

BACKGROUND

- Biosimilars are highly similar, but not identical to originator biologics. In an increasingly resource-constrained environment, switching patients from originator biologics to biosimilars is a growing practice in many jurisdictions.
- Though automatic substitution of originator biologics with biosimilars is rare in Europe, this practice excludes physicians from decisions regarding the treatment of their patients.
- The Alliance for Safe Biologic Medicines (ASBM) commissioned 15-minute web-based surveys among biologic prescribers in 6 Western European countries to empirically document their perspectives on biologic substitution.
- This survey follows one conducted in 2013 (n=470). Both may be found at: www.safebiologics.org/surveys
- As countries seek to control health costs and expand access to biologic therapies, building physician confidence in biosimilars is critical to promoting their use and reaping the cost benefits.
- These findings may serve as a resource for countries in developing biosimilar policies which build physician confidence in biosimilars.

METHODS

Eligibility Criteria

- Must prescribe biologic medicines in their practice
- Must practice in France, Germany, Italy, Spain, Switzerland, or United Kingdom.
- Must specialize in one of 10 practice areas: Dermatology, Endocrinology, Gastroenterology, Hematology Oncology, Immunology, Nephrology, Neurology, Oncology, Ophthalmology, Rheumatology

Online Surveys

Surveys were administered in March 2019 by Industry Standard Research, LLC. Prescribers were asked to rate:

- The importance of retaining sole authority to decide the most suitable biologic for their patients.
- The importance of retaining the authority to deny/prevent a substitution by indicating "Do Not Substitute" or similar language when prescribing.
- Their comfort level with a.) prescribing a biosimilar to a new (treatment-naïve) patient; and b.) switching a stable patient from an originator biologic to a biosimilar.
- Their comfort level with a biosimilar switch for non-medical reasons (e.g., cost, coverage) a.) when performed by the physician and b) when performed by a third party.
- The importance of awarding government tenders on originator biologics and biosimilars to multiple suppliers.
- The importance of national tender offers including factors besides price.

Disclosure

ASBM is a group of physicians, pharmacists, patients, researchers, manufacturers, and others working together to promote the safe introduction and use of biosimilars. This survey was funded by ASBM.

RESULTS

Responses

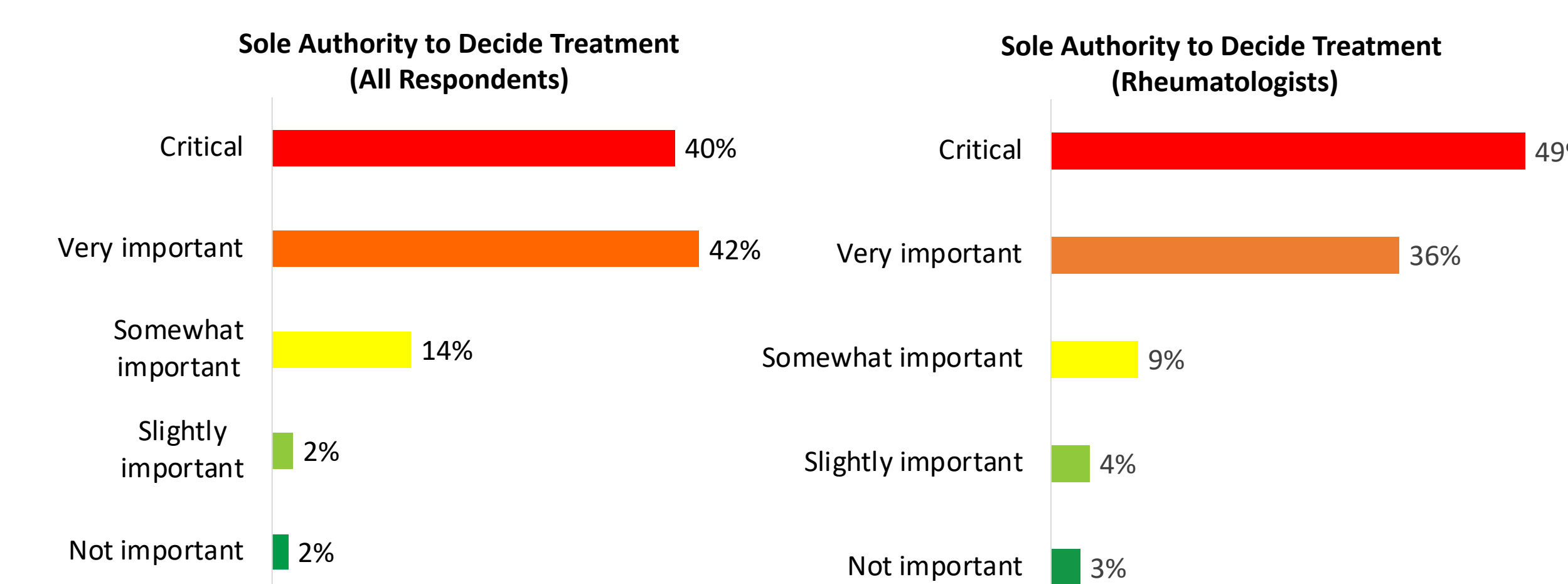
A total of 579 responses were received, 17% from each of the six countries surveyed.

