EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Campaigns @EMA – Recent examples, looking ahead

PCWP/HCPWP, 3 March 2023

Presented by
Monika Benstetter
Head of Media and Public Relations

In this presentation

- Examples of some of our campaigns in 2022
  - Good practice guide on shortages
  - Interchangeability of biosimilars
- Thinking about joint campaigns?
- European Immunisation Week 2023

Good practice guidance on prevention of shortages

July 2022

The brief

- **Increase visibility of good practice guidance among patients, consumers, healthcare professionals**
- **Raise awareness for key principles set out in the guidance**
- **Help people find information about shortages**

Web updates

News item & slider

Social media

EMA LinkedIn; Twitter; Instagram.

HMA
Heads of Medicines Agencies

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13 May 2022
EMA/397143/2020

Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use

1. Introduction

Medicine shortages as well as availability issues due to revocations or cessations of marketing authorisations are recognised as a growing issue across the EU and globally, and the COVID-19 pandemic has further increased their impact. They affect medicines of all classes and are increasingly affecting European countries. This may have a significant impact on patient care as they can lead to medicine rationing and delay of critical treatments and can require patients to use alternatives which may be less efficacious or may increase the risk of medication errors due to unfamiliarity with the new regimen. The use of alternatives may also lead to adverse events caused by unexpected drug-drug interactions and to suboptimal treatment outcomes, which can lead to additional healthcare costs. Availability issues with shortages in particular are recognised as a major area to tackle in the European Medicines Agencies Network Strategy to 20251 as well as in the European Commission's roadmap for its Pharmaceutical Strategy - Timely patient access to affordable medicines.2 The European Commission's roadmap for its Pharmaceutical Strategy and the legal mandate to reinforce the role of EMA in supply shortages in times of crisis will also provide further opportunities to pursue full transparency for shortage information, especially during times of crises.

Supply chains are complex and involve many different stakeholders, from patients and healthcare professionals to the pharmaceutical industry. The causes of shortages are multifactorial, and can include manufacturing problems causing delays or interruption in the production, shortages of raw materials, increased demand of medicines, distribution problems, labour disruptions and natural disasters. Close involvement of stakeholders is a prerequisite for avoiding and handling shortages. In addition, a successful response to medicine shortages requires a multi-layered approach that includes detection, prevention and response strategies.

This paper focuses on proactive mechanisms to prevent shortages of medicines for human use. As patients and healthcare professionals are the main actors at the end of the supply chain, their activities in preventing shortages are usually limited to demand management strategies. This paper goes beyond standard demand management strategies and also looks at measures that help to improve preparedness, planning and rationed use for medicines that are either in short supply or expected to

[1] https://www.ema.europa.eu/en/news/launch-public-consultation-joint-network-strategy-2025
[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines

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Infosheet:

Towards better prevention of medicine shortages

EMA has published key principles and examples of good practices to support patients' and healthcare professionals' organisations in preventing and managing shortages of human medicines.

What **patients' organisations** can do to prevent shortages of medicines

- Develop **observatories** in collaboration with national authorities to **collect and analyse information** from patients on shortages and their early signs.
- Work with national authorities to develop criteria and a methodology for **registries of essential and critical medicines**.
- **Communication and awareness raising** among members on causes of shortages, the safe use of alternative medicines, risks of stockpiling and where to find information on ongoing shortages.

What **healthcare professionals' organisations** can do to prevent shortages of medicines

- Develop **observatories** in collaboration with national authorities to **collect and analyse information** from healthcare professionals on shortages and their early signs.
- Work with national authorities to develop criteria and a methodology for **registries of essential and critical medicines**.
- **Communication and awareness raising** among members on causes of shortages, the safe use of alternative medicines, risks of stockpiling and where to find information on ongoing shortages.
- Work with national authorities to ensure **reporting, electronic prescribing and alert systems are linked up** to minimise workload and optimise information flows.
- Promote **transparency in the supply chain** so pharmacists can identify alternative suppliers more easily.
- Collaborate with health authorities to put in place measures to **avoid stockpiling of medicines**, when needed.
- Liaise with health authorities to issue guidance on **dose-sparing measures.**
- Encourage healthcare professionals to carry out shortage **risk assessments** for medicines with high clinical impact.

