SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

# *German Physician Perspectives on Biosimilars*

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Berlin, Germany

# *About ASBM*

# *The Alliance for Safe Biologic Medicines*

- 2010 ASBM formed to provide STAKEHOLDER GUIDANCE on biosimilars to regulators worldwide
- MEMBERS: consist primarily of physician and patient groups, EuropaBio, and BIOTECanada
- ADVISORY BOARD: Composed of Physicians, Researchers, Pharmacists, and Patients from around the world. Serves as resource on the science and clinical use of biosimilars, guides our policy recommendations
- Learn more at *www.safebiologics.org*

*“The Four Pillars”*

# ASBM’S GUIDING PRINCIPLES

PRIORITIZING PATIENT SAFETY

LEVERAGING WHAT WE HAVE LEARNED

PROMOTING PHARMACO-VIGILANCE

KEEPING DOCTORS RELEVANT

# *Recent ASBM Activity*

**August 14:** Chairman-elect Dr. Gewanter presented at the 4th Latin America Forum on Biosimilars in Brasília on physician perspectives on biosimilars


**August 24:** Co-founder and Steering Committee member Andrew Spiegel of the Global Colon Cancer Association presented at 16th PRE-ICDRA conference in Rio de Janeiro

**October 14:** Chairman presents at 59th WHO Consultation on International Nonproprietary Names

**October 20:** Presented to Italian Ministry of Health

**November 25:** Presented to Spanish Ministry of Health

# *European Prescriber Survey*

- First large-scale survey on biosimilars in Europe.
- Examined physician knowledge and prescribing practices.
- 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.
- **June 2014**: Findings were subject of research paper in the *Journal of the Generics and Biosimilars Initiative (GaBI Journal)*


*Conducted by Industry Standard Research, October-November 2013*

# *EU Physician Survey Identified Need for Education… and Distinguishable Names.*

BIOSIMILAR KNOWLEDGE

- Only 22% of respondents consider themselves ”very familiar” with biosimilars. 25% cannot define or have not heard about biosimilars before
- 37% of prescribers are unaware that clinical trials in one indication may lead to the approval of a biosimilar in multiple or all indications of the reference product

IF TWO MEDICINES SHARE AN INTERNATIONAL NON-PROPRIETARY NAME (INN):

- 54% incorrectly believe this implies they are structurally identical
- 61% believe this implies they been approved for the same indications, this may not be the case

WHEN PRESCRIBING BIOLOGICS:

- 24% use only the non-proprietary name, which may lead to patients receiving the wrong medicine

ADVERSE EVENT REPORTING:

- 54% of prescribers use both brand and INN
- 29% only report the brand name
- 17% only communicate the INN, which may lead to false attribution of adverse events.

# *European Physicians and Pharmacy Substitution*

Physicians are very serious about their leading role in deciding whether a patient should receive an originator biologic medicine or a biosimilar.

- 62% stated that it is “not acceptable” for a pharmacist to determine which biologic medicine to dispense.
- 72% of prescribers consider it “Critical” or “Very Important” to be notified in the case of a substitution
- 74% considers it “critical” or “very important” that physicians be able to block a substitution by writing “dispense as written” or “do not substitute”

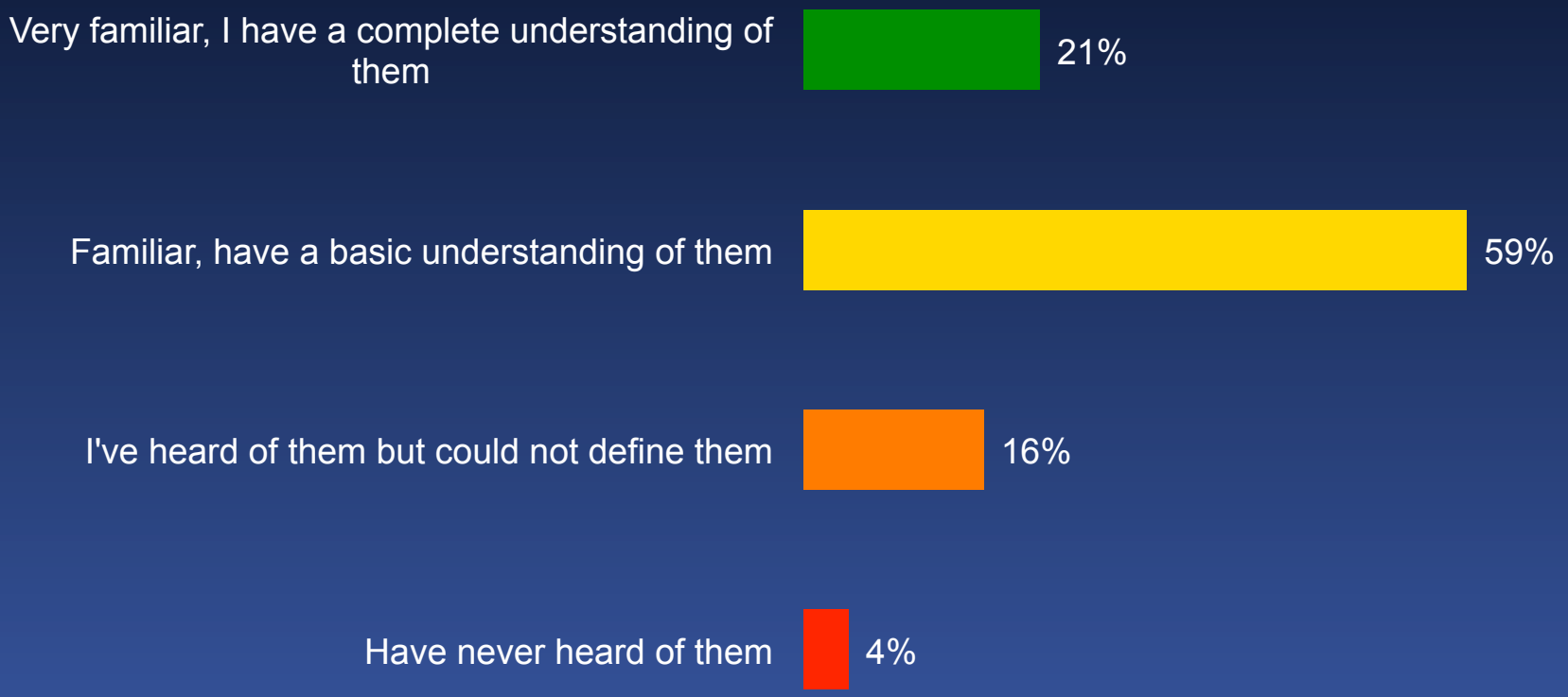
# *German Physician Responses*

# *Familiarity with Biologic Medicines*

*"How familiar are you with biologic medicines?" (N=94)*

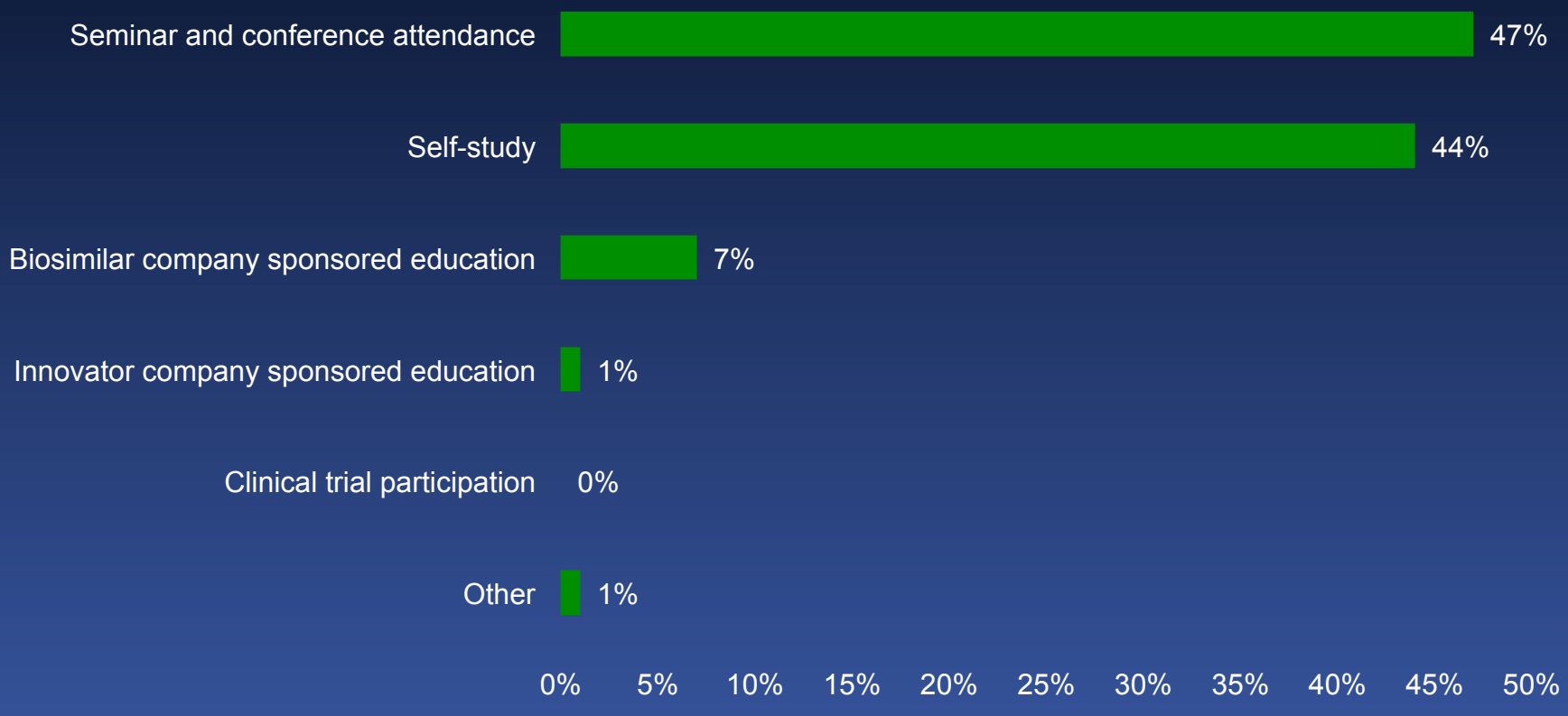
# *Familiarity with Biosimilar Medicines*

