SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

GaBi
GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

European Prescribers' Trust in Prescribing and Switching of Biosimilars

Michael S. Reilly, Esq,
Executive Director, Alliance for Safe Biologic Medicines

ASBM Physician Surveys 2012-2022

U.S. Physicians
2012: n=376
2015 n=400
2015: n=400
2019: n=202
2021 n=401

Canadian Physicians
2014: n=427
2017: n=427
2022 (in development)

European Physicians
(France, Italy, Germany, Spain, Switzerland, UK)
2013: n=470
2019: n=579

Latin American Physicians
(Argentina, Brazil, Colombia, Mexico)
2015: n=399

Australian Physicians
2016: n=160

All surveys available at www.SafeBiologics.org/surveys

Sharing Perspectives With Regulators

WORLD HEALTH ORGANIZATION INN CONSULTATIONS
(2013-2022)

AUSTRALIAN DEPARTMENT OF HEALTH, THERAPEUTIC GOODS ADMINISTRATION (2017)

HEALTH CANADA, CANADIAN HEALTH MINISTRY (2017)

INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES (ICDRA) (2016, 2018)

ASBM INTERNATIONAL REGULATOR FORUMS ON NOMENCLATURE HARMONIZATION
(FDA, HEALTH CANADA, WHO) 2018–2019

EU COMMISSION/EMA BIOSIMILARS MEETING (2019)

U.S. FDA/FEDERAL TRADE COMMISSION WORKSHOP ON BIOSIMILAR COMPETITION
(MARCH 2020)

Learning from Europe

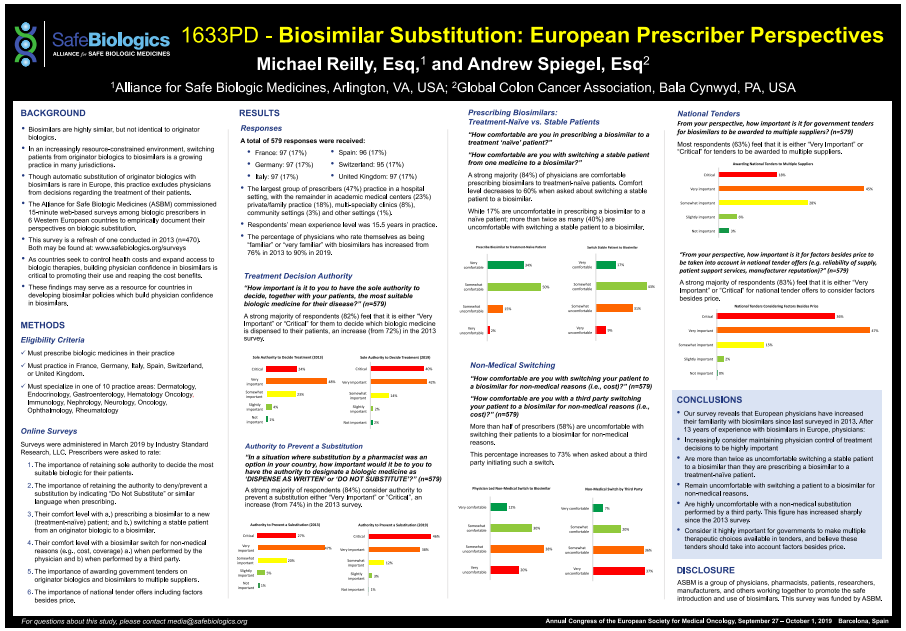
- Europe is widely acknowledged as a global leader in biosimilars, for successfully developing a robust and sustainable biosimilars program.
- To understand this success, it is critical to understand the central role physicians and their perspectives play in European biosimilar policy development.

Learning from European Physicians

- In Fall 2019, Alliance for Safe Biologic Medicines (ASBM) commissioned a survey of physicians in 6 Western European countries to empirically document their perspectives on biologic substitution.
- 579 responses were received; distributed equally among the 6 countries surveyed.
- Respondents must prescribe biologics, and must practice in France, Germany, Italy, Spain, Switzerland, or the United Kingdom.
- Drawn from 10 practice areas: Dermatology, Endocrinology, Gastroenterology, Hematology Oncology, Immunology, Nephrology, Neurology, Oncology, Ophthalmology, Rheumatology
- **This survey is a refresh of one conducted in 2013 (n=470)**

