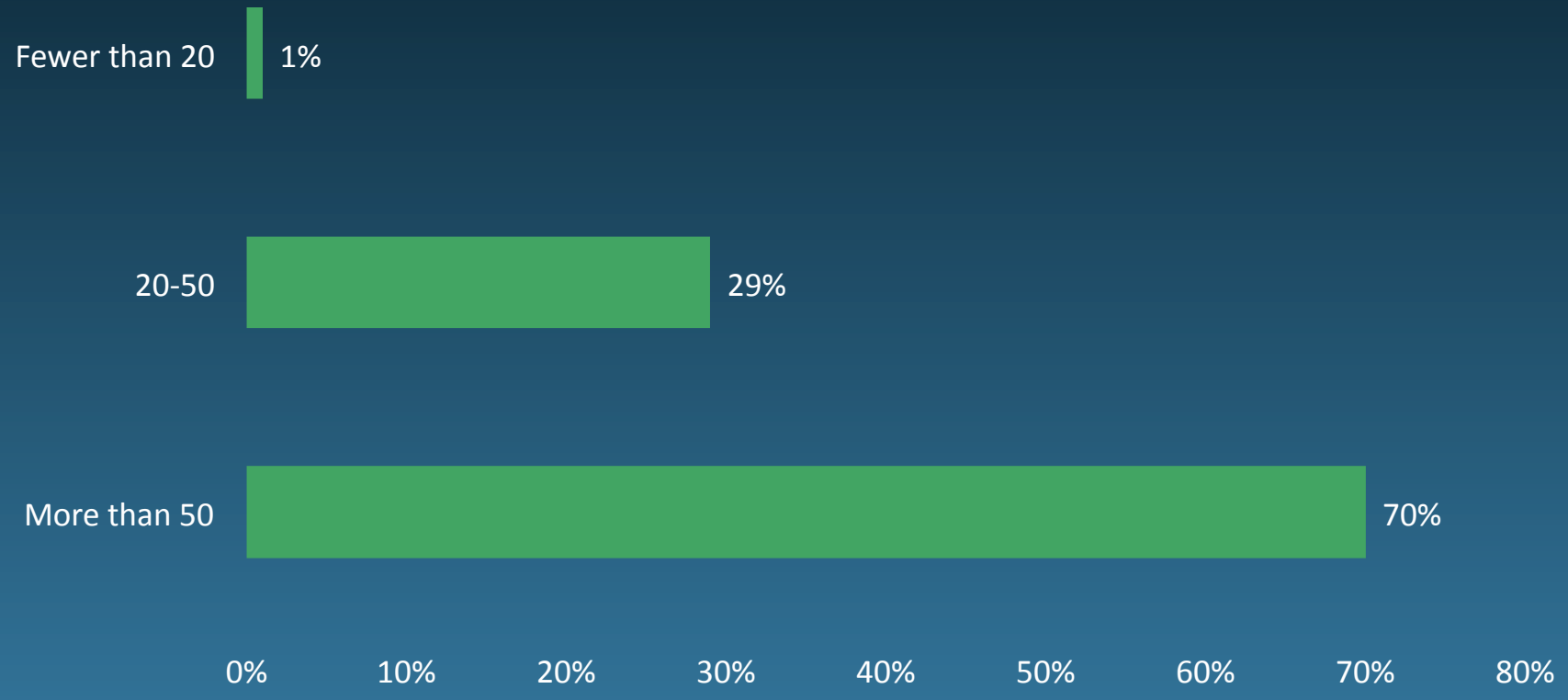
Experience Level of Respondents

Most respondents had between 11-20 years of experience:



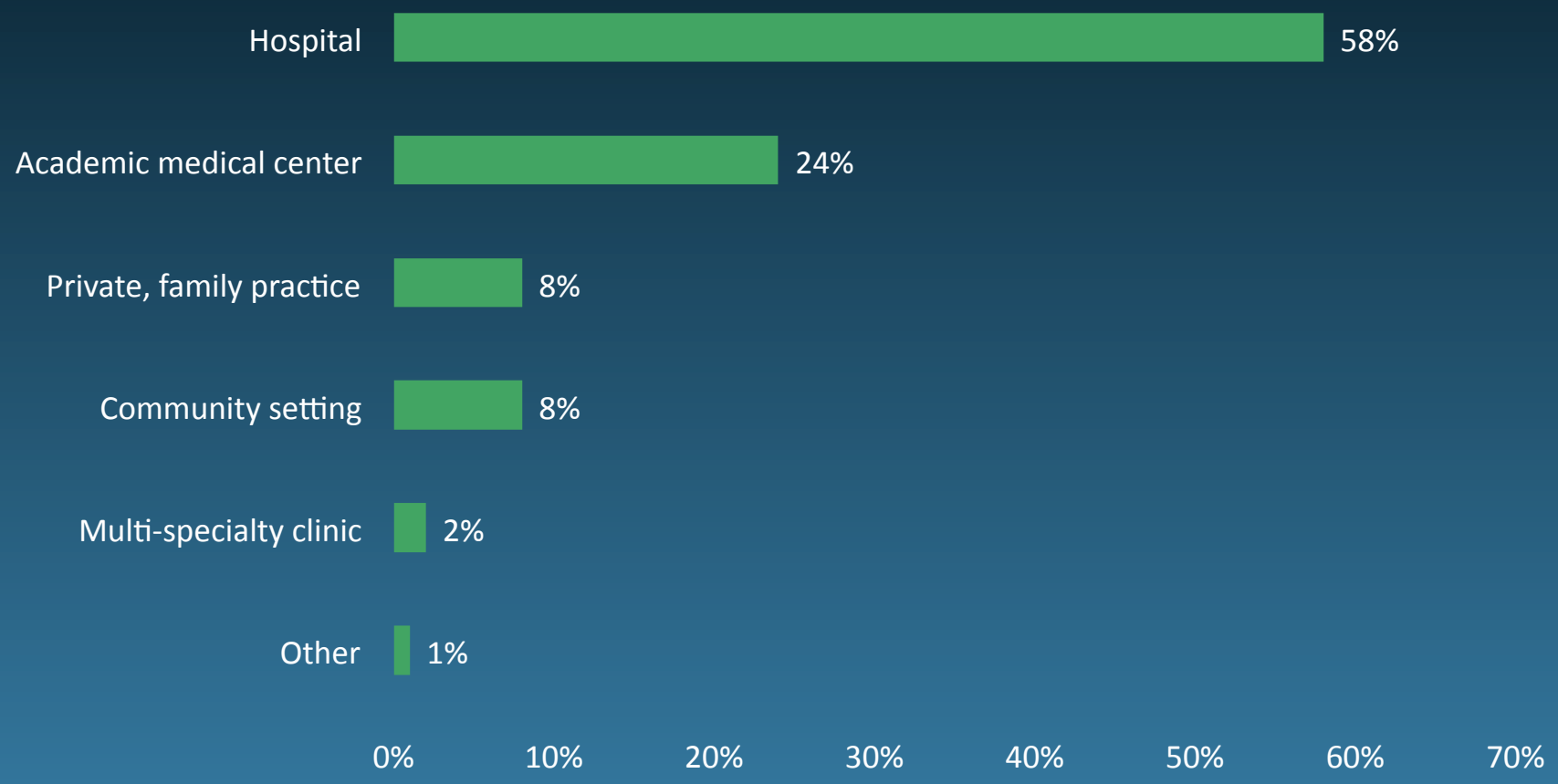
Appointments Per Week

Most respondents had more than 50 appointments per week:



