Stakeholders' perceptions on biosimilars:

Surveys to PCOs, HCPs, HMA & Industry

PCWP HCPWP, 2 July 2024

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EU strategy for improving understanding on biosimilars

Improving understanding to increase trust

Continuous education

Guide for HCPs
2017

Patients' Q&A
2016

Enhanced transparency on benefit-risk

Medicine overviews

Collaboration with stakeholders

Building up on a successful multi-stakeholder approach set up by the EC

- **EMA working parties with healthcare professionals and patients/consumers**

Supporting consistent messages

Guide for HCPs translations

Video

1 PCWP-HCPWP meeting: Stakeholders' perceptions on biosimilars

https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf
First published in Sep 2022 and updated in Apr 2023

Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

References:

1. Interchangeability of Biosimilars: A European Perspective. Pekka Kurki, Leon van Aerts, Elena Wolff-Holz, Thijs Giezen, Venke Skibeli, Martina Weise. BioDrugs 2017 Apr;31(2):83-91
2. Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened One Voice messaging. Liese Barbier, Allary Mbuaki, Steven Simoens, Paul Declerck, Arnold G. Vulto, and Isabelle Huys. Frontiers in Medicine 2022, Vol 9, 820755
3. Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective. Pekka Kurki, Sean Barry, Ingrid Bourges, Panagiota Tsantili, Elena Wolff-Holz. Drugs 2021 Nov;81(16):1881-1896
4. The safety of switching between therapeutic proteins. Ebbers H, Muenzberg M, Schellekens H. Expert Opinion Biol Ther. 2012;12:1473-85
5. Biosimilars in the EU - Information guide for healthcare professionals (europa.eu)

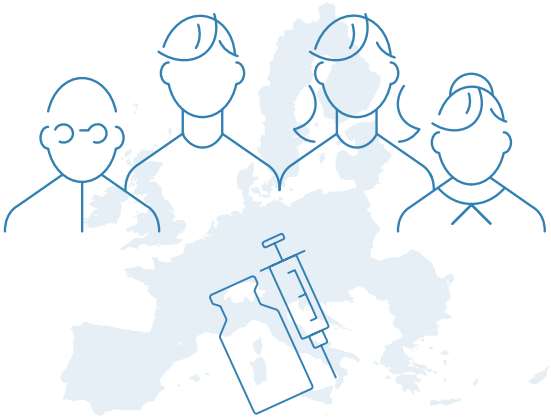
https://www.ema.europa.eu/en/documents/other/qa-statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf
First published in Jan 2023 and revised in Apr 2023

21 April 2023
EMA/93740/2023 Rev. 1
European Medicines Agency

Q&A on the Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU

Following the publication of the joint EMA-HMA statement on interchangeability of biosimilar medicinal products approved in the EU, both EMA and National Competent Authorities (NCAs) have received questions for clarification from healthcare professionals and other members of the public. This questions and answers (Q&A) document addresses follow-up questions received after publication of the statement.

Biosimilar toolkit for Member States



HMA Working Group on Biosimilars

- **New modular information pack** on biosimilars targeting healthcare professionals and patients.
- Toolkit available to Member States to support their own communication campaigns – **flexibility based on needs**
- **Including up-to-date EU materials** developed to date
- **New information elements** on:
  - ✓ Biosimilar regulatory **approval process**
  - ✓ **Efficacy and safety** of biosimilars
  - ✓ **Interchangeability**
  - ✓ **Case studies** on uptake of biosimilars resulting in savings

2024 biosimilar work

Objectives

- **Review and update of current EMA communication materials** on biosimilars.
- Review and progress on translations.
- **Survey & Gap analysis**:

✓ Understand perception of biosimilar materials and information needs

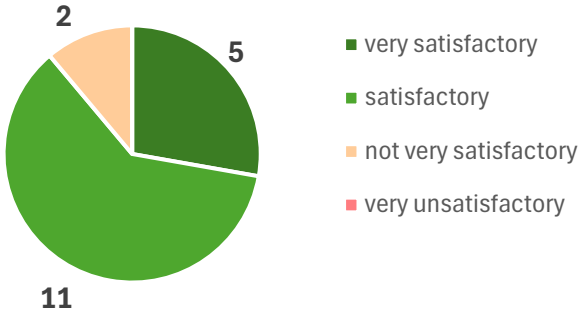
✓ Understand factors impacting biosimilar uptake and possible solutions to bottlenecks

First interim results of the survey to HMAs

➢ 18 responses (out of 31 agencies contacted)

- **Role of the agencies to enhance the uptake of biosimilars:**
  - providing information on biosimilars,
  - participation in the preparation legislative measures (e.g. automatic substitution).