Survey Presented at ESMO Congress 2019

- The survey findings were presented at the European Society of Medical Oncology 2019 Congress in Barcelona, Spain.
- The physicians in attendance were surprised by one finding in particular:
- ***As familiarity and comfort with biosimilars increased, so did the importance to physicians of maintaining control of treatment decision.***



SafeBiologics ALLIANCE for SAFE BIOLOGIC MEDICINES

1633PD - **Biosimilar Substitution: European Prescriber Perspectives**

Michael Reilly, Esq,[1] and Andrew Spiegel, Esq[2]

[1]Alliance for Safe Biologic Medicines, Arlington, VA, USA; [2]Global Colon Cancer Association, Bala Cynwyd, PA, USA

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 is a refresh of 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:

1. The importance of retaining sole authority to decide the most suitable biologic for their patients.
2. The importance of retaining the authority to deny/prevent a substitution by indicating "Do Not Substitute" or similar language when prescribing.
3. 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.
4. 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.
5. The importance of awarding government tenders on originator biologics and biosimilars to multiple suppliers.
6. The importance of national tender offers including factors besides price.

RESULTS

Responses

A total of 579 responses were received:

- France: 97 (17%)
- Germany: 97 (17%)
- Italy: 97 (17%)
- Spain: 96 (17%)
- Switzerland: 95 (17%)
- United Kingdom: 97 (17%)

- 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.

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.

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.

Prescribing Biosimilars: 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.

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.

This percentage increases to 73% when asked about a third party initiating such a switch.

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. After 13 years of experience with biosimilars in Europe, physicians:
- Increasingly consider maintaining physician control of treatment decisions to be highly important
- 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 increased sharply since the 2013 survey.
- 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.

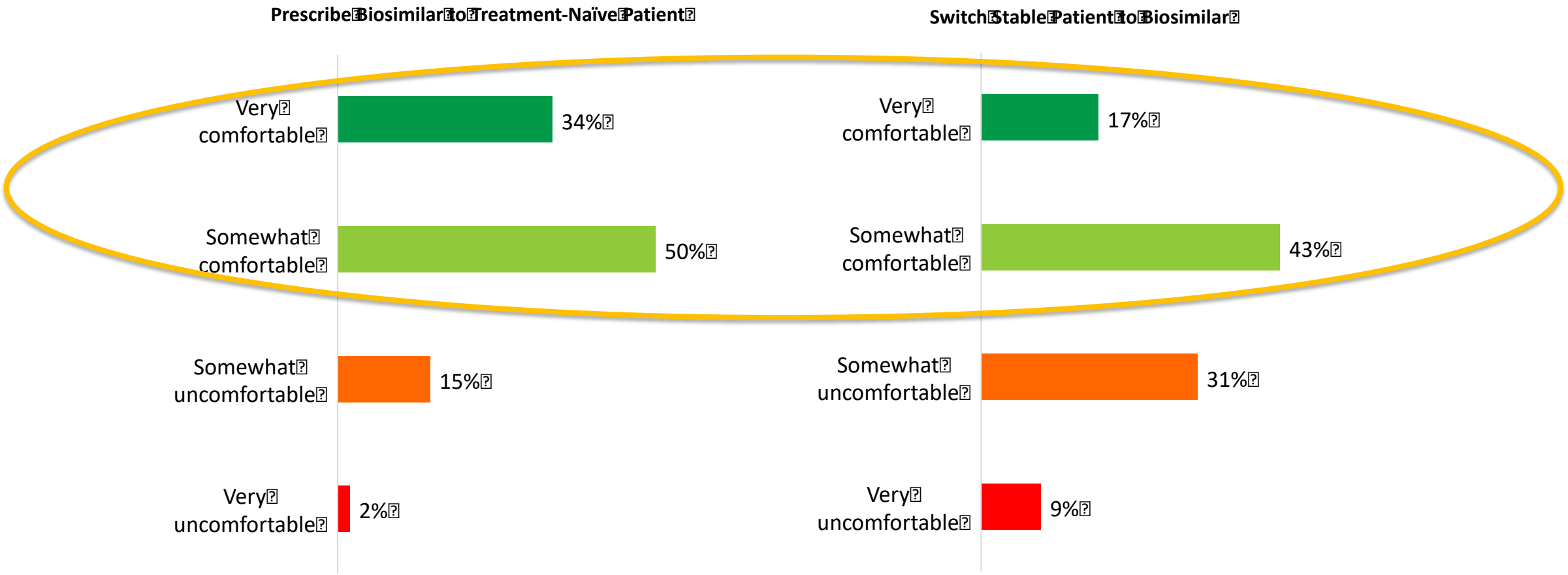
DISCLOSURE

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.