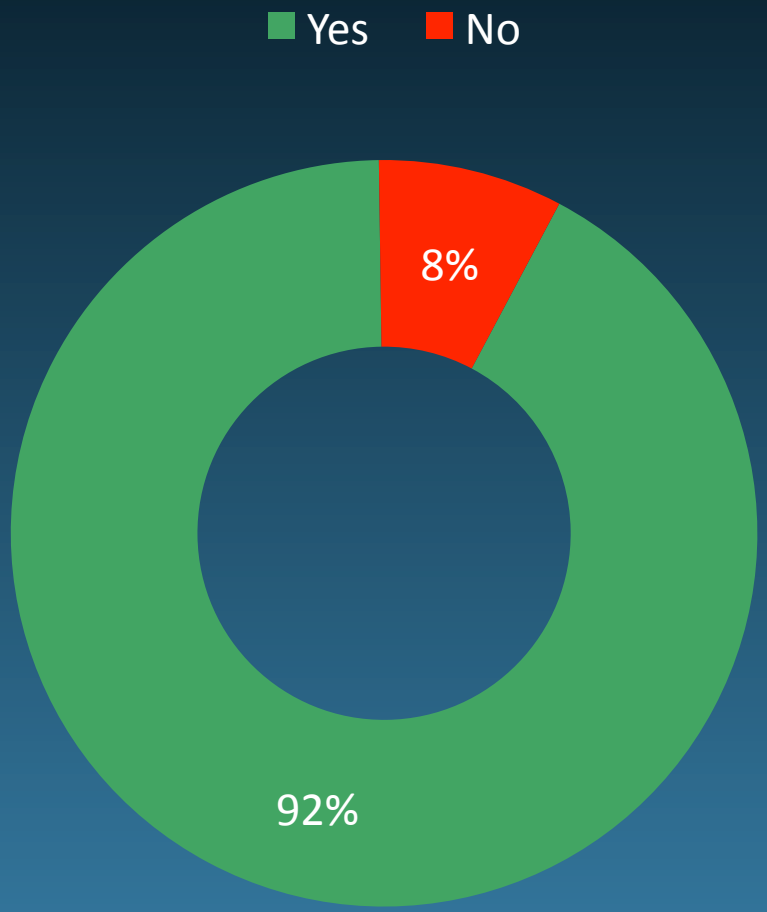
Practice Setting

The majority of respondents work in a Hospital setting:



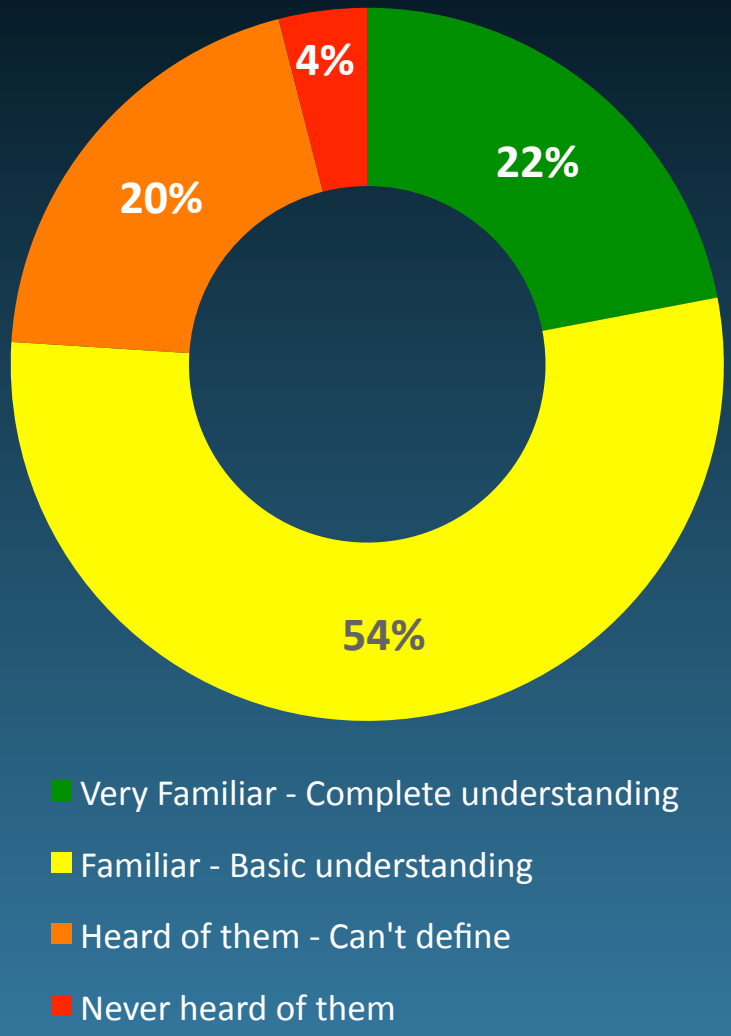
Experience Prescribing Biologic Medicines

- 92% of respondents prescribe biologics in their practice.