- **How satisfactory is the biosimilar situation in your country?**



- **Major obstacles for the uptake of biosimilars:**
  - lack of trust on biosimilars among prescribers and/or patients,
  - lack of incentives for the prescribers,
  - prescribing policies,
  - non-optimal procurement procedures.

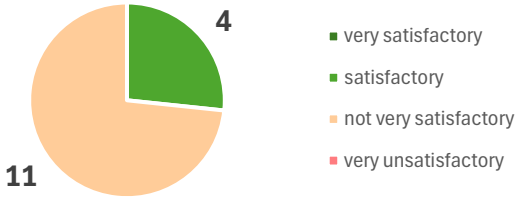
- **Information gaps on the websites (national or EMA):**
  - comparative efficacy and safety (biosimilar vs originator),
  - info in lay language,
  - up-to-date list of licensed biosimilars.

- **Future actions for HMA Biosimilar Working Group:**
  - to provide the TOOL KITs,
  - to give recommendation how to use them in national information,
  - social media campaigns.

First interim results of the survey to Industry

➢ 15 responses (10 companies producing biosimilars + 5 producing both originators & biosimilars)

- **How companies provide information on biosimilars:**
  - Own website;
  - Information campaigns;
  - Meeting prescribers.
- **How is the uptake of biosimilars by patients?**



- **Factors are currently inhibiting uptake of biosimilars by patients:**
  - Non-optimal procurement procedures;
  - Lack of experience with biosimilars by HCPs;
  - Limitations in national health budgets.
- **Factors inhibiting prescription of biosimilars by healthcare professionals:**
  - Lack of experience with biosimilars by HCPs;
  - Non-optimal procurement procedures;
  - Lack of guidelines by clinical societies (national or EU/EEA) on interchangeability/switching/automatic substitution at pharmacy level;
  - Lack of trust among healthcare professionals (HCPs).
- **Factors could enhance uptake of biosimilars:**
  - Support from national authorities;
  - Sharing practices;
  - Acceptance and trust by healthcare professionals;
  - Effective procurement processes.

HMA
Heads of Medicines Agencies

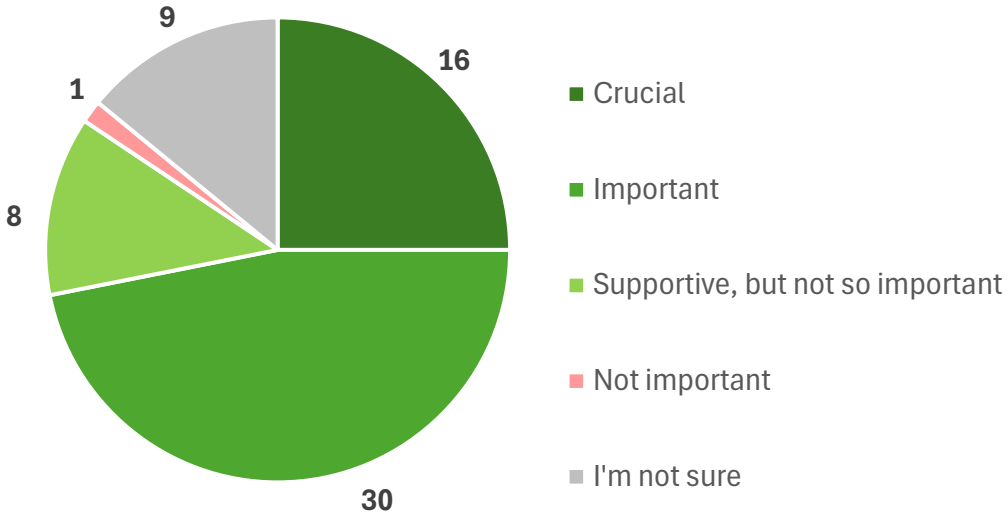
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patients and Consumers