- The largest group of prescribers (47%) practice in a hospital setting, with the remainder in academic medical centers (23%) private/family practice (18%), multi-specialty clinics (8%), community settings (3%) and other settings (1%).
- Respondents' mean experience level was 15.5 years in practice.
- The percentage of physicians who rate themselves as being "familiar" or "very familiar" with biosimilars has increased from 76% in 2013 to 90% in 2019.
- Rheumatologists (n=80) demonstrated the highest familiarity among practice areas surveyed (99% "familiar" or "very familiar")

Treatment Decision 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=579)

- A strong majority of Respondents (82%) feel that it is either "Very Important" or "Critical" for them to decide which biologic medicine is dispensed to their patients, an increase (from 72%) in the 2013 survey.
- Among Rheumatologists this percentage that considered this authority "Very Important" or "Critical" increased from XX in 2013 to 85% in 2019.

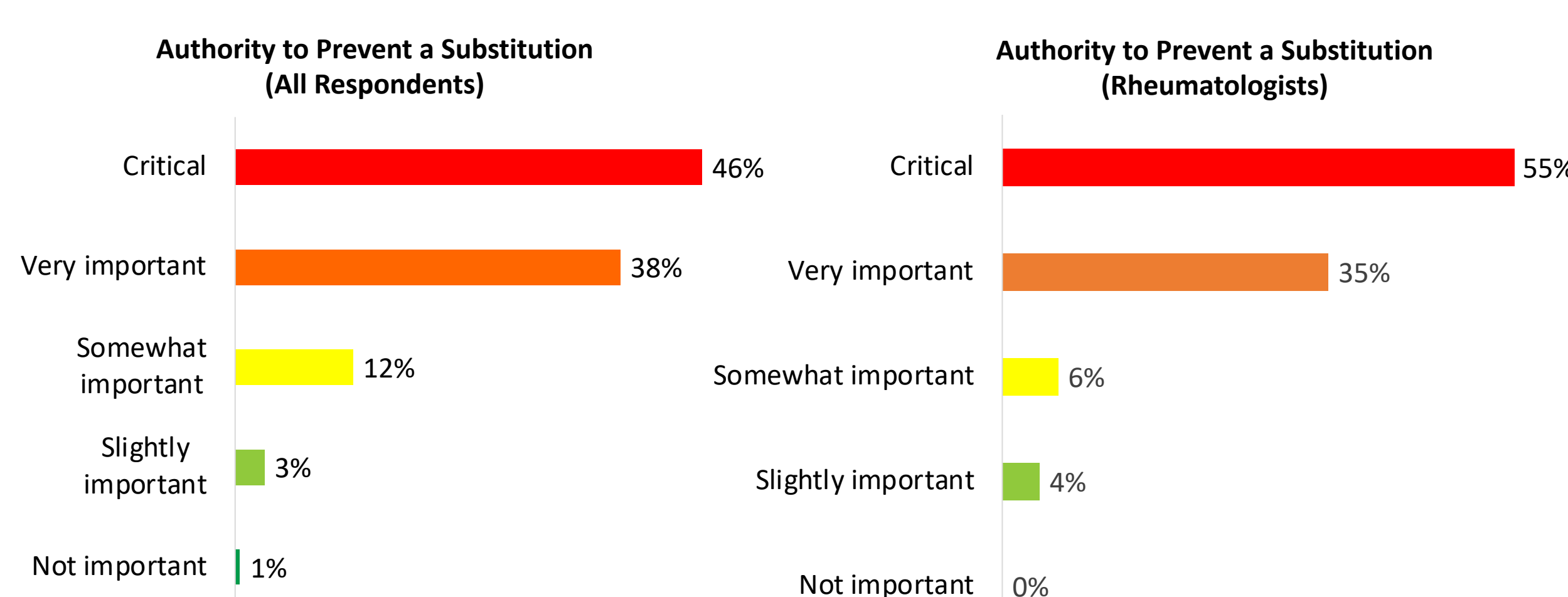


Authority to Prevent a Substitution

"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=579)