Familiarity Level with Biosimilars

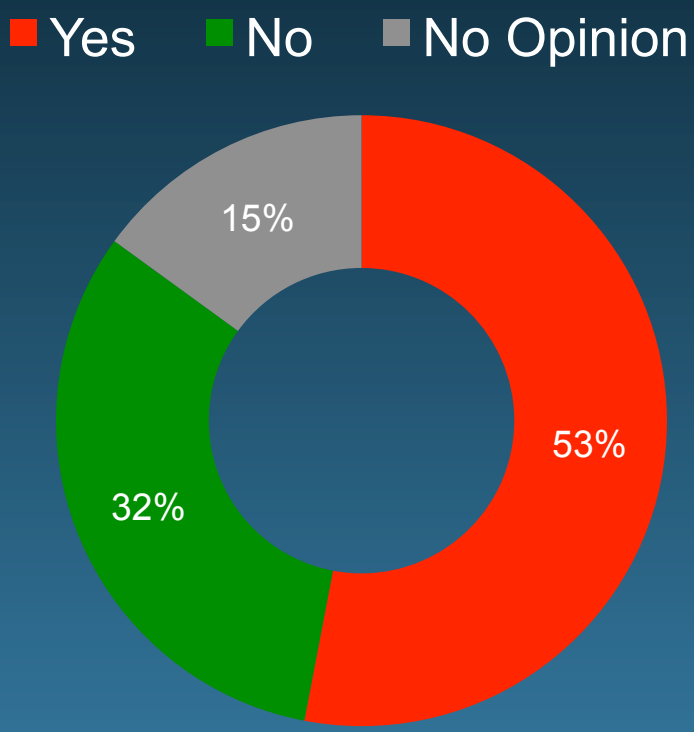
- 54% possess only a “basic understanding” of biosimilars
- Only 22% consider themselves “very familiar” with biosimilars
- 20% have heard of them but cannot define
- 4% have never heard of them



Same Non-proprietary Name = Structurally Identical?

"If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that the medicines are structurally identical?" (N=470)

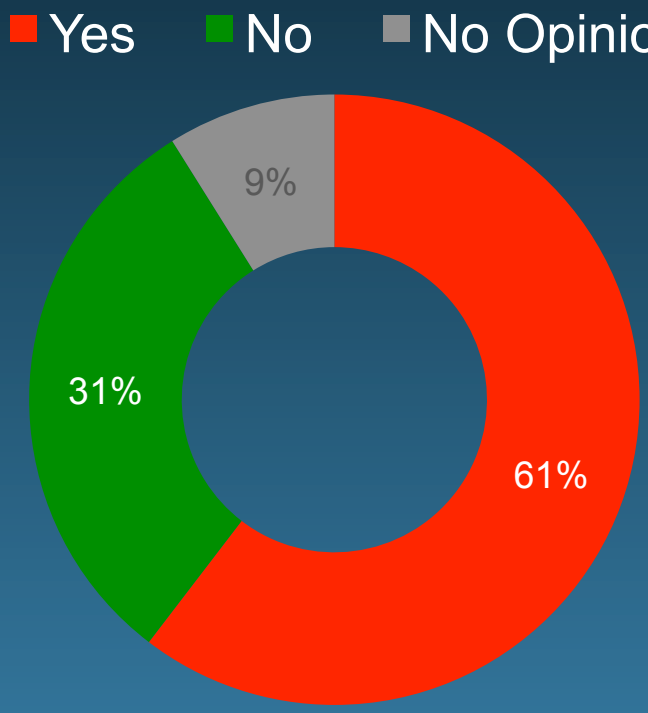
- 53% of respondents mistakenly believe biosimilars with identical non-proprietary name as its reference biologic is structurally identical to that reference biologic.



Same Non-proprietary name – Same Indications?

"If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that the medicines are approved for the same indications?" (N=470)

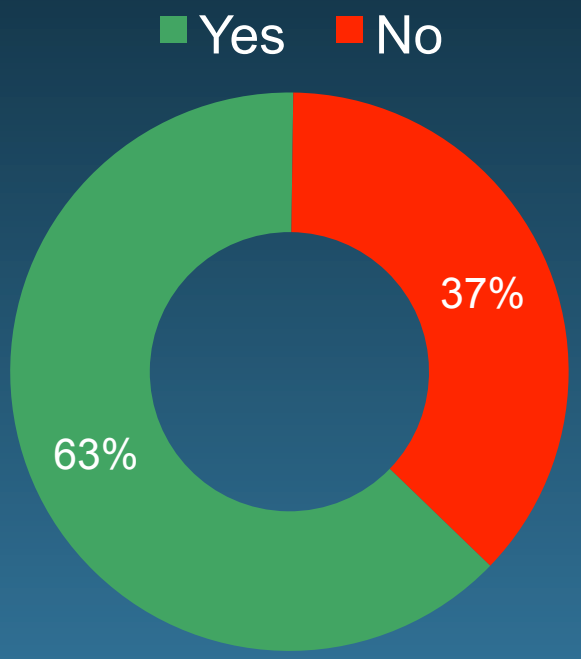
- 61% of respondents believe biosimilars with an identical non-proprietary name as its reference biologic is approved for the same indications, which may not be the case.