*"How familiar are you with biosimilar medicines?" (N=94)*



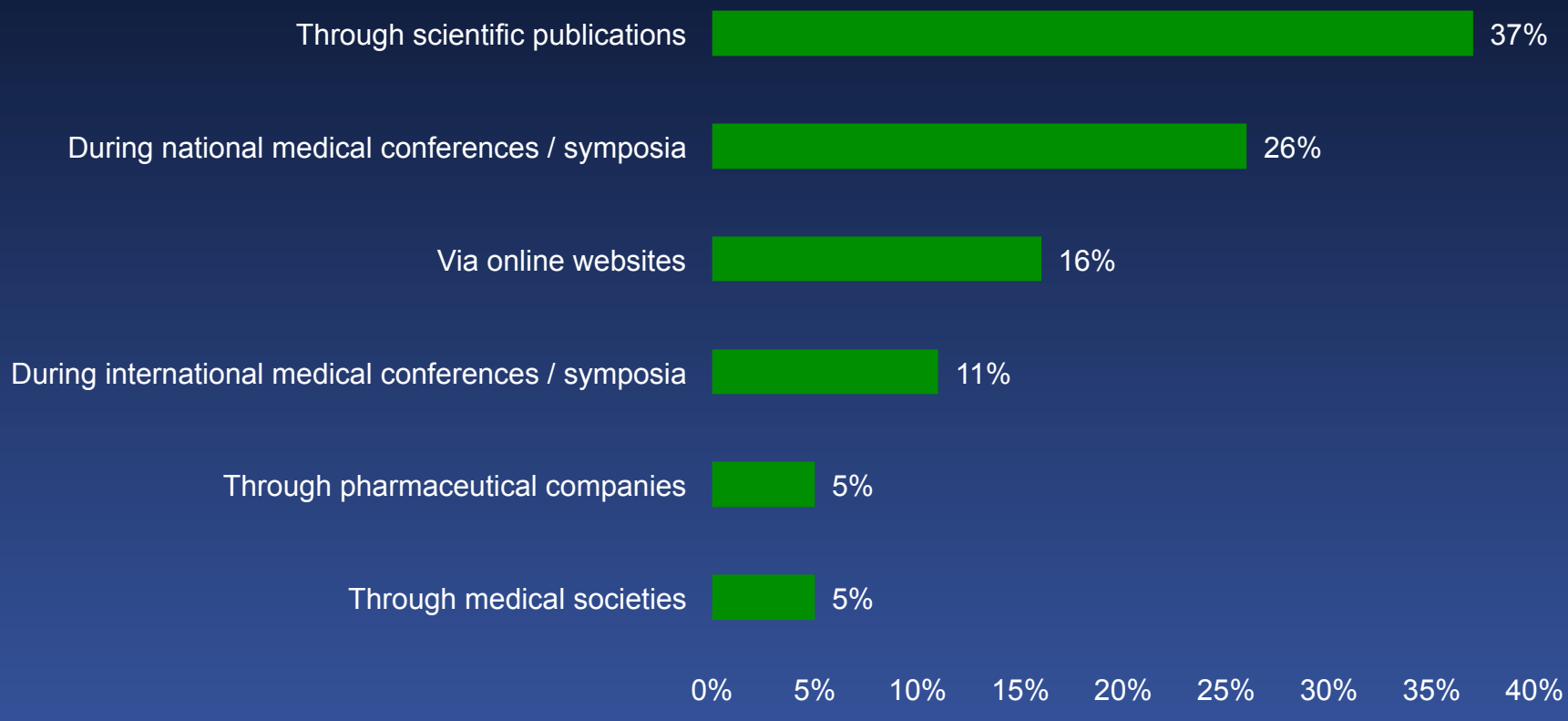
# *How Respondents Learn About Biosimilars*

*"How did you become familiar with biosimilar medicines?" (N=75)*



# How You Would Prefer to Learn About Biosimilars

*"How would you prefer to learn about biosimilars?" (N=19)*



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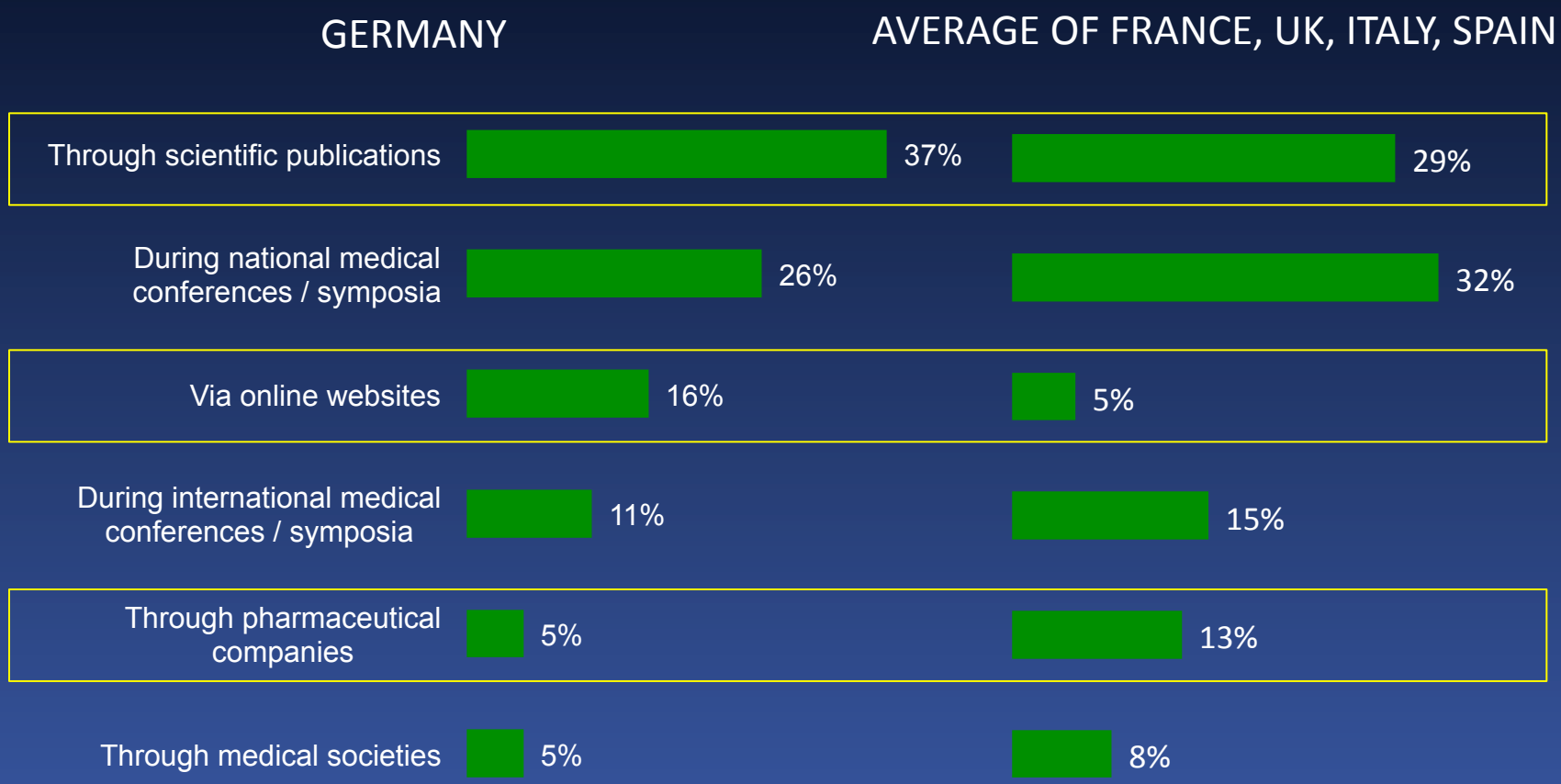
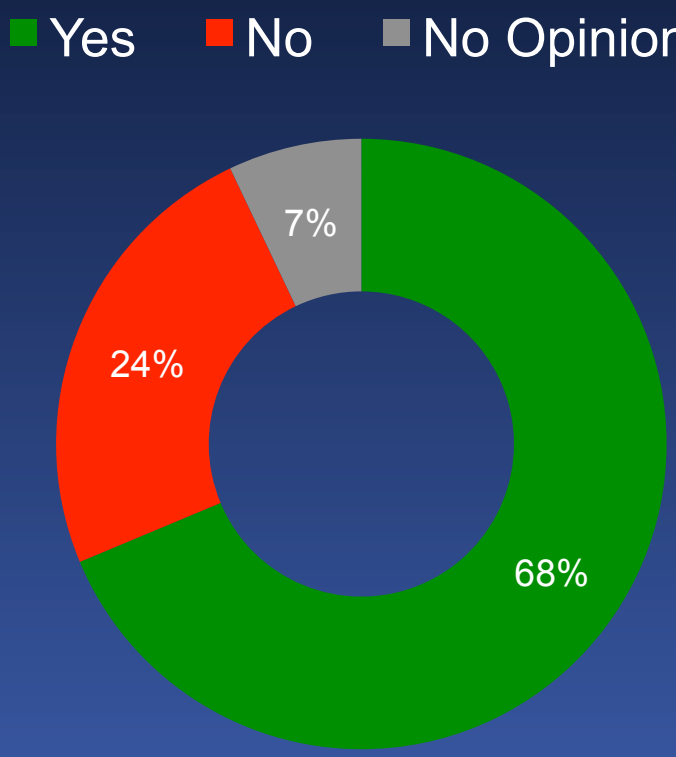