For questions about this study, please contact media@safebiologics.org

Annual Congress of the European Society for Medical Oncology, September 27 – October 1, 2019 Barcelona, Spain

2019 European Survey: Biosimilars for New vs. Switching Stable Patients



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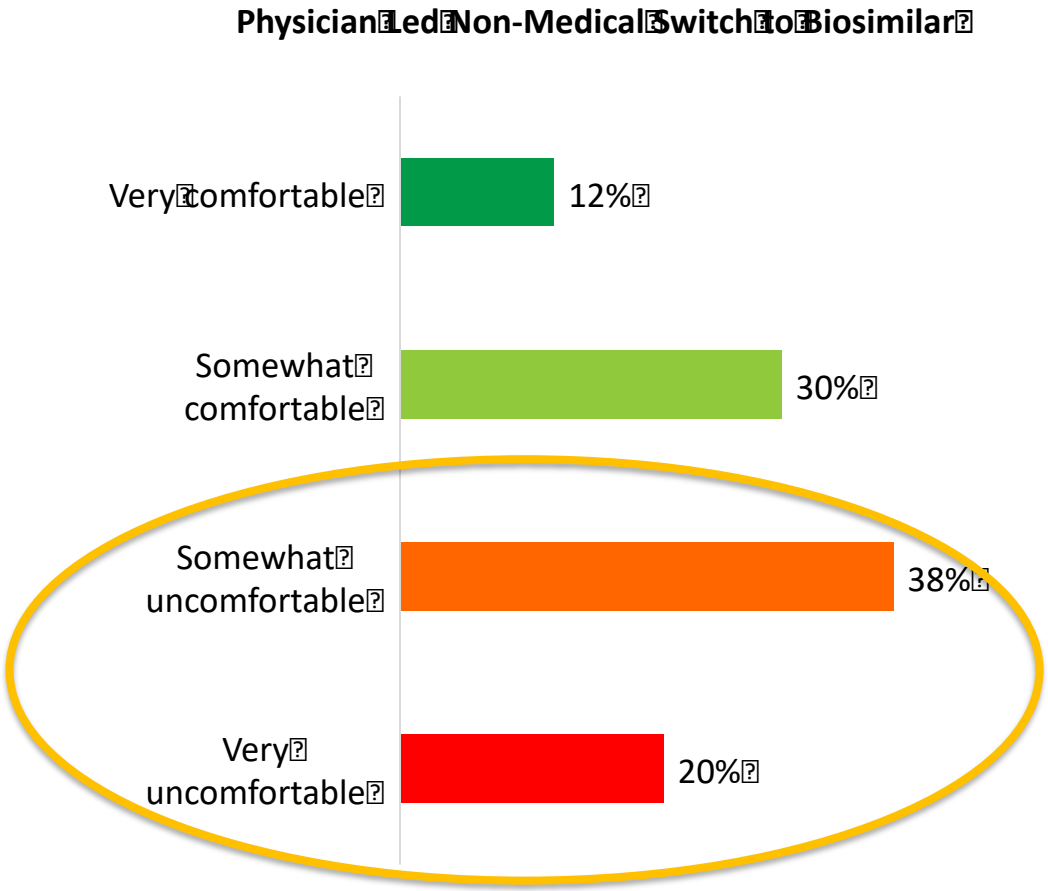
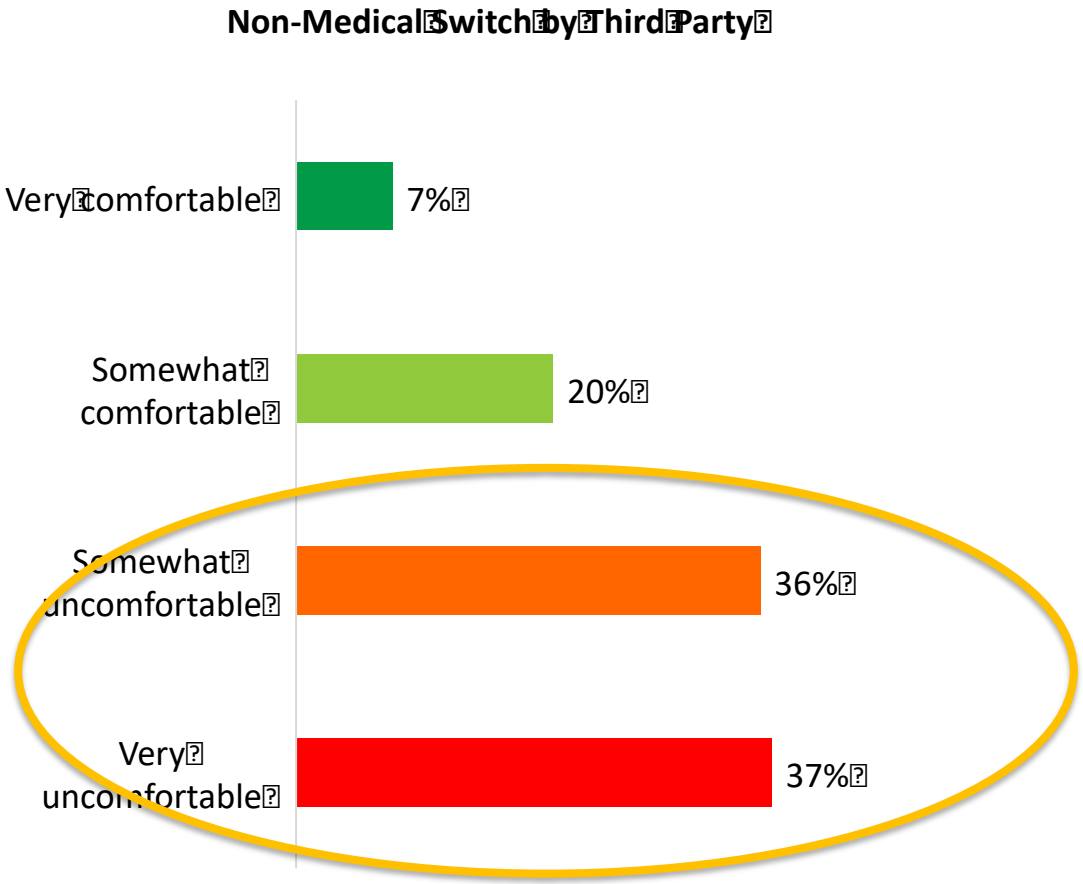
2019 European Survey: Non-Medical and/or Third-Party Switching