Awareness of Indication Extrapolation

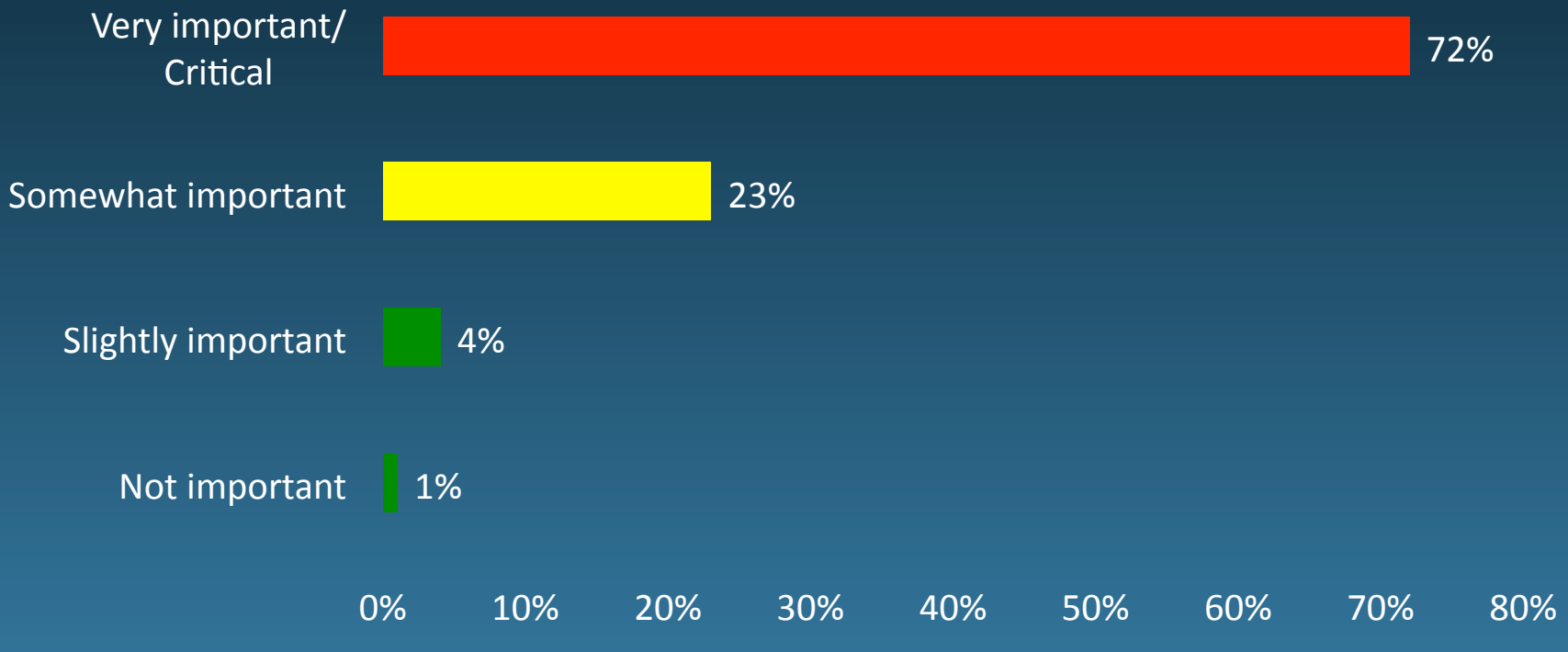
"Are you aware that a biosimilar may be approved for several or all indications of the innovator product on the basis of clinical trials in only one of those indications?" (N=470)

- 37% of prescribers are unaware that clinical trials in one indication may lead to approval of a biosimilar in multiple or all indications of the reference product



