The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME response to the Survey on biosimilar medicines to healthcare professional representatives

On 17 May 2024, the CPME Board adopted the 'CPME response to the Survey on biosimilar medicines to healthcare professional representatives' (CPME 2024/089).

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Survey on biosimilar medicines to healthcare professional representatives

Fields marked with * are mandatory.

Introduction and data protection notice

Purpose of the survey

With this survey we are inviting **healthcare professional representatives** to express their views on biosimilars and the communication about them.

Your feedback will help us **check levels of awareness** about the information materials on biosimilars prepared by the EU Medicines regulatory network, including the statement on interchangeability of biosimilars, and **assess their clarity and usefulness**. Our goal is to **improve how we explain biosimilar** medicines to the public.

We expect that it will take you approximately **15 minutes** to complete this survey. We thank you very much in advance for your contribution.

If you have any questions, technical or content-related, please do not hesitate to contact florence.borrelly-konyakhin@ema.europa.eu.

Data protection notice

In this survey, the EMA does not collect or process personal data. Therefore, please make sure that you do not reveal your identity or include any personal data in the free text answers. The survey is designed to collect the answers only in an aggregate and anonymous format. The responses will only be evaluated and the results shared in an aggregate way.

For the collection of data in this survey EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: https://ec.europa.eu/eusurvey/home/privacystatement

The EU Survey external system uses:

- Session "cookies" in order to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated.
- Local storage to save copies of the inputs of a participant to a survey in order to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause. The local storage contains the IDs of the questions and the draft answers.
- Once a participant has submitted one's answers successfully to the server or has successfully saved a draft on the server, the data is removed from the local storage.

☑ I confirm that I have read and understood the data protection notice.

About you

* 1. What is your profession?

- ○ General practitioner/ family doctor
- ○ Medical specialist
- ○ General nurse
- ○ Specialist nurse
- ○ Hospital pharmacist
- ○ Community pharmacist
- ◉ Other

* If "other", please specify:

The Standing Committee of European Doctors (CPME) is responding to the survey on behalf of European doctors.

* 2. For how many years have you been practising?

- ○ < 1 year
- ○ 1-5 years
- ○ 6-10 years
- ○ 11-15 years
- ◉ > 15 years

* 3. In which EU/EEA country are you practising?

BE - Belgium

* 4. Are you a prescriber?

- ◉ Yes
- ○ No

Biosimilars in your country

*

5. Do you consider that there is sufficient access to biologic therapy, including biosimilars and reference products, in your country?

- ○ Yes
- ○ No
- ◉ I'm not sure

* 6. Do you think that the information provided by your national competent authority on biosimilars is sufficient?

- ◉ Yes
- ○ No
- ○ I'm not sure

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

- ◉ Crucial
- Important
- ○ Supportive, but not so important
- ○ Not important
- ○ I'm not sure

Biosimilars in your practice

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

- ◉ Yes
- ○ No
- ○ Not applicable

* 9. What factors influence your decision to prescribe / dispense a biosimilar over the reference product or vice versa?

Select one or more as relevant.

- ☑ Regulatory approval
- ☑ Personal experience with biosimilar or reference product use
- ☐ Patient preference
- ☑ Cost considerations
- ☑ Clinical evidence and efficacy
- ☑ Reimbursement policies
- ☑ Availability of the product
- ☑ Institutional policies and guidelines
- ☐ Influence by colleagues, seniors or other third parties
- ☑ Information material provided by the European Medicines Agency (EMA) (e.g. guide for healthcare professionals)
- ☐ Information provided by my national regulatory agency
- ☐ Availability of government or institutional incentives for switching patients to biosimilars
- ☐ Other
- ☐ Not applicable

* 10. In your opinion, what are the key challenges associated with biosimilars in your field of practice, including interchangeability/prescriber-led switching between biosimilars?

Select one or more as relevant.

- [ ] Regulatory clarity
- [x] Clinical data requirements
- [x] Immunogenicity concerns
- [ ] Healthcare professional's confidence
- [x] Patient confidence
- [ ] Medical society acceptance
- [ ] Lack of treatment guidelines on usage of biosimilars published by clinical societies
- [ ] Lack of real-world evidence
- [x] Healthcare professional training
- [ ] Pharmacovigilance strategies
- [ ] Product availability
- [x] Differences in dose, application or device
- [ ] Other

Your opinion on HMA-EMA information material on biosimilars

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

Select one or more as relevant.

- [x] The overall EMA webpage on biosimlars
- [x] The information guide for patients
- [x] The information guide for healthcare professionals
- [ ] The information videos
- [ ] No, I don't use any of the above-mentioned resources

* 11.1. When reading/watching the information, have you encountered any of the challenges listed below?

Select one or more as relevant.