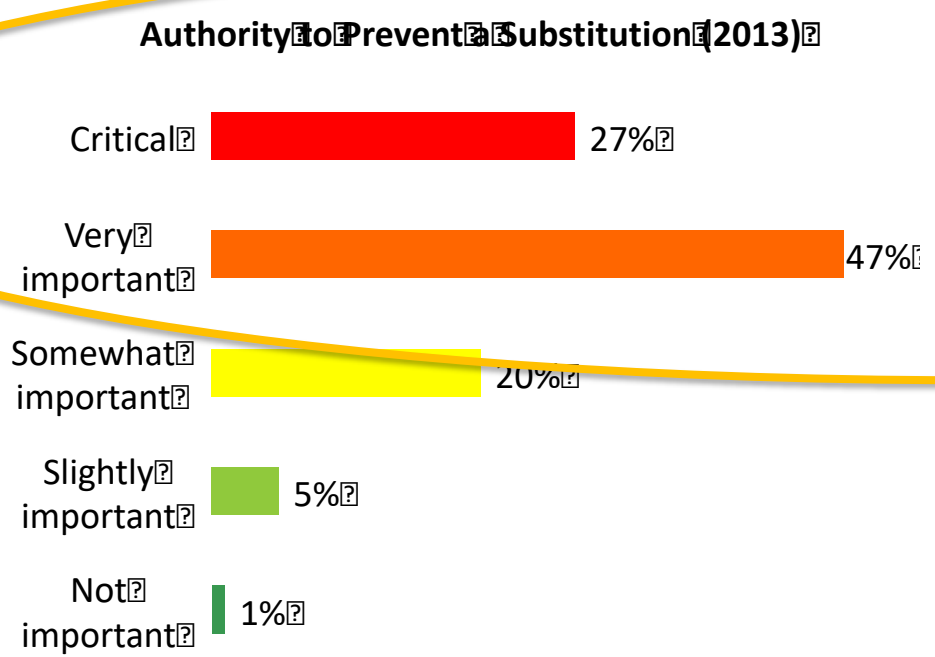
58% are uncomfortable with switching their patients to a biosimilar for non-medical reasons.