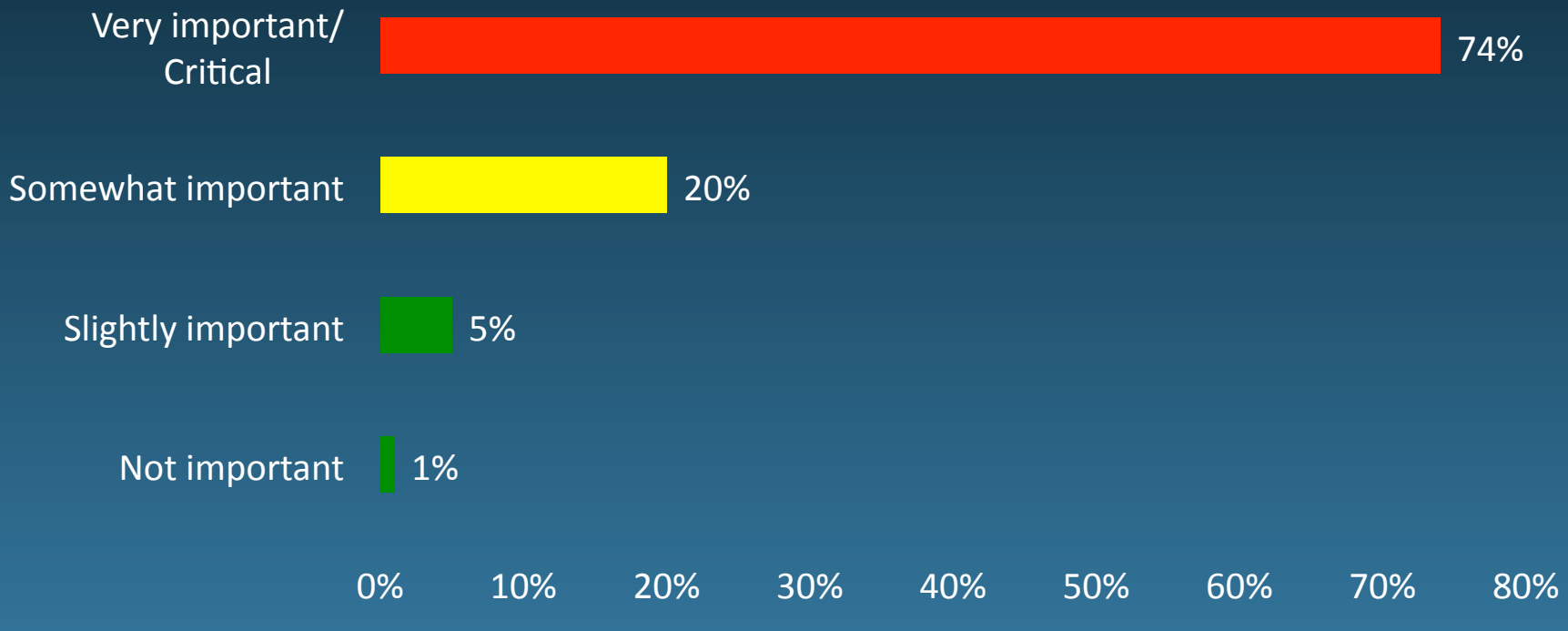
Importance of Sole Prescribing Authority

"How important is it to you to have the sole authority to decide, together with your patients, the most suitable biologic medicine for their disease?" (N=470)



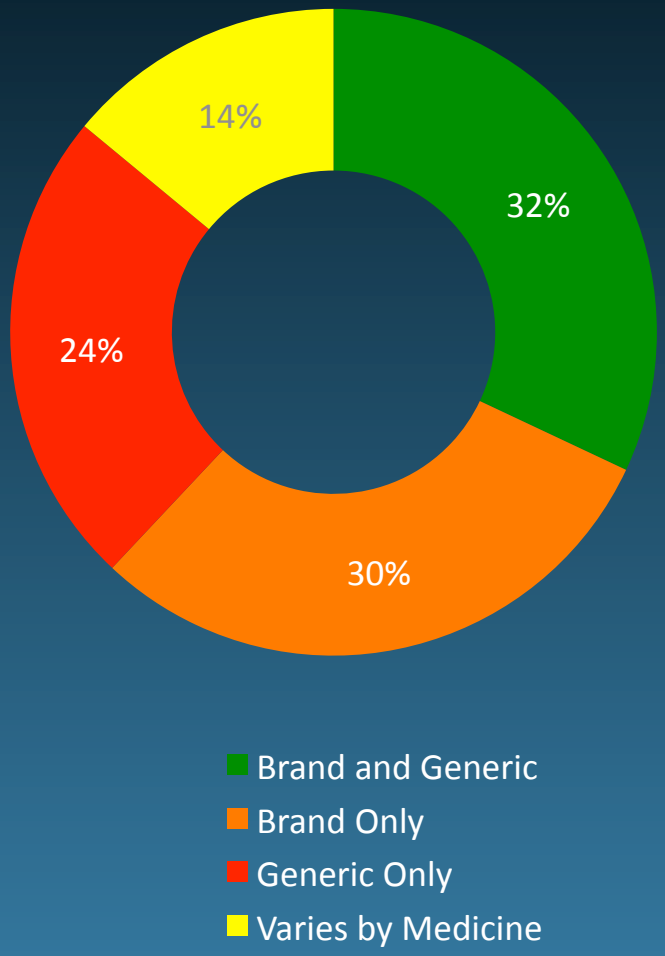
Importance of "Dispense As Written" Authority