64 respondents

Biosimilar knowledge

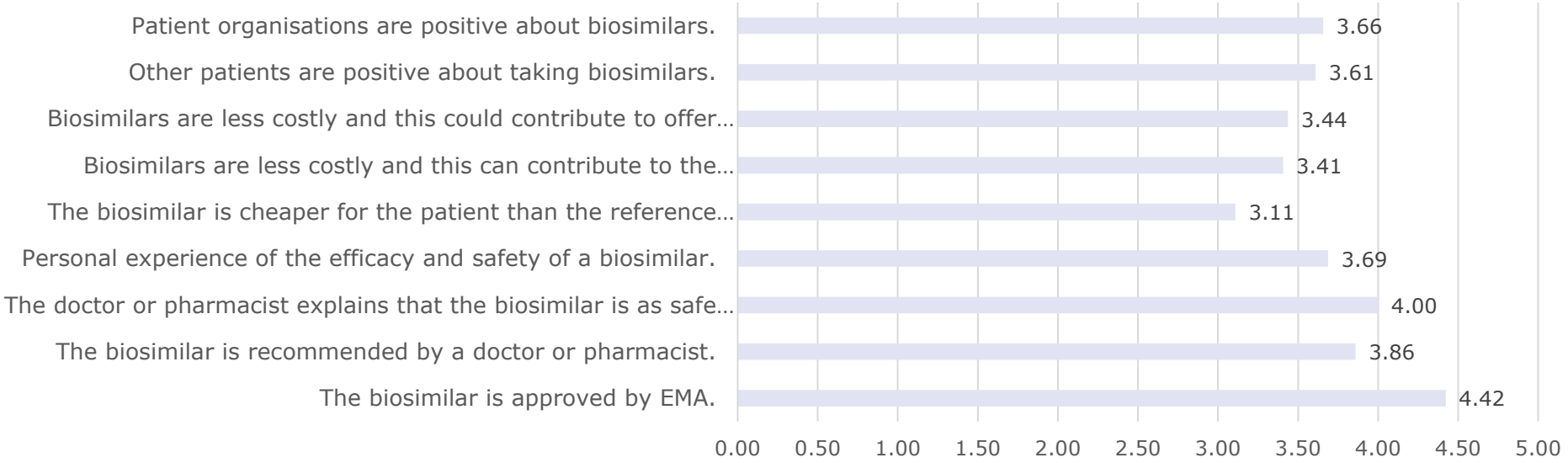
8. How important do you think is the impact of treatment guidelines published by clinical societies on biosimilars for the uptake of biosimilars in your country?



Biosimilar knowledge

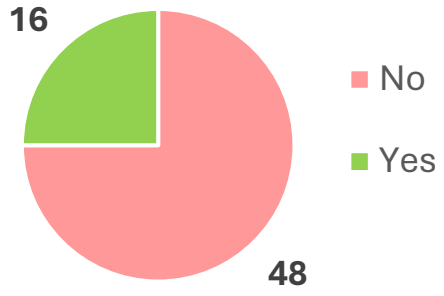
9. What factors contribute to make patients feel positive about taking a biosimilar?

Please rate the following elements from 1 to 5 with 5 being the best and 1 being the worst.