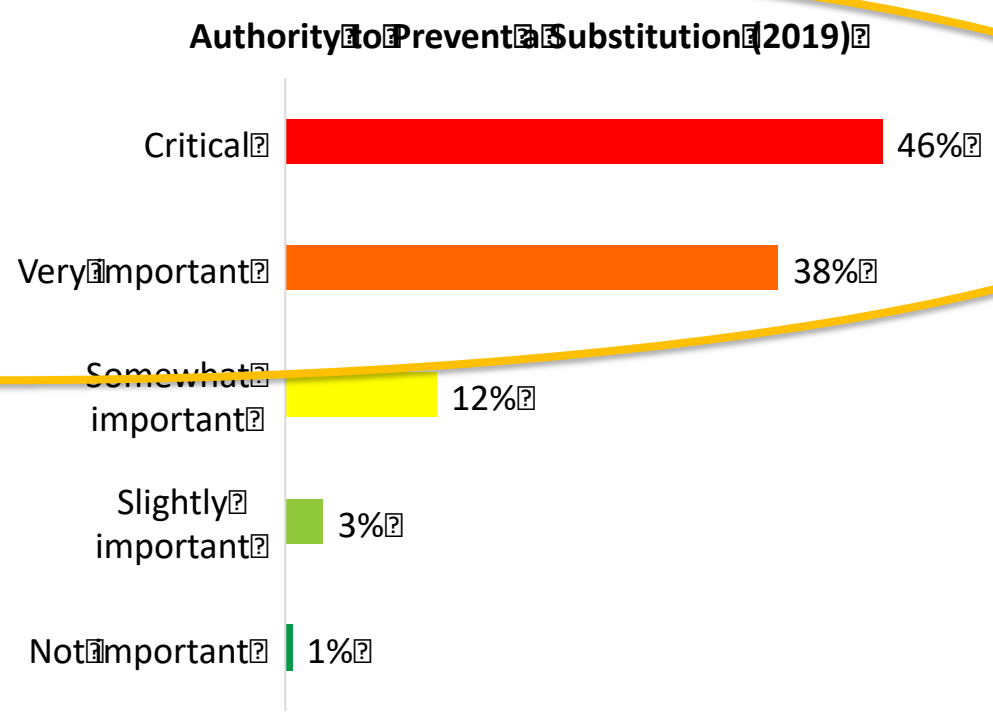
This percentage increases to 73% when asked about a third party initiating such a switch.

