



# **Biosimilar Breakout Session:**

## **HMA-EMA Multi-stakeholder workshop on shortages**

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1-2 March 2023

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# Objectives of session on biosimilars

## HMA-EMA multi-stakeholder workshop on shortages

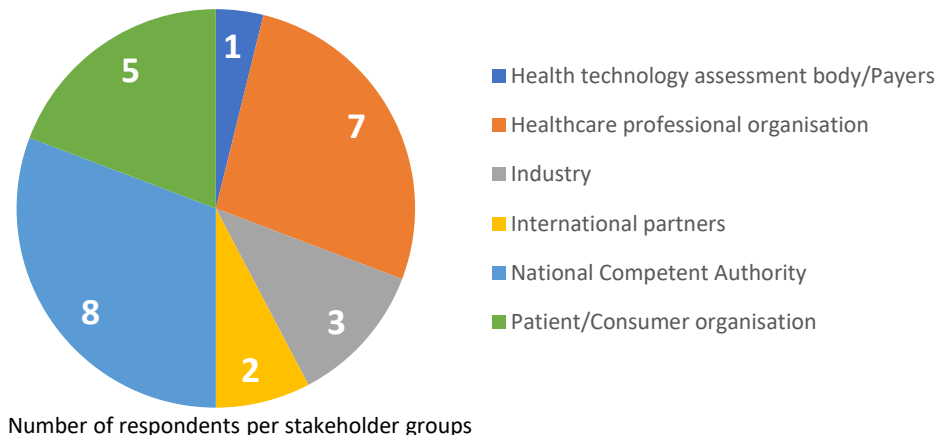


- **Understand stakeholders' experience on shortages** of biological medicines, including biosimilars and gather views on **whether availability of biosimilars could** be a good way to **prevent shortages** of biologicals
- Provide an **overview** of the work **of HMA working group on biosimilars** and explain the **EU scientific position on interchangeability**
- Understand how the work undertaken by the **European Medicines Agencies Network** could **prevent potential shortages of biologicals** and **increase the uptake of biosimilars**

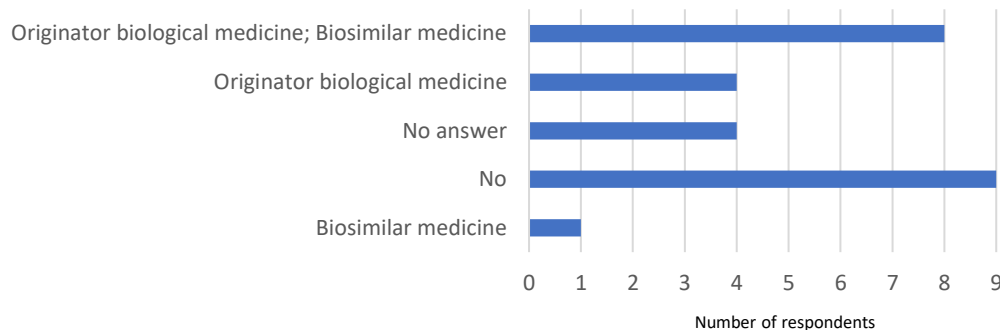
# Pre-meeting survey findings

- 26% of registered participants replied to the pre-meeting survey (n=26)
- Majority of respondents (77%, 20 out of 26) are based in EU; respondents also from Australia, Norway, UK and USA

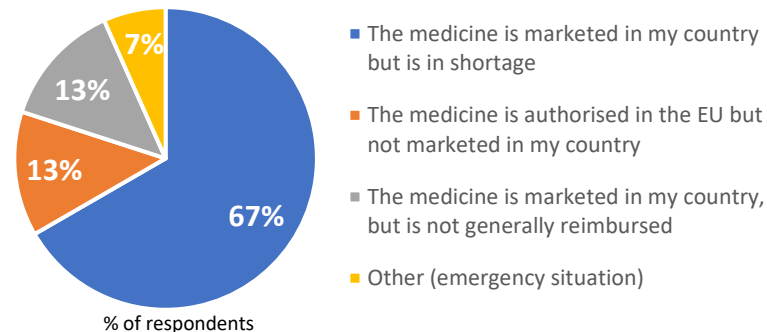
## Who you are representing:



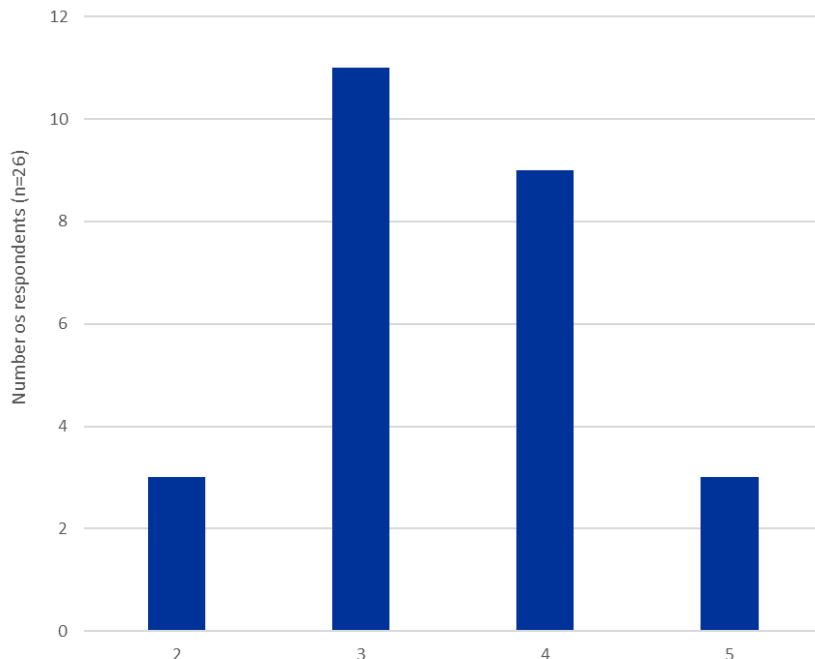
## Have you experienced shortages of any of the following types of medicine:



## What is the perceived reason of the shortage?



## How well informed are you about biosimilars?

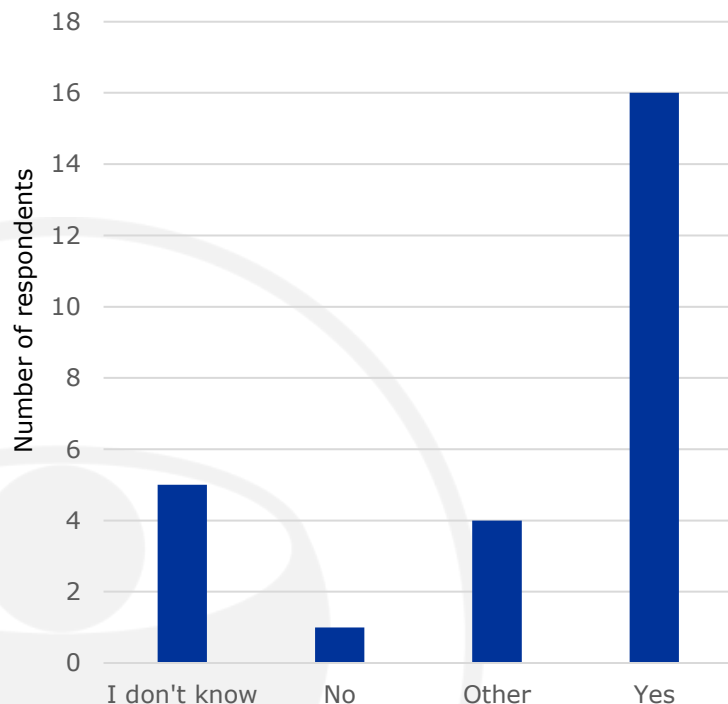


Rating: 1 = not at all, 2 = not very much, 3 = somewhat, 4 = a fair amount, 5 = a great deal

- 84% of respondents have no reason not to trust **interchangeability of biosimilars**
- 4/25 respondents identified the following reasons for not trusting interchangeability of biosimilars:
  - HCP: Unfortunately, only few comparative studies have been published in ophthalmology on switching from original to a biosimilar - with mixed results as in the field of uveitis
  - HCP: You cannot treat all biologicals the same. Some biologicals can be copied and for others this is difficult. Also, not sensible to use mix of biosimilars e.g. adalimumab has 6 biosimilars so patient training needed if move from one to another as injectable with all different pen devices and you need to add cost of training the patient.
  - NCA: Efficacy can be lowered by development of anti-antibodies to one product. Changing back to that product would not be rational.
  - Patients: its not same technology.

# Pre-meeting survey findings

## Do you think biosimilars are useful alternatives to prevent potential shortages of biological medicines?



- Some respondents provided another answer:
  - **HCP:** Due to financial pressures, ophthalmologists are switching to biosimilars but only for those patients one feels that can be safely to do so and this requires careful monitoring of any changes. Overall ophthalmologists are not opposed to biosimilars, but it would be appropriate to introduce some rules. For the time being, the recommendation is that the prescribing doctors retain their freedom to prescribe the original drug in severe cases.
  - **Industry:** Availability of biosimilars to prevent shortages would be likely be related to prescribing and reimbursement practices, defined on a country level. Biologics/ Biosimilars may not be automatically interchangeable at pharmacy level – this is country specific. Additionally, physicians are not often keen to automatically exchange for a biosimilar if a patient is already stable on that medicine.
  - **NCA:** Mainly we think that biosimilars can prevent potential shortages, but in the long run if the competition is hard and prices go very low, it might also happen that some of the originals/biosimilars will leave the market if they become unprofitable.
  - **Patients:** Maybe in some place. But biosimilar is not the same as brand.

- 26% of registered participants replied to the pre-meeting survey (n=26) , with 77% of respondents (20 out of 26) based in the EU
- Wide representation of stakeholders, including patients, consumers and HCPs
- There is room for increasing information on biosimilars - over 50% of respondents (13 out of 25) are not very informed or somewhat informed
- Half of respondents (50%, 13 out of 26) have experienced a shortage of a biological or a biosimilar
- 84% (21 out of 25) of respondents have no reason not to trust interchangeability of biosimilars
- Reasons for lack of trust on interchangeability (16%, 4 out of 25) include lack of comparative studies, resource implications when training patients to use another device after switching and potential loss of efficacy due to immunogenicity
- Over half of respondents (62%, 16 out of 26) consider biosimilars as an useful alternative to prevent shortages of biological medicines

# Thank you for listening

## Further information

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See websites for contact details

**Heads of Medicines Agencies** [www.hma.eu](http://www.hma.eu)  
**European Medicines Agency** [www.ema.europa.eu](http://www.ema.europa.eu)

The European Medicines Agency is  
an agency of the European Union