# *Non-proprietary Name Implications – Structurally Identical?*

*"If two medicines have the same non-proprietary scientific name, does this suggest to you or imply that the medicines are structurally identical?" (N=94)*



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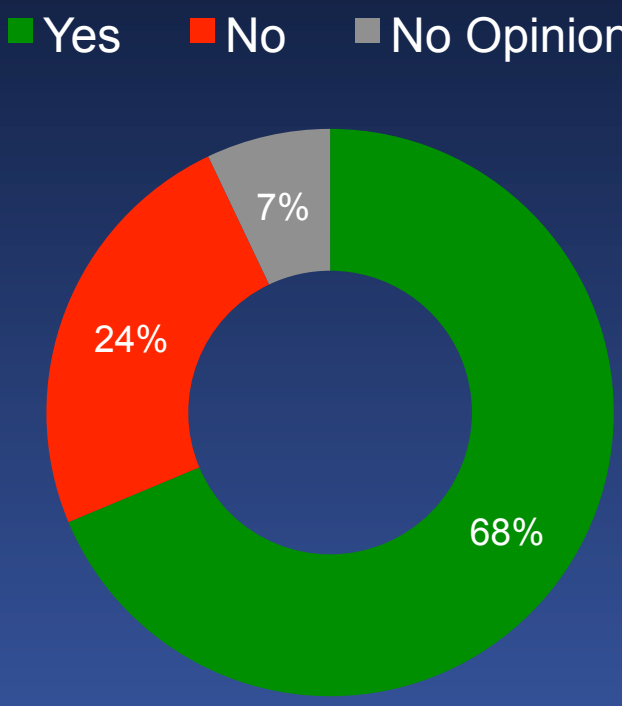
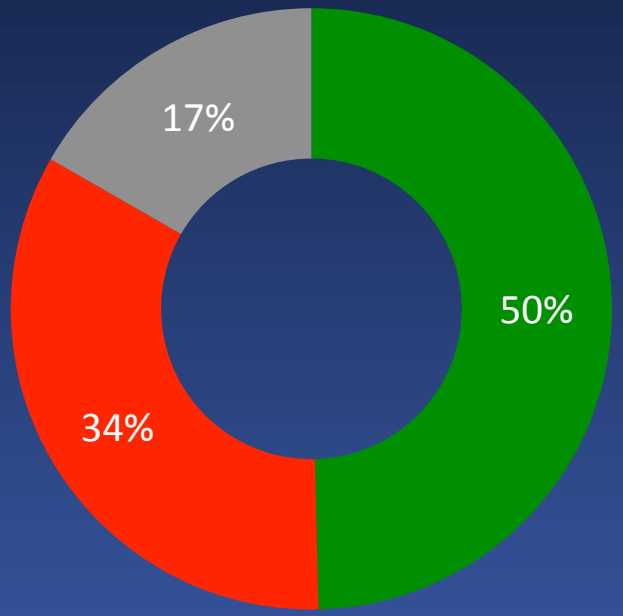


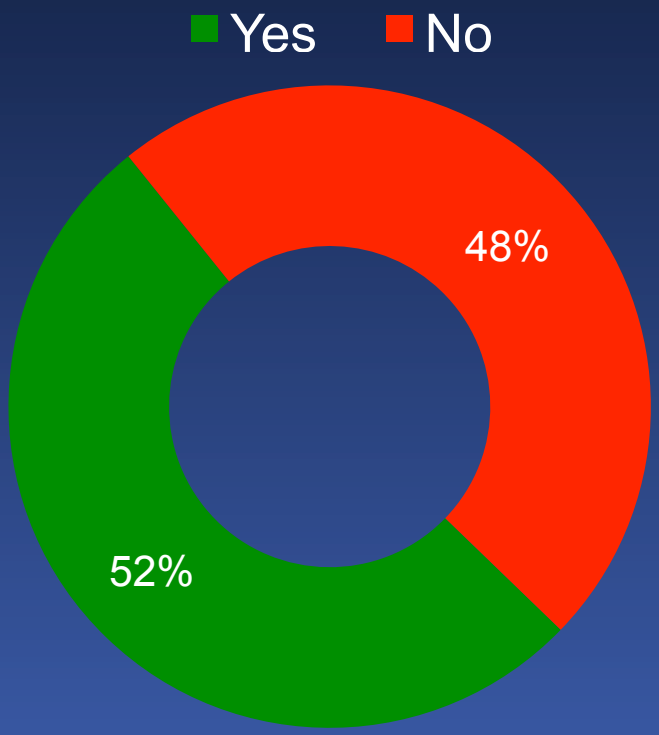

GERMANY




AVERAGE OF FRANCE, UK, ITALY, SPAIN

# *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=94)*



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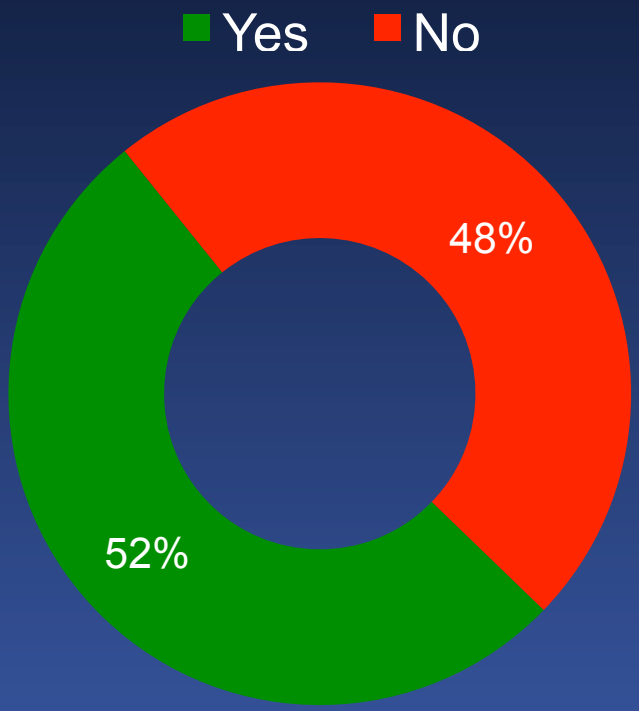