"In a situation where substitution by a pharmacist was an option in your country, how important would it be to you to have the authority to designate a biologic medicine as 'DISPENSE AS WRITTEN' or 'DO NOT SUBSTITUTE'?" (N=470)



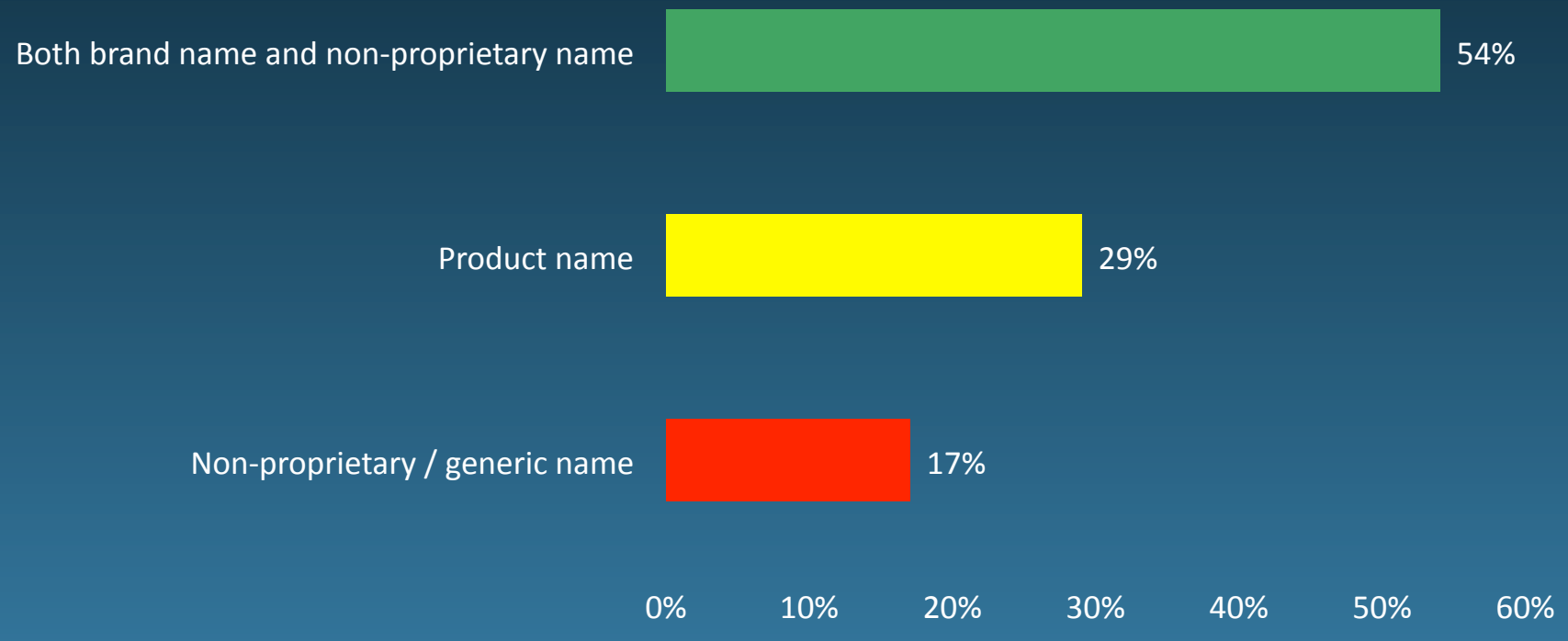
Identifying Biologic Medicines in Patient Record

- Only 32% of respondents use brand name and non-proprietary name (INN) to identify the exact biologic being prescribed.
- 24% use INN only, which could result in patients receiving the wrong medicine.