A strong majority of Respondents (84%) consider authority to prevent a substitution either "Very Important" or "Critical", an increase (from 74%) in the 2013 survey.

90% of Rheumatologists considered this authority "Very Important" or "Critical", the highest percentage among the practice areas surveyed.

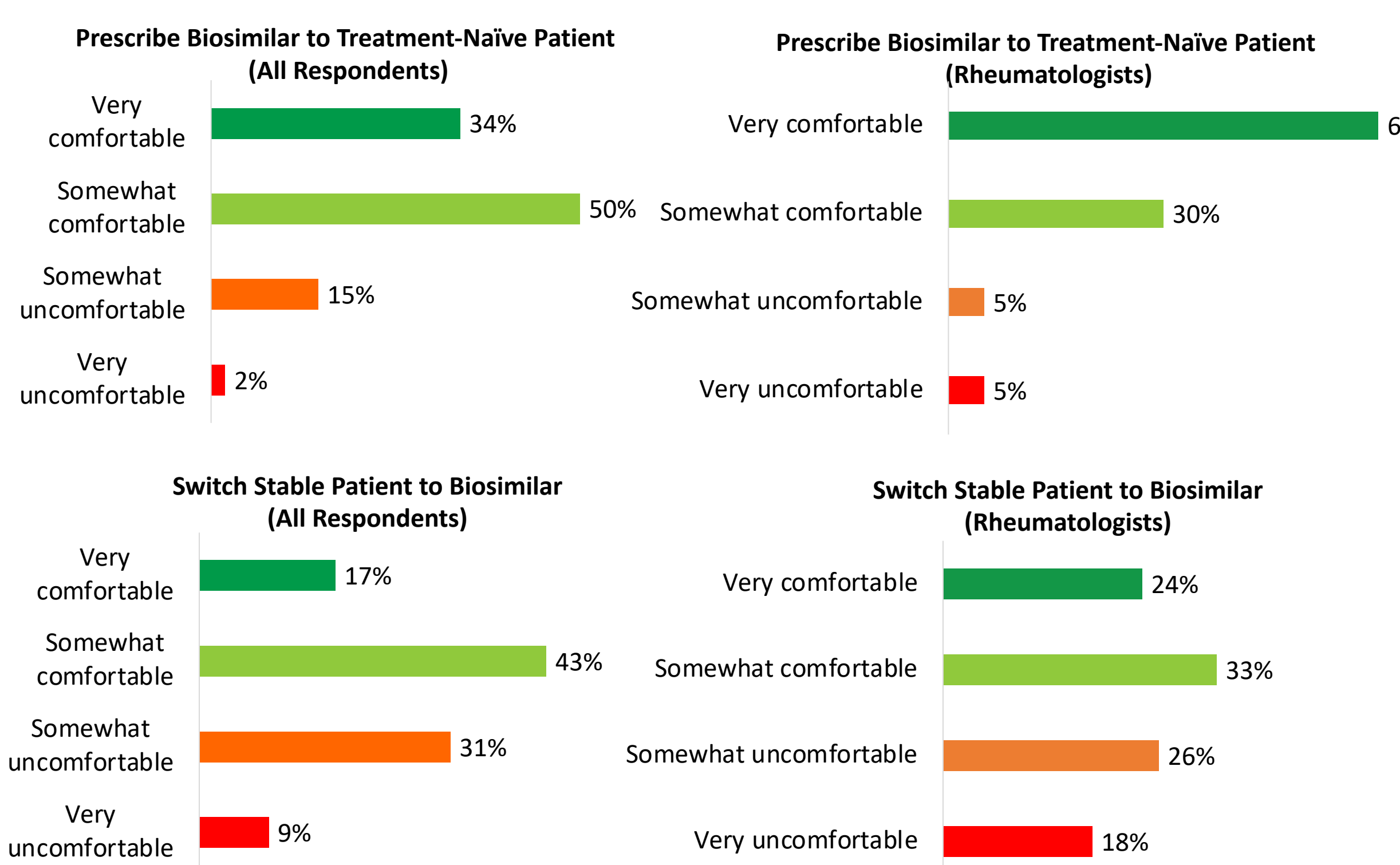


Prescribing to Treatment-Naïve vs. Stable Patients

"How comfortable are you in prescribing a biosimilar to a treatment-naïve patient?"