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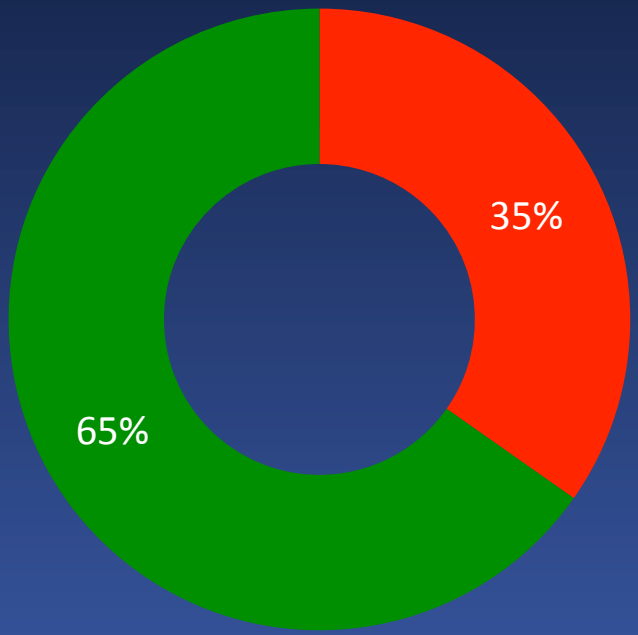
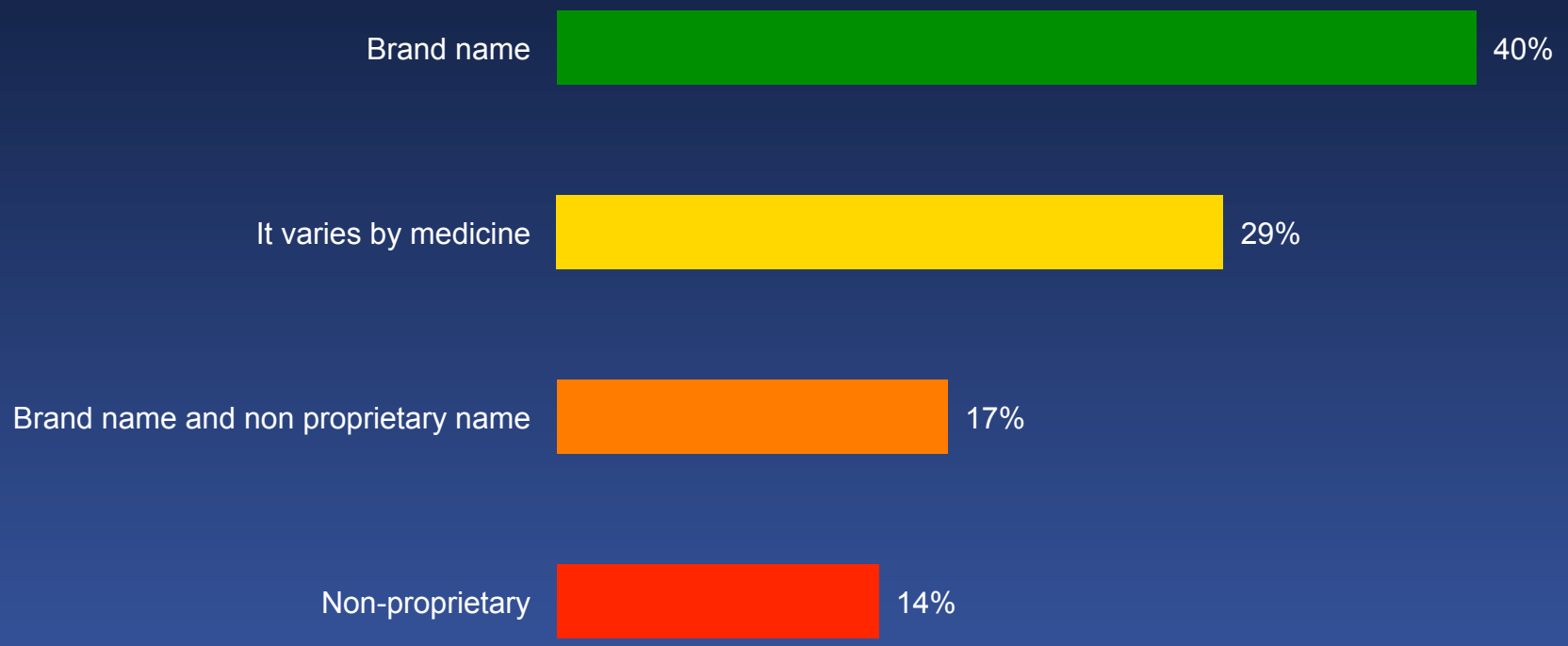



AVERAGE OF FRANCE, UK, ITALY, SPAIN


Prescribing, Recording, & AE Reporting

# *Biologic Recording – Patient Record*

*"How do you identify a biologic medicine for prescription or recording in a patient record? Do you identify the medicine by brand name (eg, Remicade, Herceptin) or non-proprietary name (eg, infliximab, trastuzumab)?" (N=63)*



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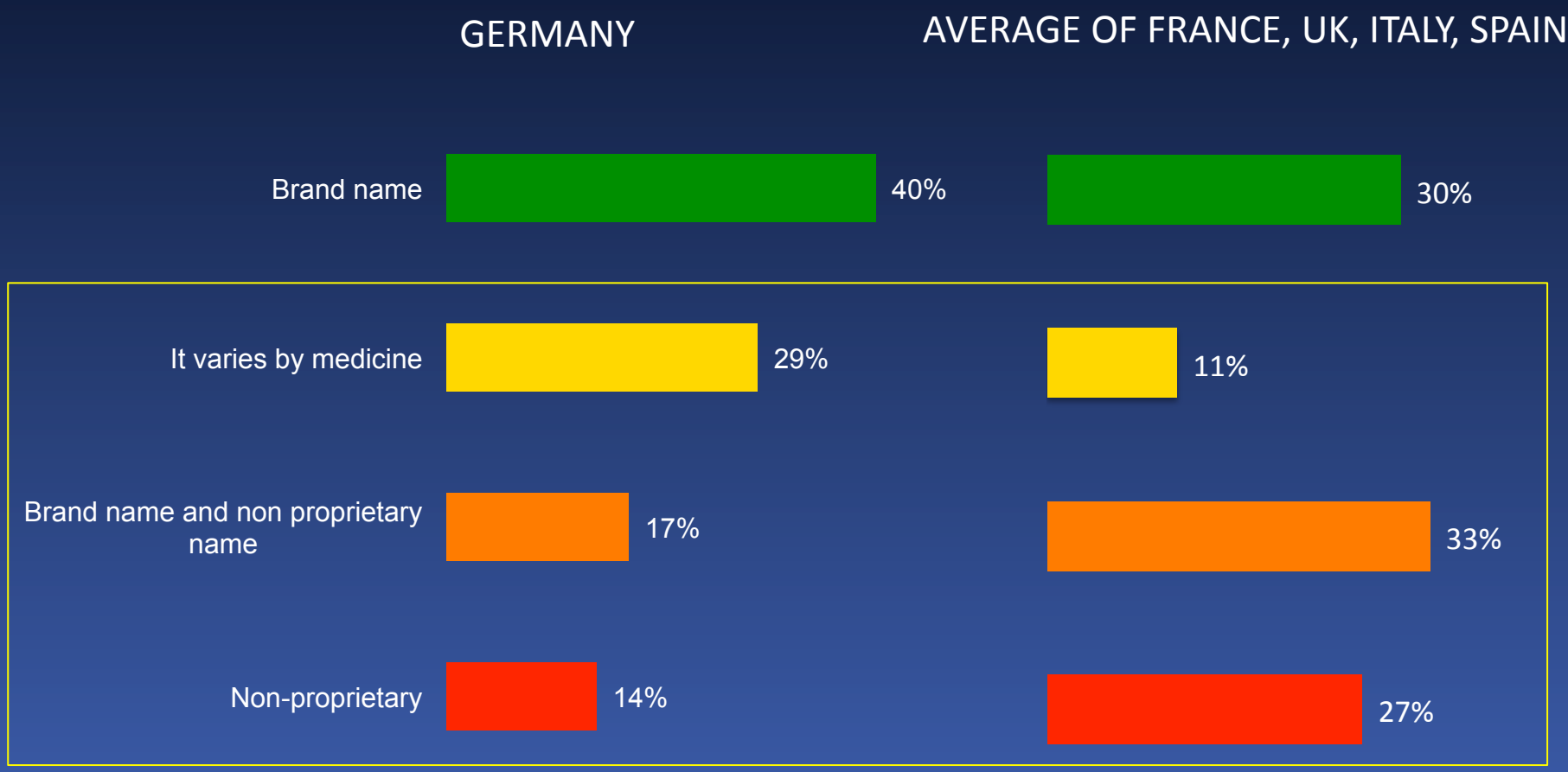
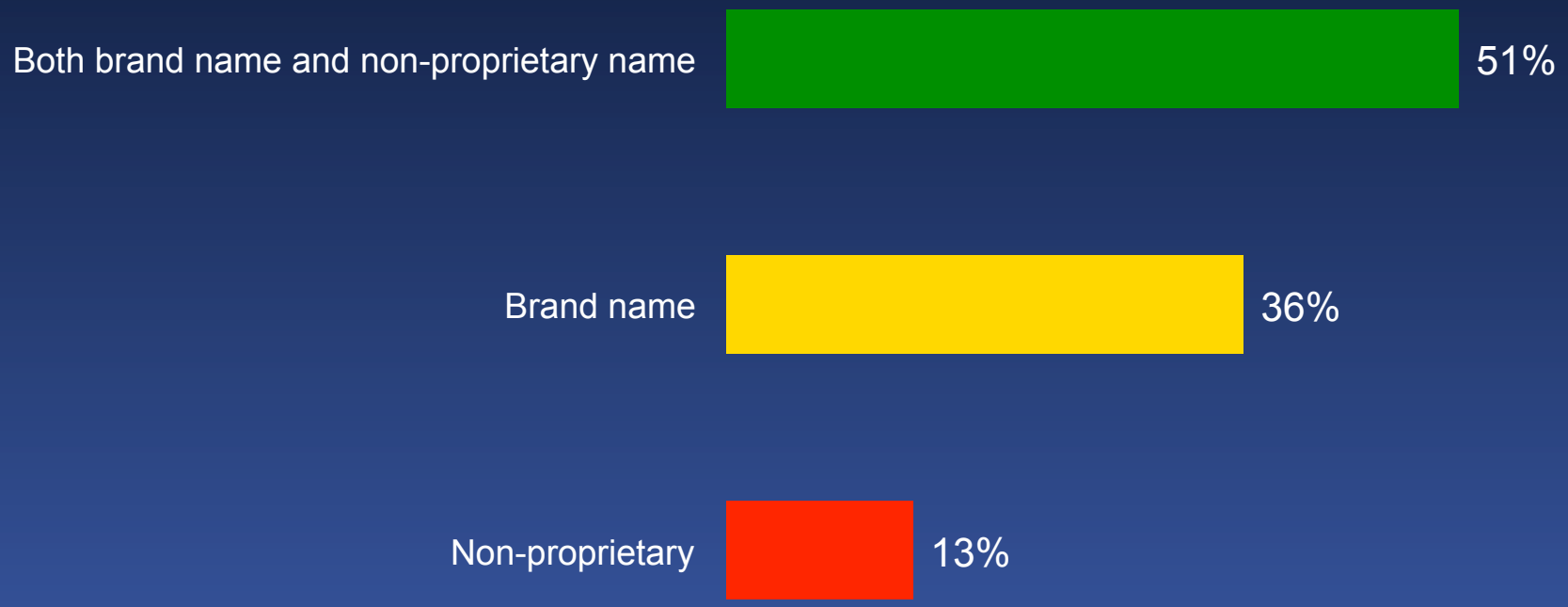