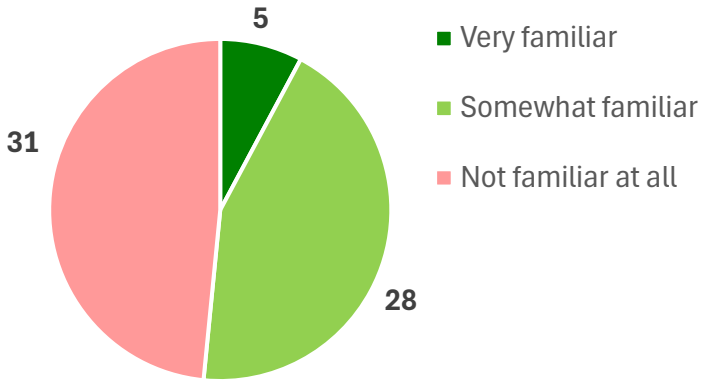


EMA/HMA information

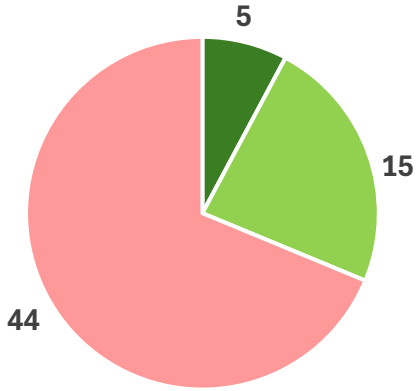
11. Do you think that the information on biosimilars provided by the national health authority of your country to patients or the general public is sufficient?



12. How familiar are you with the information on biosimilars published on the European Medicines Agency (EMA)'s website?

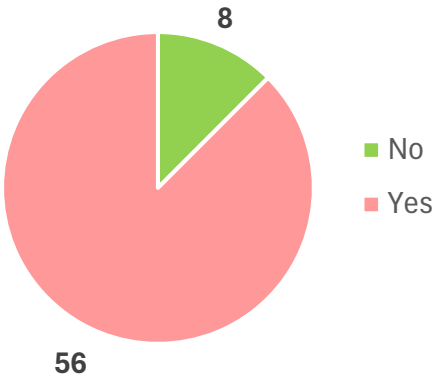


14. How familiar are you with the HMA-EMA joint statement on biosimilar interchangeability and the accompanying communication materials?