"How comfortable are you with switching a stable patient from one medicine to a biosimilar?"

- A strong majority (84%) of physicians are comfortable prescribing biosimilars to treatment-naïve patients. Comfort level decreases to 60% when asked about switching a stable patient to a biosimilar.
- While 17% are uncomfortable in prescribing a biosimilar to a naïve patient; more than twice as many (40%) are uncomfortable with switching a stable patient to a biosimilar.
- Rheumatologists were more comfortable than most practice areas prescribing a biosimilar to a bio-naïve patient (90% were comfortable) and slightly less comfortable than average switching a stable patient to a biosimilar (44% were uncomfortable.)

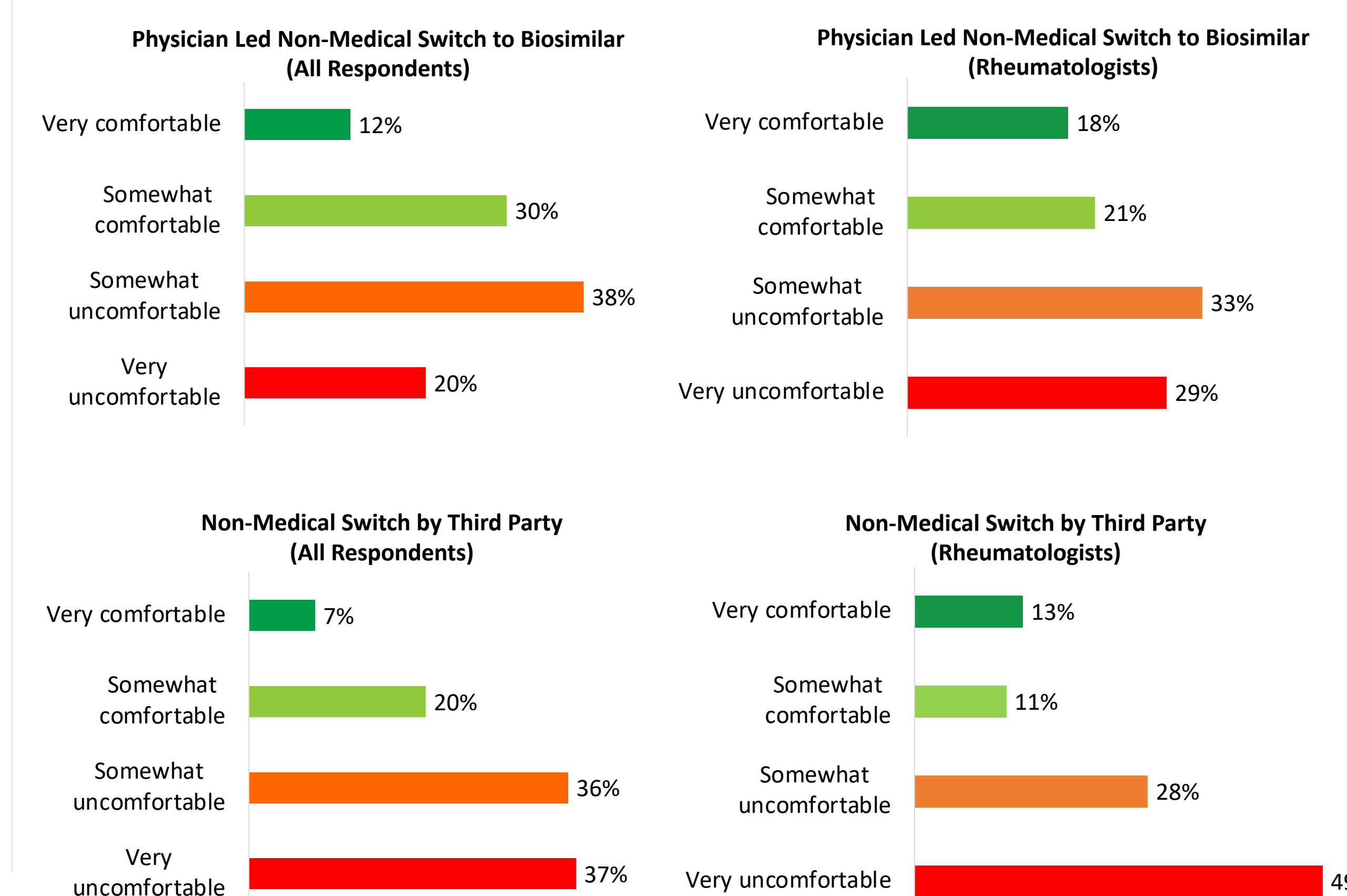