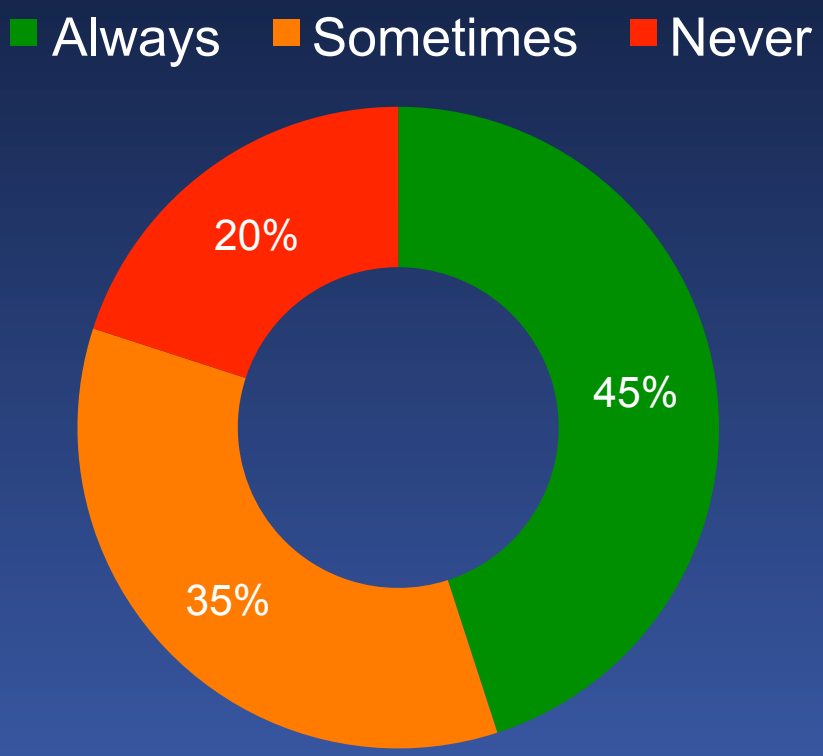
# *Biologic Recording – Adverse Events*

*"Physicians play an important role in the identification and reporting of unexpected or serious adverse events to their national regulatory agencies and manufacturers. In the context of identifying a biologic (or, if you don't prescribe biologics, any other drug) for purposes of reporting an adverse event, how do you identify the medicine?" (N=94)*