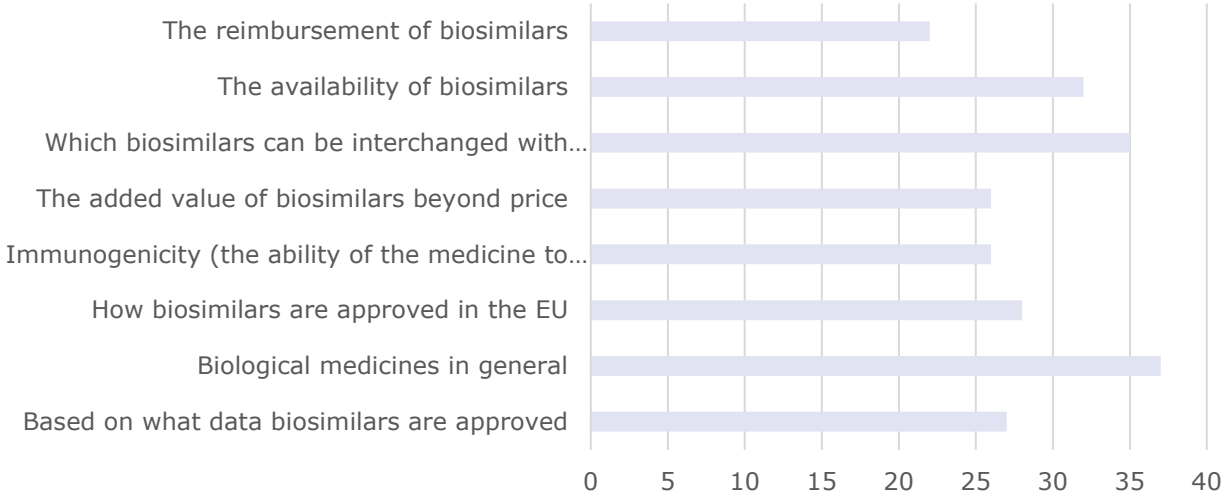


Biosimilar education needs

16. Do you think patients in your therapeutic area(s) need more information about biosimilars?



16.1 If yes, on what topic(s) would you like to see additional information? Select one or more as relevant.



Summary

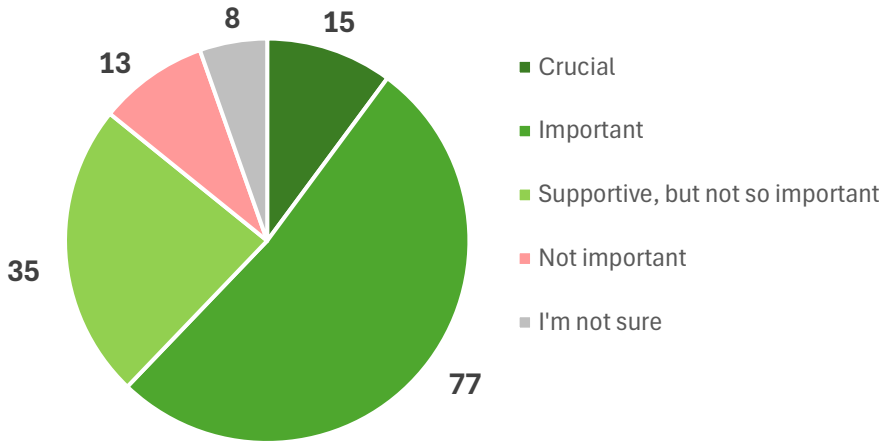
- This survey reached a **heterogeneous group of patient representatives** from various countries from Europe with experience in various disease groups, forming a **trust-worthy patient sample**
- Throughout the survey, patients described the need for more **information**, and underlined that available and **new information needs to be more patient-friendly**
- The approval of biosimilars by EMA is indicated as important, yet the various information provided by EMA seems not to reach patients maximally.

HealthCare Professionals

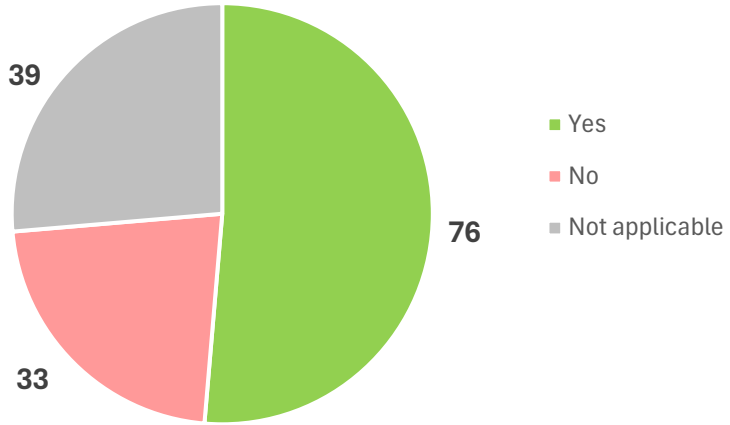
148 respondents

Biosimilar knowledge

7. How important are treatment guidelines published by clinical societies on biosimilars for the uptake of biosimilars in your country?