Non-Medical Switching

"How comfortable are you with switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)

"How comfortable are you with a third party switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)

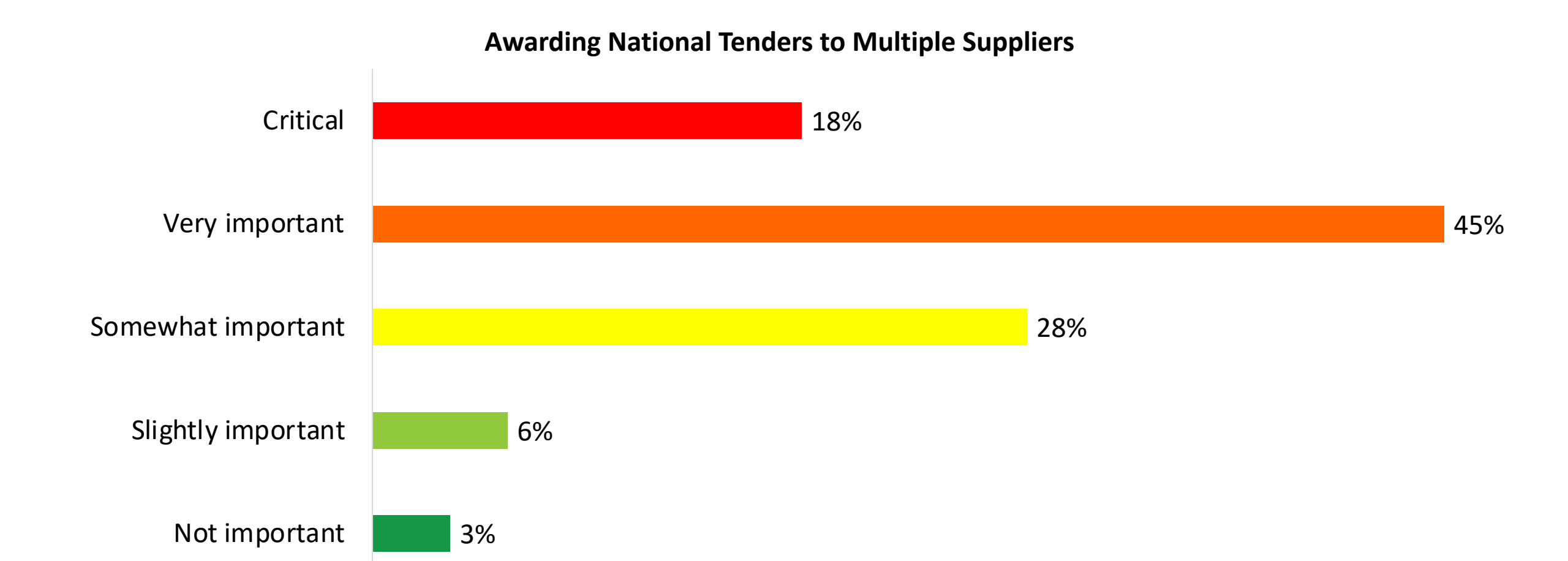
- More than half of prescribers (58%) are uncomfortable with switching their patients to a biosimilar for non-medical reasons. 29% of Rheumatologists are "very uncomfortable" compared to an average of 20% across specialties.
- This percentage increases to 73% when asked about a third party initiating a non-medical switch, with a significantly higher percentage of Rheumatologists "very uncomfortable" (49% compared to an average of 37% across specialties.)