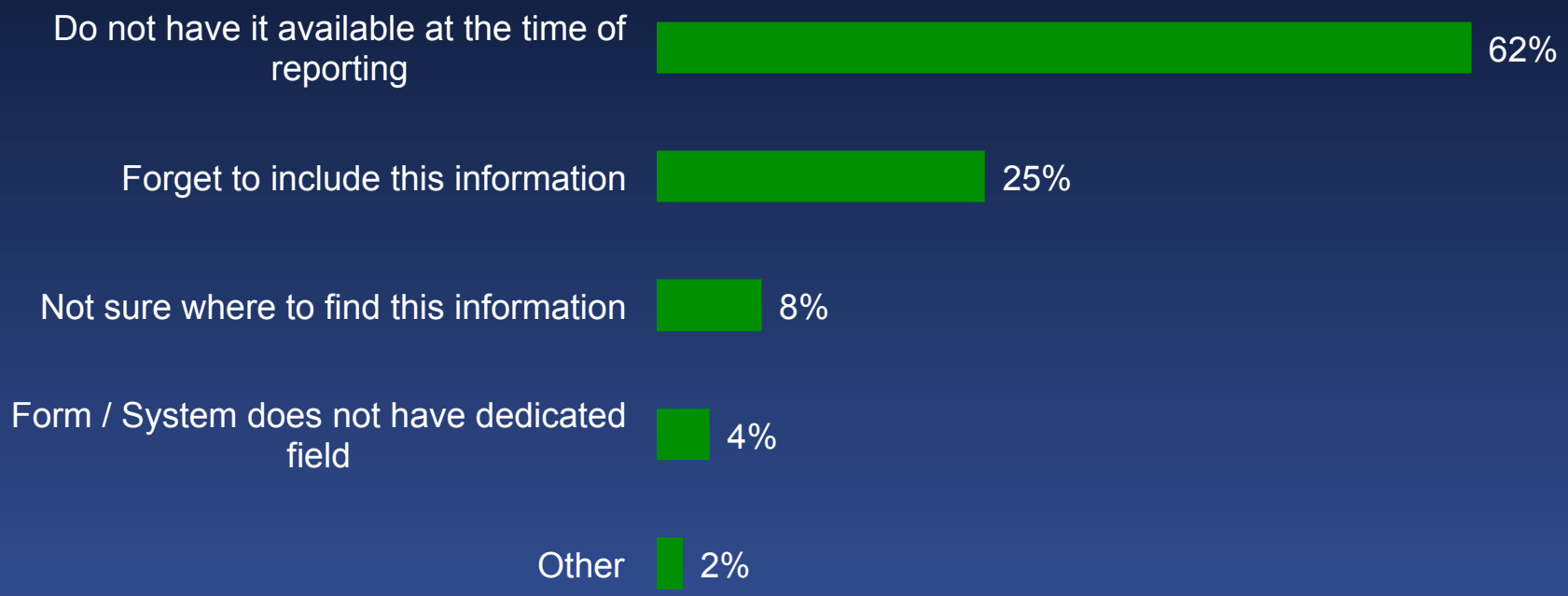
# *Batch Number Inclusion*

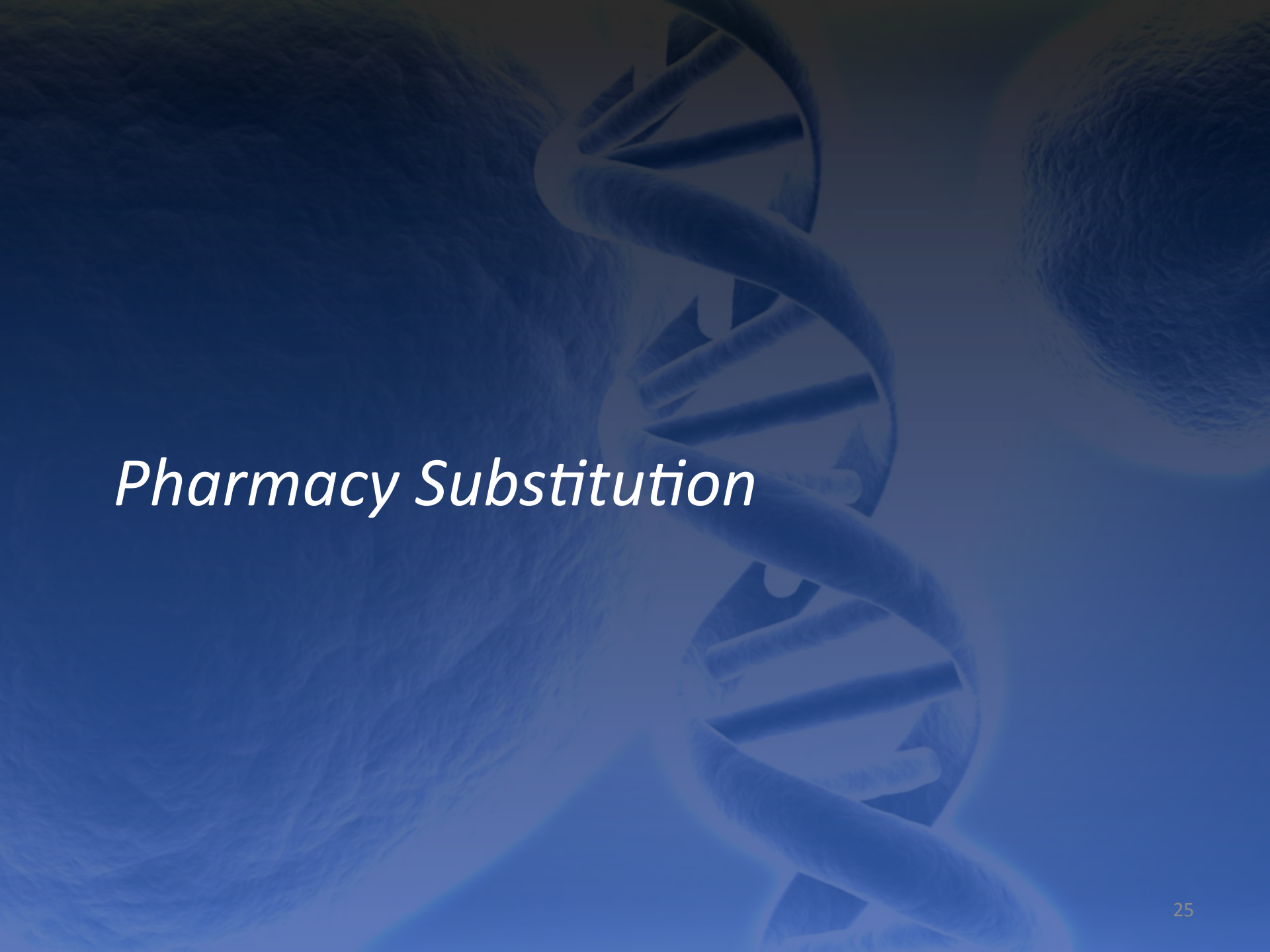
*"How often do you include the batch number when reporting adverse events?" (N=94)*



# *Reason for Not Including Batch Number*

*"If your answer to question 18 was 'Sometimes' or 'Never', what are the main reasons for not reporting the batch number?" (N=52)*