Importance of Authority to Prevent a Substitution Has Increased

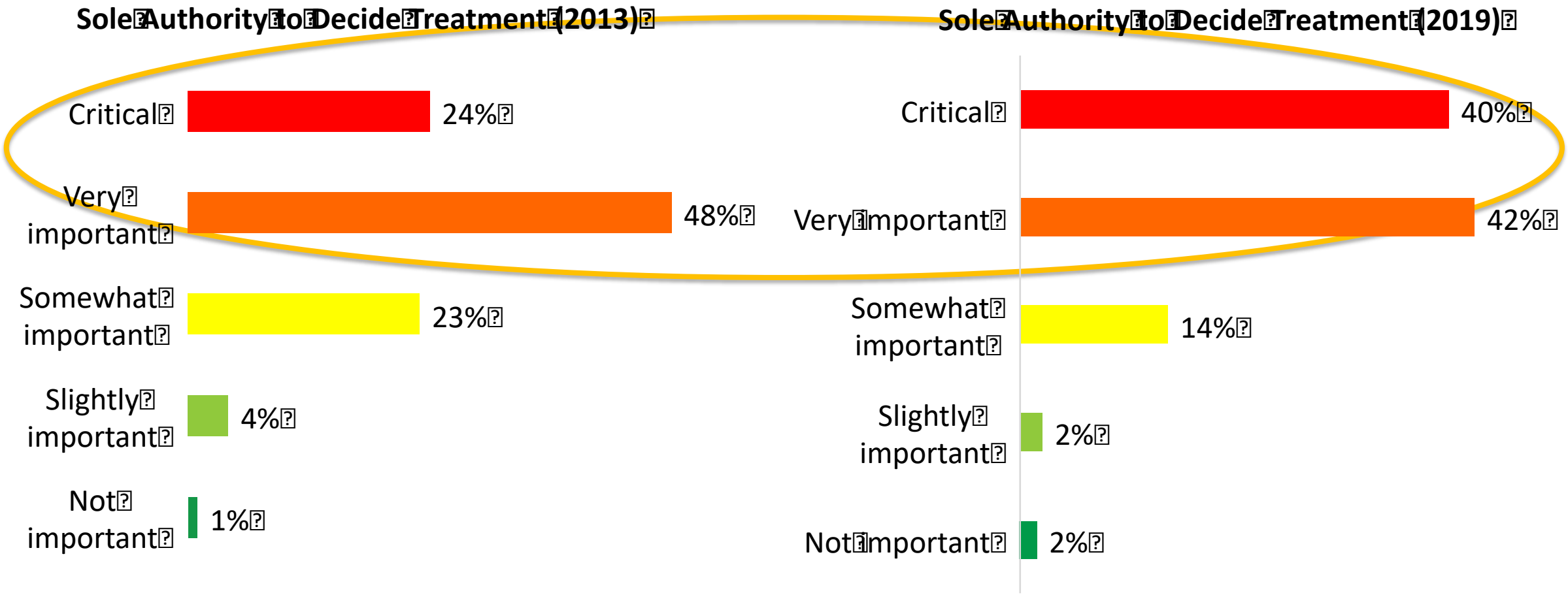
Q: "In a situation where substitution by a pharmacist was an option in your country, how important would it be to you to have the authority to designate a biologic medicine as 'DISPENSE AS WRITTEN' or 'DO NOT SUBSTITUTE'?" (n=579)