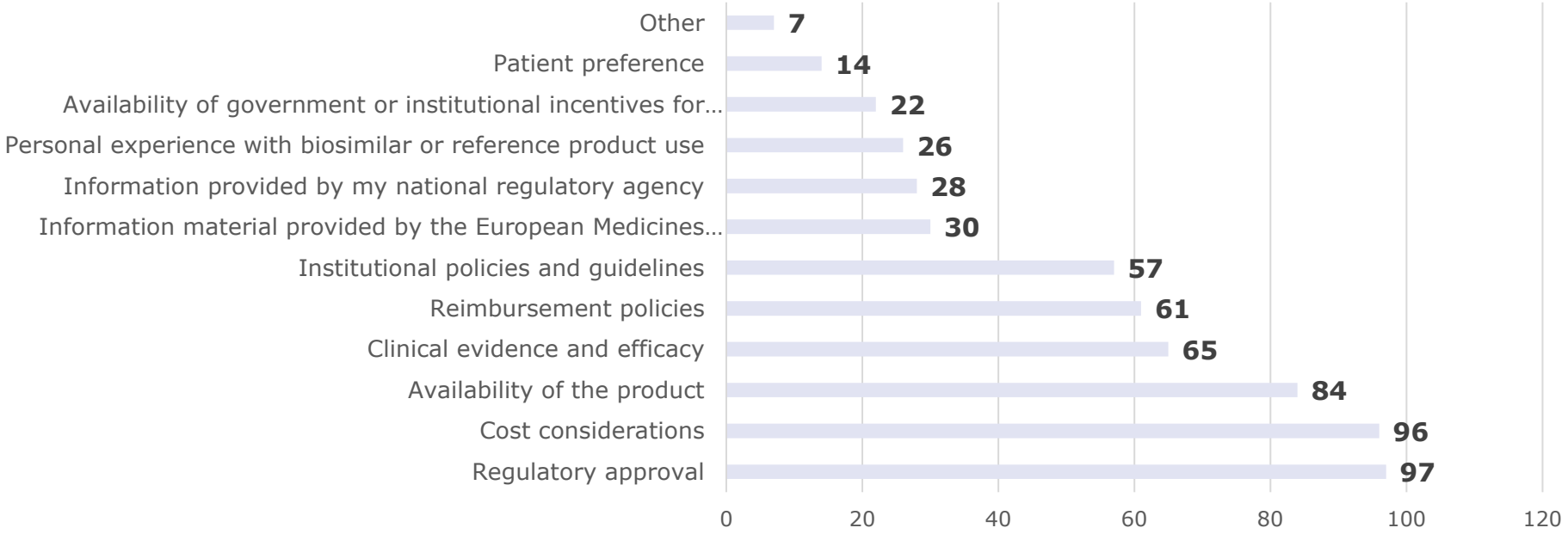


8. If you prescribe biologic medicines, do you interchange biosimilars and reference products?



Biosimilar knowledge

9. What factors influence your decision to prescribe / dispense a biosimilar over the reference product or vice versa? Select one or more as relevant.

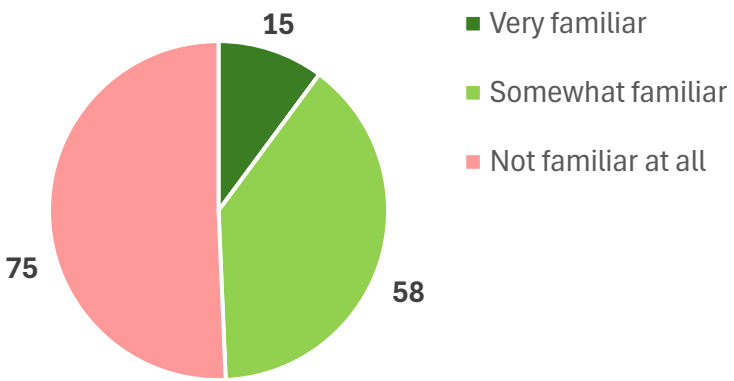


EMA/HMA information

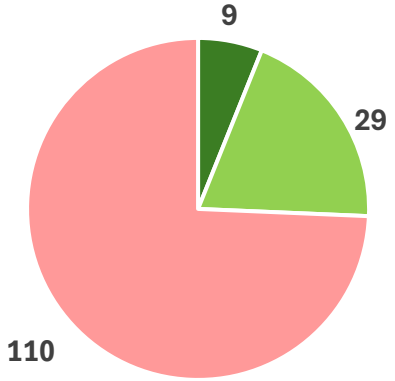
11. Do you use the following information material provided by the European Medicines Agency (EMA) on biosimilars?

No, I don't use any of the above-mentioned resources	**84**
The information guide for HCPs	45
The information guide for patients	21
The overall EMA webpage on biosimilars	45

12. How familiar are you with the EMA statement on biosimilar interchangeability and the accompanying communication materials?