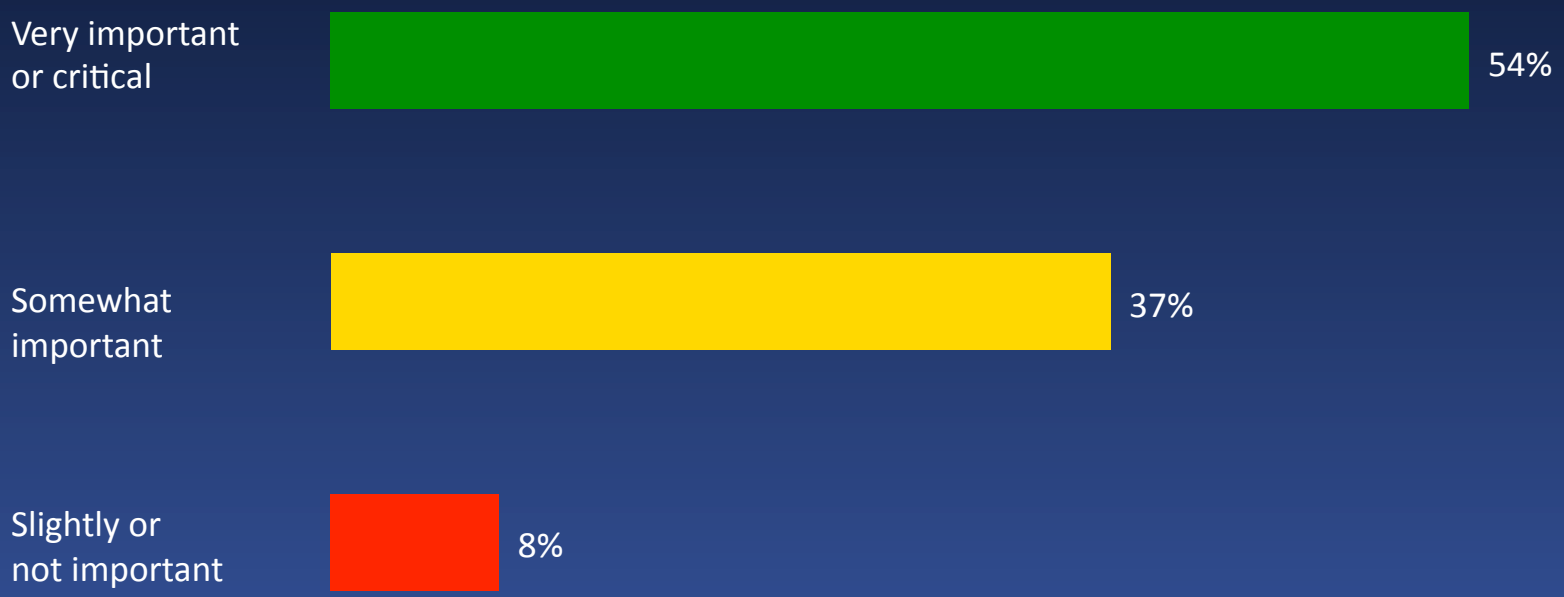




# *Pharmacy Substitution*

# *Importance of 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=94)*



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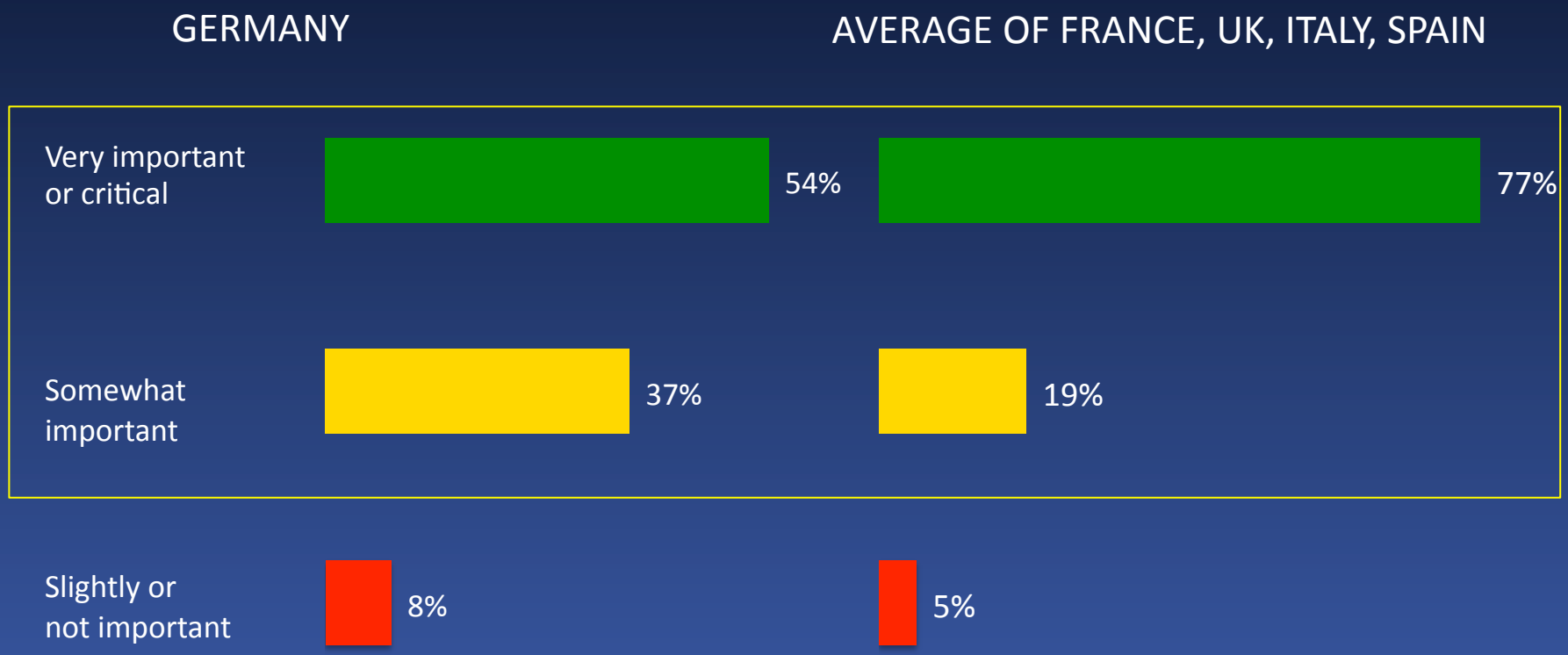

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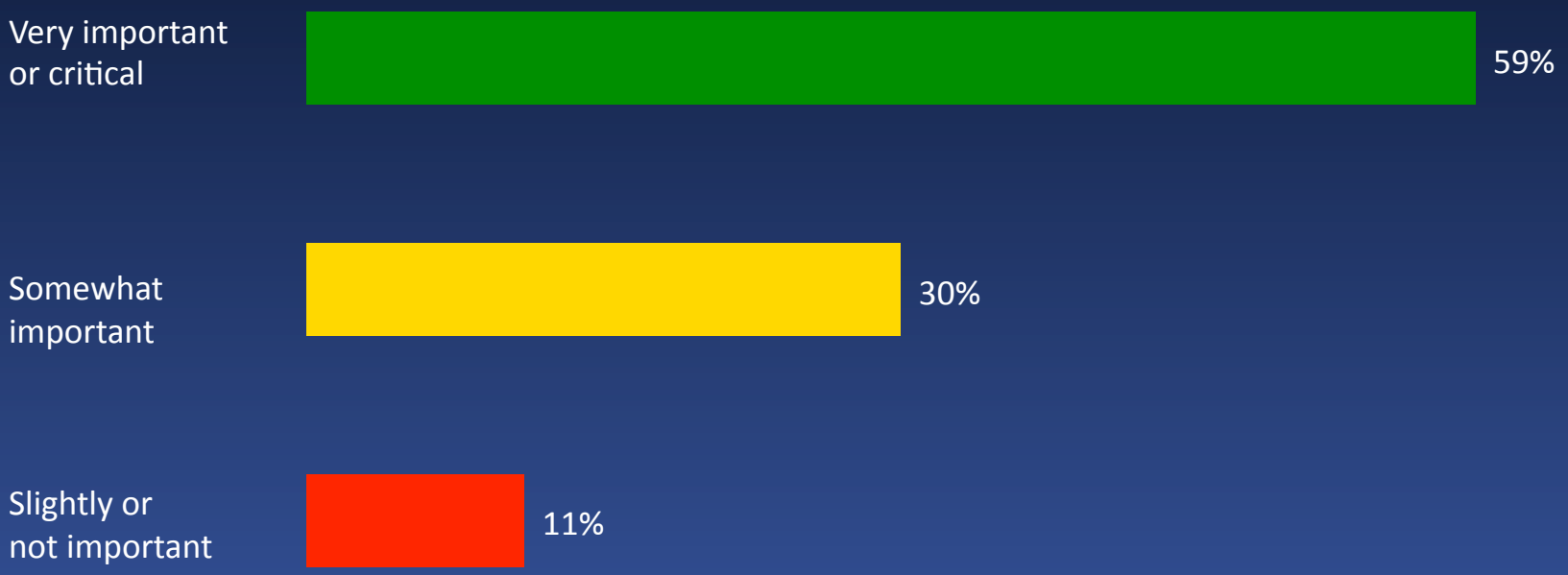

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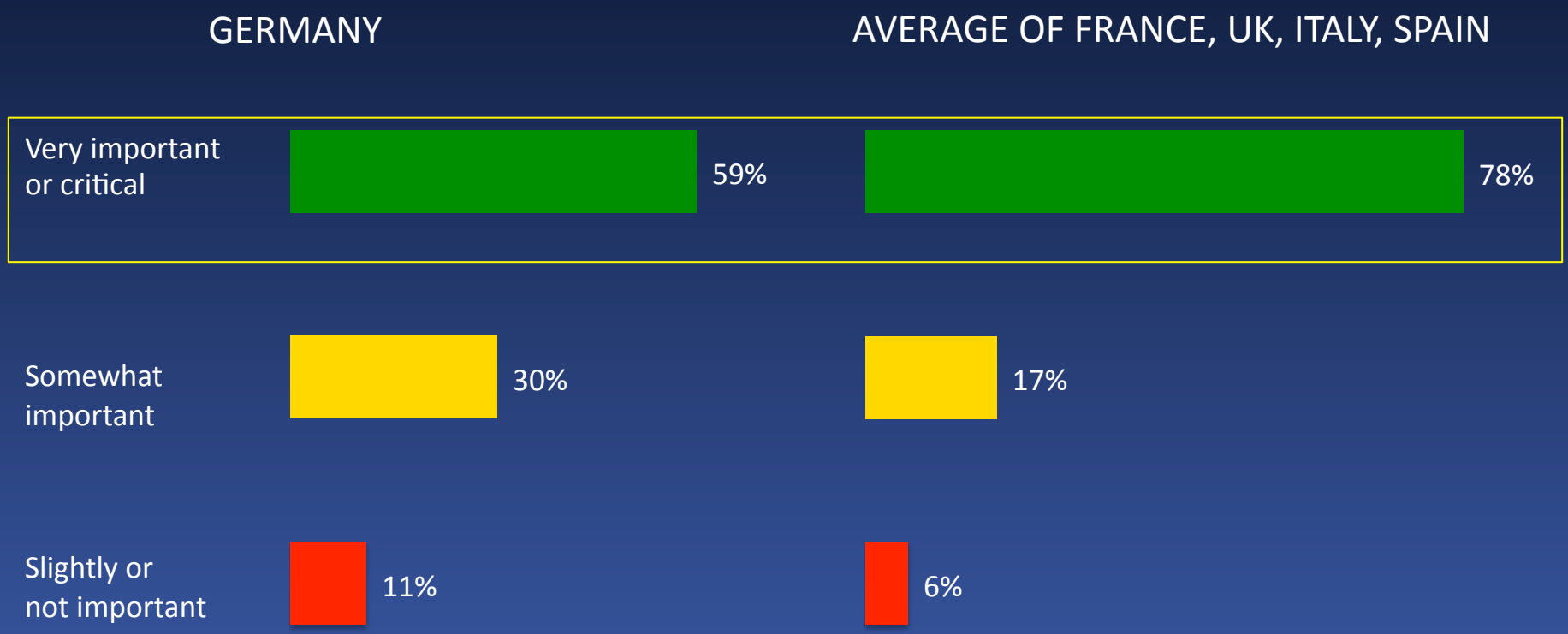