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.**



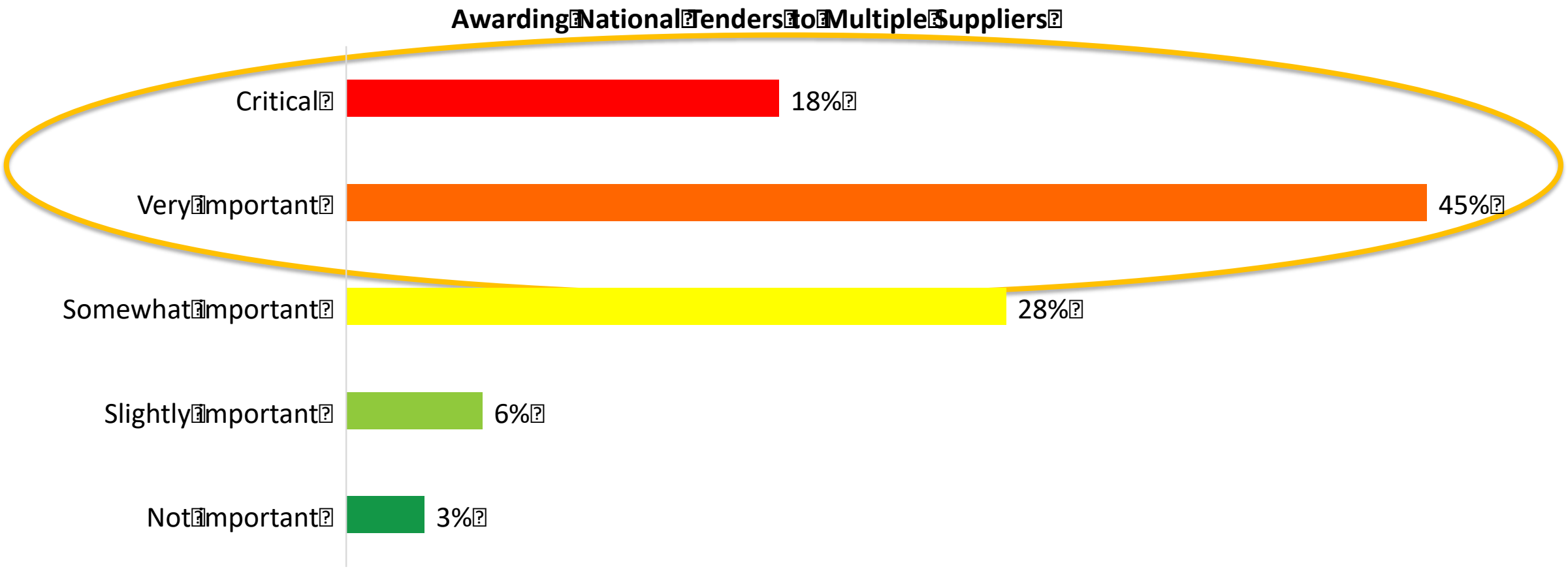


Importance of Treatment Decision Authority Also Increased from 2013



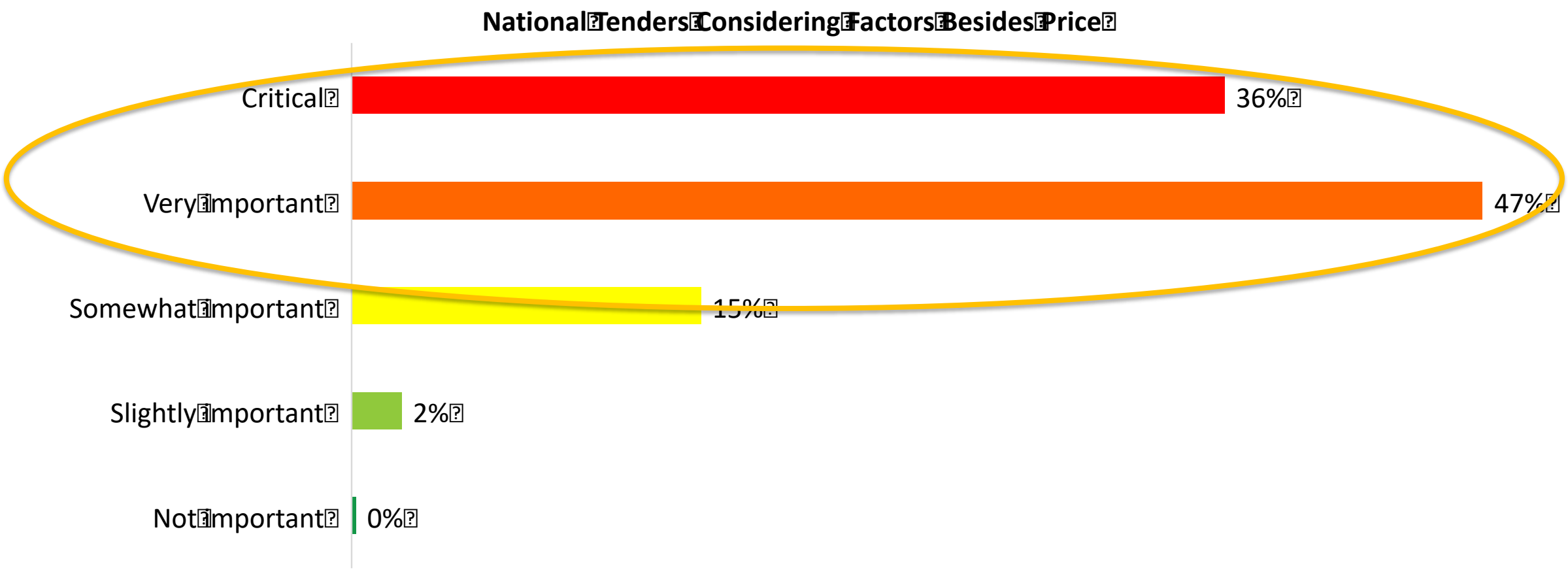
A strong majority of respondents (82%) feel that it is either “Very Important” or “Critical” for them to decide which biologic medicine is dispensed to their patients, **an increase (from 72%) in 2013 survey.**

National Tenders: Importance of Multiple Suppliers



Most respondents (63%) feel that it is either “Very Important” or “Critical” for tenders to be awarded to multiple suppliers.

National Tenders: Importance of Factors Beside Price



A strong majority of respondents (83%) feel that it is either “Very Important” or “Critical” **for national tender offers to consider factors besides price.**

Survey Conclusions

Our survey reveals that European physicians have increased their familiarity with biosimilars since last surveyed in 2013. After 13 years of experience with biosimilars in Europe, physicians:

- Increasingly consider maintaining physician control of treatment decisions to be highly important
- 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 increased sharply since the 2013 survey.
- 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.

View the full 2019 European Physician Survey at www.safebiologics.org/surveys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Thank You for Your Attention