National Tenders

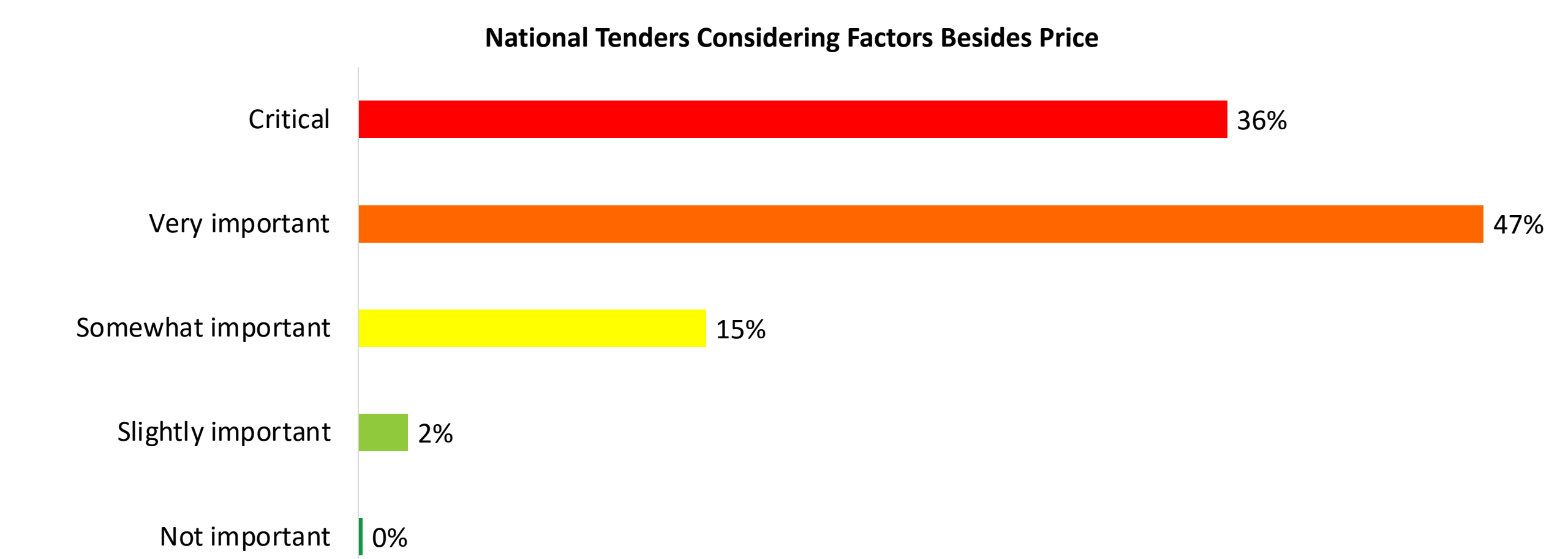
From your perspective, how important is it for government tenders for biosimilars to be awarded to multiple suppliers? (n=579)

- Most Respondents (63%) feel that it is either "Very Important" or "Critical" for tenders to be awarded to multiple suppliers.



"From your perspective, how important is it for factors besides price to be taken into account in national tender offers (e.g. reliability of supply, patient support services, manufacturer reputation)?" (n=579)

- A strong majority of Respondents (83%) feel that it is either "Very Important" or "Critical" for national tender offers to consider factors besides price.



CONCLUSIONS

Our survey reveals that European physicians have increased their familiarity with biosimilars since last surveyed in 2013.

Rheumatologists have the highest familiarity among the practice areas surveyed.

In addition, after 13 years of experience with biosimilars, European physicians:

- Increasingly consider maintaining physician control of treatment decisions to be highly important.
- Are highly comfortable with prescribing biosimilars to bio-naïve patients. Rheumatologists are the most comfortable among specialties surveyed.
- Are more than twice as uncomfortable switching a stable patient to a biosimilar than they are prescribing a biosimilar to a treatment-naïve patient.
- Remain uncomfortable with switching a patient to a biosimilar for non-medical reasons.
- Are highly uncomfortable with a non-medical substitution performed by a third party. This figure has also increased sharply since the 2013 survey. Rheumatologists are less comfortable than average with a third-party-initiated non-medical switch.
- Consider it highly important for governments to make multiple therapeutic choices available in tenders and believe these tenders should take into account factors besides price.