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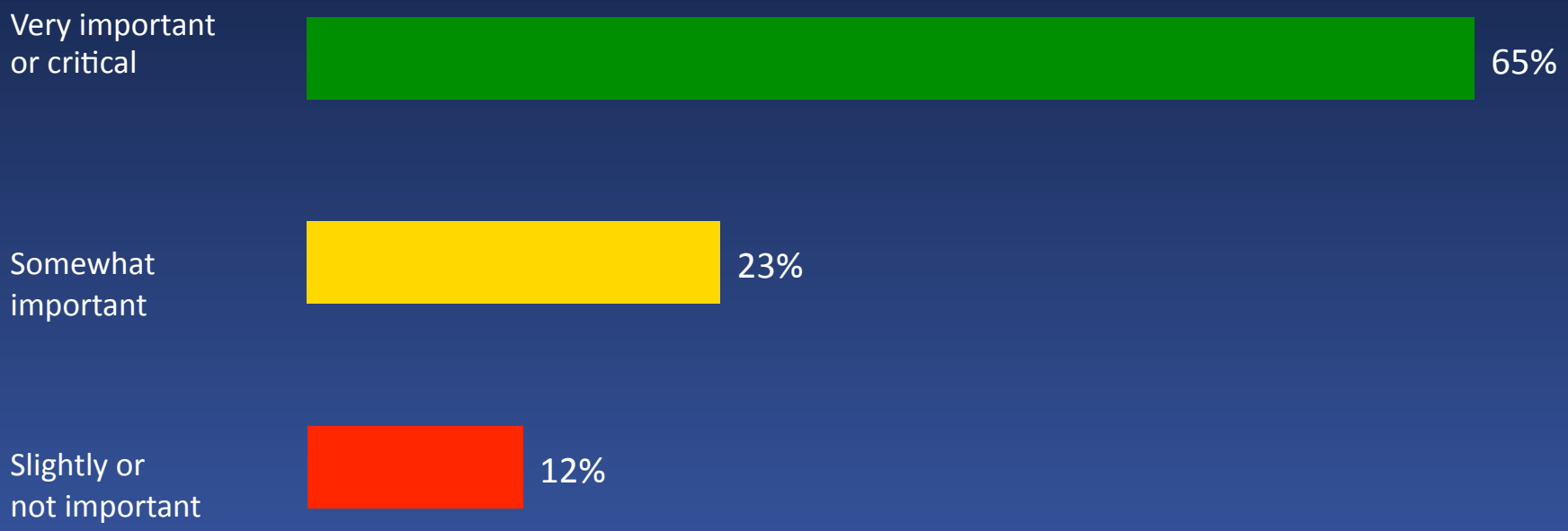

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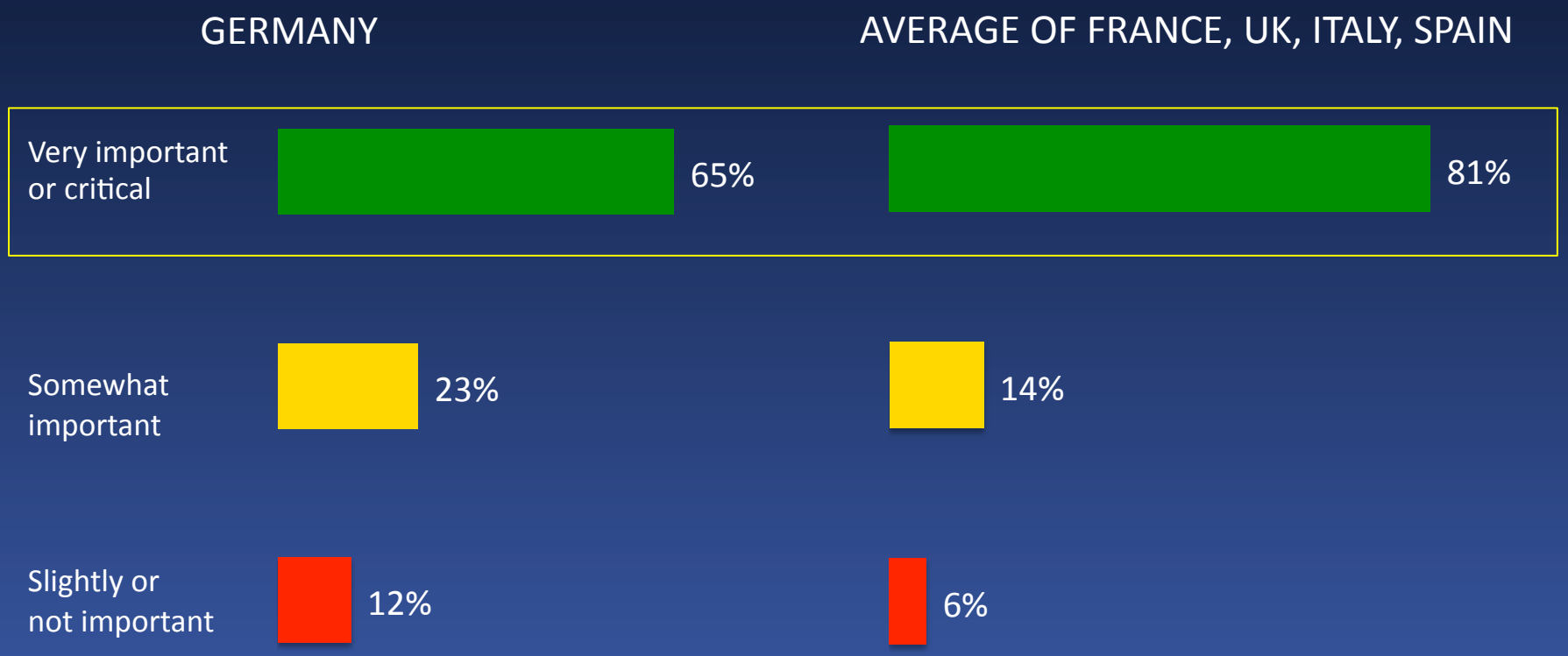
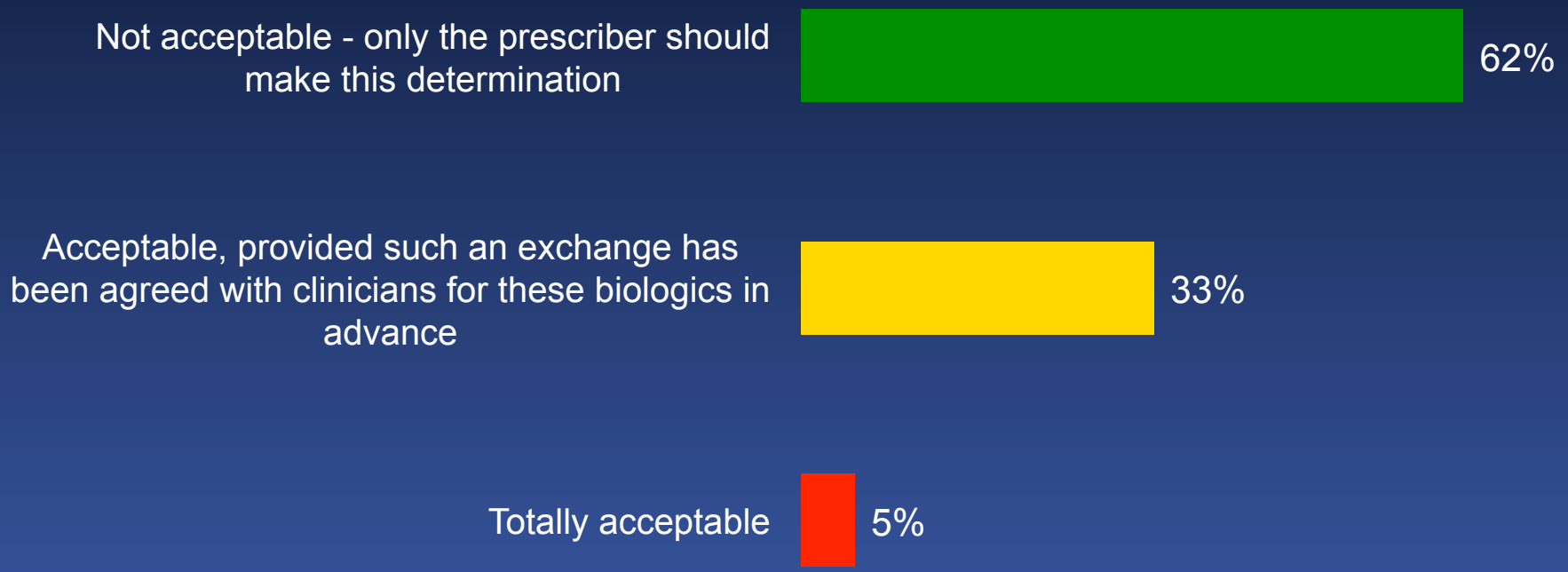


# *Acceptability of pharmacist determination*

*"How acceptable would it be for you if the pharmacist made the determination which biologic (innovator or biosimilar) to dispense to your patient on initiation of treatment?" (N=94)*



# *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.


*Thank You For Your Attention*