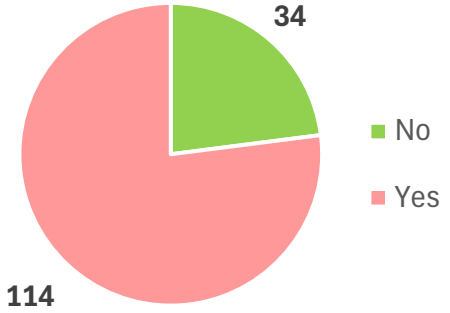


13. How familiar are you with the accompanying Q&A document?

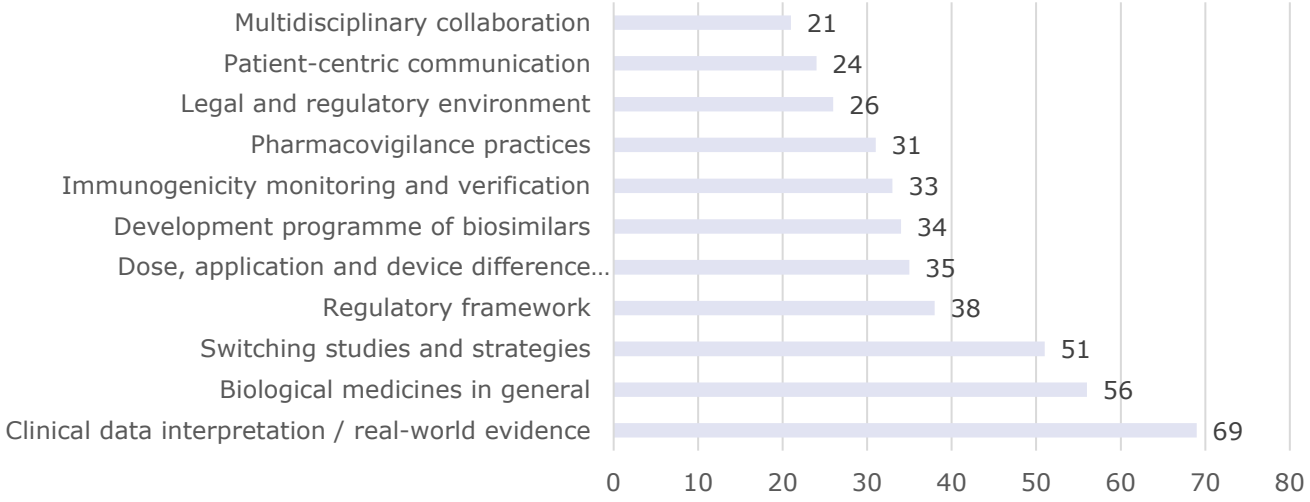


Biosimilar education needs

16. Do you believe there is a need for additional education or training for healthcare professionals on the use of biosimilars?



16.1 If yes, what specific topics do you think require more emphasis in education or training?



Summary

- This survey reached a **heterogeneous group of healthcare professionals** (HCP) from various countries across Europe. There was a slight **overrepresentation of Italians – oncologists**.
- HCPs expressed also the **need for more information**, especially on real-world evidence.
- EMA information channels are reaching only a subset of HCPs.

A full analysis of all stakeholder surveys will be carried out by EMA/HMA and recommendations for the toolkits will be prepared

With thanks to:

HMA BSWG: Esa Heinonen, Venke Skibeli, Bernard Duggan, Rene Anour
EMA: Steffen Thirstrup, Juan Garcia, Florence Borrelly-Konyakhin, Kaisa Immonen

Thank you for your attention

Further information

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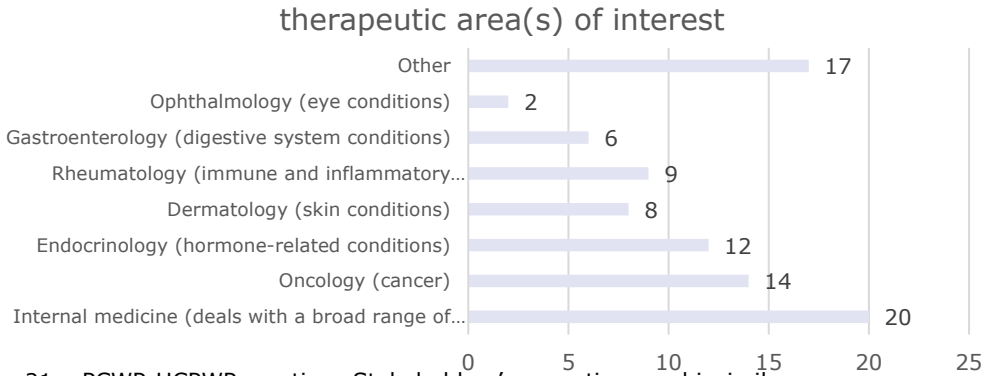
Heads of Medicines Agencies: HMA Working Group of Biosimilars (BSWG)