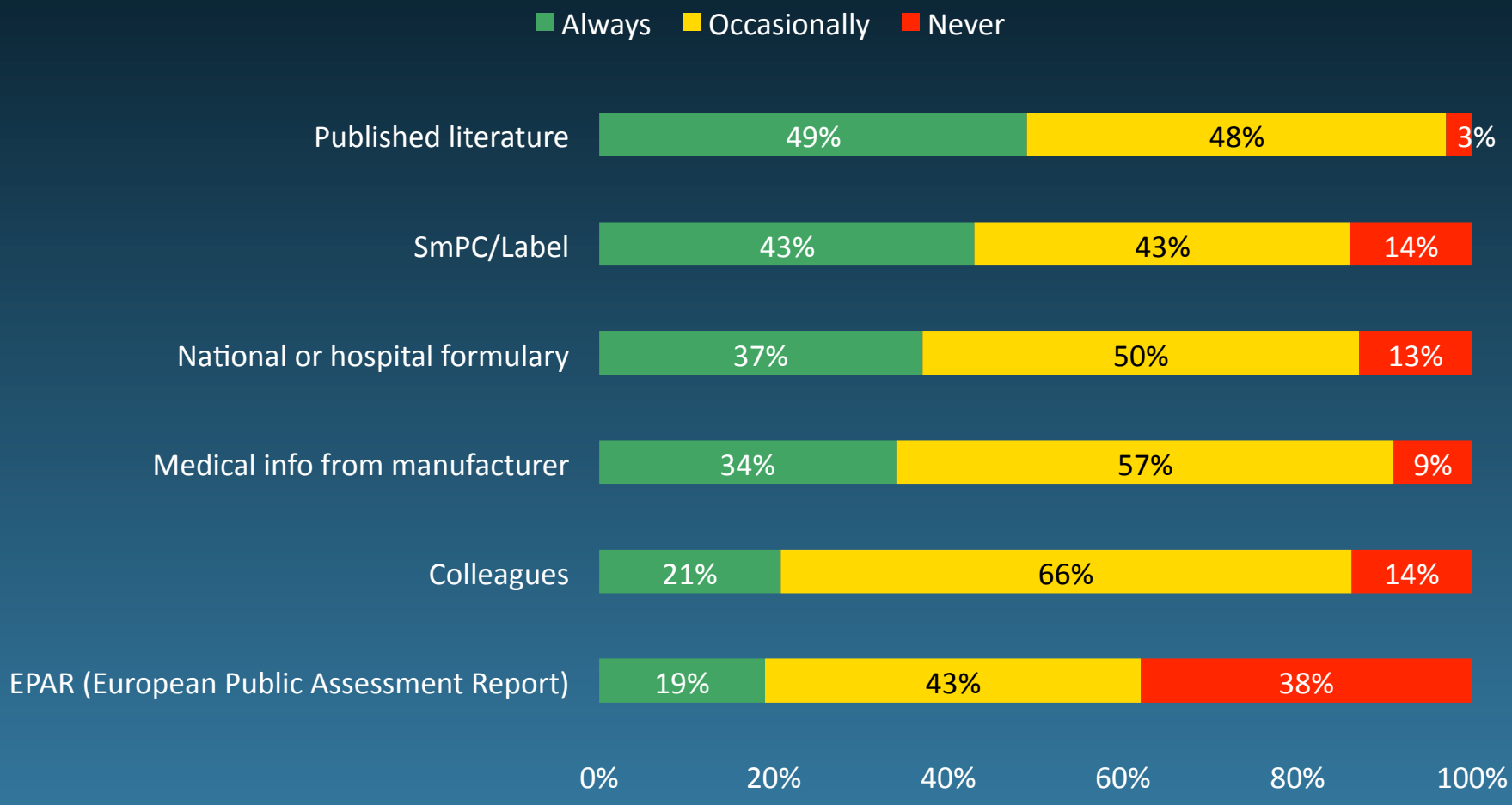
Reporting Adverse Events

- 17% report only the INN. Identical INN for two different medicines can result in pooling of adverse events, false attribution and other difficulties.



Information Sources Used For Learning About Medicines

"How often do you use each of the following sources to learn about the details of a medicine for prescribing and monitoring?" (N=470)



What We Learned

Survey identifies strong need for additional education and information on biosimilars among the European physician community.

Both physician misconceptions about biosimilars, and their prescribing practices, indicate a need for a clear naming scheme with distinguishable nonproprietary names for all biologics, including biosimilars, to facilitate clear prescribing and monitoring.

Physicians are gaining confidence in biosimilars, but remain adamant about need to retain sole prescription authority because of the complex nature of biologics.

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