- [ ] Complex language (e.g. the words used are too difficult or technical)
- [x] Length and density (e.g. the material is too short / too long)
- [ ] Lack of clarity (e.g. the information is ambiguous)
- [ ] Limited access to prior knowledge (e.g. the evidence behind the information is questionable)
- [ ] Technical complexity (e.g. the information is not applicable in my setting)
- [ ] Language barrier (e.g. the information is not available in my native/working language and/or I am not confident to assess the information in English)
- [ ] No, I find the information understandable
- [x] Other

11.2. If "other", please specify:

The overall EMA website should be more user-friendly to allow a quick access to the information. Also, when reading/watching the information, there is challenges regarding its length and density (e.g., the material is too long).

* 12. In September 2022, the EMA and Heads of national Medicines Agencies (HMA) published a joint "statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU" (updated in 2023). How familiar are you with the EMA statement on biosimilar interchangeability and the accompanying communication materials?

- (●) Very familiar
- ( ) Somewhat familiar
- ( ) Not familiar at all

* 12.1. Have you encountered any challenges in understanding the HMA-EMA joint statement on biosimilar interchangeability?

Select one or more as relevant.

- [ ] Complex language (e.g. the words used are too difficult or technical)
- [ ] Length and density (e.g. the material is too short / too long)
- [ ] Lack of clarity (e.g. the information is ambiguous)
- [ ] Limited access to prior knowledge (e.g. the evidence behind the information is questionable)
- [ ] Technical complexity (e.g. the information is not applicable in my setting)
- [ ] Language barrier (e.g. the information is not available in my native/working language and/or I am not confident to assess the information in English)
- [x] No, I find the information understandable
- [ ] Other

* 13. Following the publication of the joint EMA-HMA statement on interchangeability, in April 2023, the EMA published a dedicated Questions and Answers (Q&A) document to address frequent queries regarding interchangeability of biosimilar medicines in the EU. How familiar are you with this Q&A document?

- (●) Very familiar
- ( ) Somewhat familiar
- ( ) Not familiar at all

* 13.1. Have you encountered any challenges in understanding this Questions & Answers document?

Select one or more as relevant.

- [ ] Complex language (e.g. the words used are too difficult or technical)
- [ ] Length and density (e.g. the material is too short / too long)
- [ ] Lack of clarity (e.g. the information is ambiguous)
- [ ] Limited access to prior knowledge (e.g. the evidence behind the information is questionable)
- [ ] Technical complexity (e.g. the information is not applicable in my setting)
- [ ] Language barrier (e.g. the information is not available in my native/working language and/or I am not confident to assess the information in English)
- [x] No, I find the information understandable
- [ ] Other

* 14. What changes or improvements would you recommend in the EMA guidelines/materials on biosimilar interchangeability?

Select one or more as relevant.

- [x] Clarity on interchangeability criteria
- [ ] Extrapolation guidance (indication)

- [x] Guidance on switching practices (multiple switching or changes in formulation)
- [ ] Patient education
- [x] Healthcare professional education
- [x] Clear communication strategies
- [ ] Other

* 15. How would you like to be informed on further updates on biosimilars, including interchangeability?
Select one or more as relevant.

- [ ] Medical journals and online medical databases
- [x] Clinical guidelines and protocols
- [x] Professional associations and societies
- [x] HMA-EMA website/newsletter/events
- [ ] Conferences and congresses
- [x] Medical websites/medical news outlets
- [ ] Medical books and textbooks
- [ ] Social media platforms
- [x] Continuing Medical/Professional Education and Development (CME/CPD) programmes
- [ ] Medical podcasts and webinars
- [x] Hospital and healthcare system communications/clinical decision support systems
- [ ] National medicines agencies
- [ ] Other

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

- ( ) No
- (•) Yes

* 16.1. If yes, what specific topics do you think require more emphasis in education or training?
Select one or more as relevant.

- [ ] Biological medicines in general
- [x] Regulatory framework
- [ ] Development programme of biosimilars
- [ ] Clinical data interpretation / real-world evidence
- [x] Immunogenicity monitoring and verification
- [x] Immunogenicity monitoring and verification Patient-centric communication
- [x] Patient-centric communication
- [x] Switching studies and strategies
- [ ] Pharmacovigilance practices
- [ ] Legal and regulatory environment
- [ ] Dose, application and device difference management
- [x] Multidisciplinary collaboration
- [ ] Other

Please feel free to share anything else about healthcare professionals' information needs regarding interchangeability or other aspects of biosimilars.

Regarding question 6, we would like to provide additional information that, for example, Germany has published its first guideline on biosimilars in 2009.
It is also worth mentioning the IQVIA study from last year on Biosimilars that is accessible through the following link: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/assessing-the-biosimilar-void/iqvia-institute-assessing-the-biosimilar-void-10-23-forweb.pdf

Contact

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