Back-up slides

Patient & Consumer survey - Demographical data

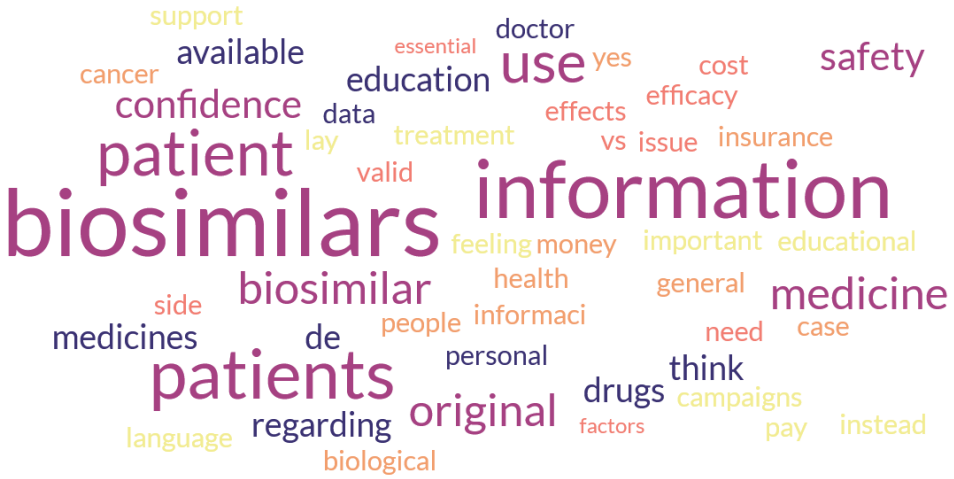
n=64

As a family member / informal carer to a patient	6
As a patient / person living with a chronic health condition	11
As a patient advocate not affiliated to a patient organisation	9
As a patient advocate not affiliated to a patient organisation; As a patient / person living with a chronic health condition	3
As a representative of a patient organisation	22
As a representative of a patient organisation; As a patient / person living with a chronic health condition	13



#country	Name	#participants
1	Austria	1
2	Belgium	6
3	Bulgaria	2
4	Cyprus	2
5	Czechia	1
6	Denmark	2
7	Estonia	1
8	Finland	2
9	France	2
10	Germany	6
11	Greece	1
12	Ireland	8
13	Italy	12
14	Luxembourg	1
15	Netherlands	4
16	Norway	2
17	Poland	1
18	Portugal	3
19	Romania	1
20	Slovenia	1
21	Spain	5

10. Can you think of any other factor(s) that could make patients feel positive about taking a biosimilar? Do you have any further comments on patients' confidence in biosimilars?



Healthcare professional survey - Demographical data

n=148

Community pharmacist	10
General practitioner/ family doctor	4
Hospital pharmacist	25
Medical specialist	105
Other	4

Years of Practice	
> 15 years	77
11-15 years	29
6-10 years	29
1-5 years	13

Dermatology	3
Internal medicine	8
Oncology	68
Ophthalmology	1
Other	23
Gynecology	1
hematology	7
Neuro oncologist	1
Neurologist - Neuro-oncologist	1
Neurology	1
Neurosurgery	1
Nuclear Medicine	2
Pulmonology and thoracic oncology	1
Radiation Oncology	2
Surgery	2
surgical oncology	1
thoracic oncology/pulmonology	1
Urology	2
Rheumatology	2

Healthcare professional survey - Demographical data

n=148

Are you a prescriber?	
No	39
Community pharmacist	10
General practitioner/ family doctor	1
Hospital pharmacist	24
Medical specialist	1
Other	3
Yes	109
General practitioner/ family doctor	3
Hospital pharmacist	1
Medical specialist	104
Other	1

1	Austria	5
2	Belgium	22
3	Bulgaria	1
4	Croatia	5
5	Cyprus	1
6	Czechia	2
7	Denmark	1
8	Finland	1
9	France	12
10	Germany	5
11	Greece	2
12	Iceland	1
13	Ireland	2
14	Italy	32
15	Latvia	1
16	Lithuania	1
17	Netherlands	14
18	Poland	4
19	Portugal	9
20	Romania	2
21	Slovak Republic	1
22	Slovenia	5
23	Spain	19