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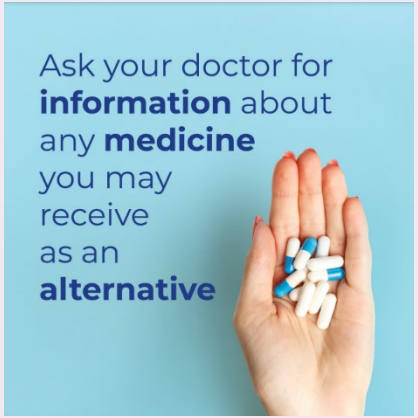


Interchangeability of biosimilars

September 2022

The brief

- **Raise awareness for formalised CHMP position that biosimilars can be interchanged.**

- Reinforce attitudes to biosimilars as a high-quality alternative to brand products.
- Support changes in GP’s prescribing behaviour

Web updates

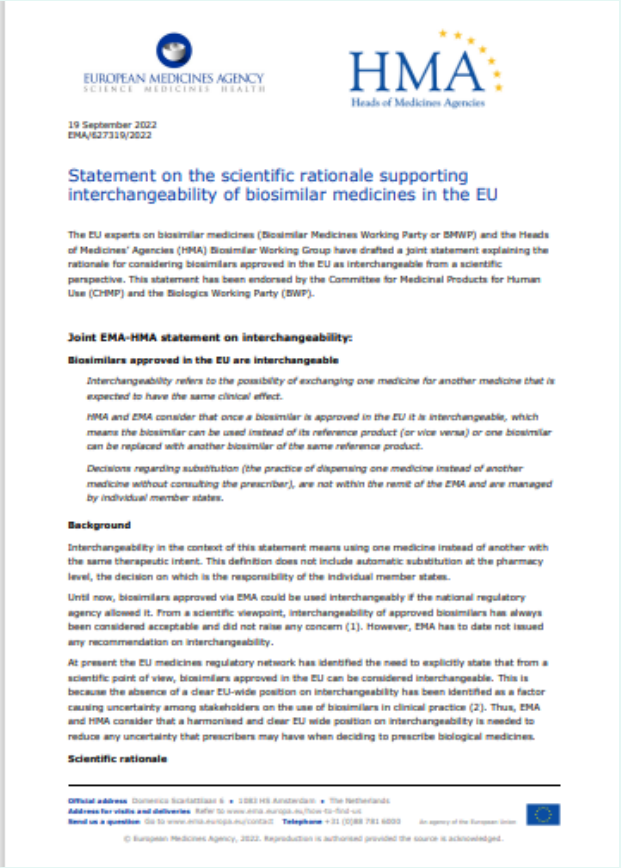
News item & slider

Social media

EMA LinkedIn; Emer LinkedIn; Twitter; Instagram.

Stakeholders as multipliers

Comms package shared with e.g. WGCP, PCWP, HCPWP.



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HMA
Heads of Medicines Agencies

19 September 2022
EMA/627319/2022

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

The EU experts on biosimilar medicines (Biosimilar Medicines Working Party or BMWP) and the Heads of Medicines' Agencies (HMA) Biosimilar Working Group have drafted a joint statement explaining the rationale for considering biosimilars approved in the EU as interchangeable from a scientific perspective. This statement has been endorsed by the Committee for Medicinal Products for Human Use (CHMP) and the Biologics Working Party (BWP).

Joint EMA-HMA statement on interchangeability:

Biosimilars approved in the EU are interchangeable

Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect.

HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product.

Decisions regarding substitution (the practice of dispensing one medicine instead of another medicine without consulting the prescriber), are not within the remit of the EMA and are managed by individual member states.

Background

Interchangeability in the context of this statement means using one medicine instead of another with the same therapeutic intent. This definition does not include automatic substitution at the pharmacy level, the decision on which is the responsibility of the individual member states.

Until now, biosimilars approved via EMA could be used interchangeably if the national regulatory agency allowed it. From a scientific viewpoint, interchangeability of approved biosimilars has always been considered acceptable and did not raise any concern (1). However, EMA has to date not issued any recommendation on interchangeability.

At present the EU medicines regulatory network has identified the need to explicitly state that from a scientific point of view, biosimilars approved in the EU can be considered interchangeable. This is because the absence of a clear EU-wide position on interchangeability has been identified as a factor causing uncertainty among stakeholders on the use of biosimilars in clinical practice (2). Thus, EMA and HMA consider that a harmonised and clear EU wide position on interchangeability is needed to reduce any uncertainty that prescribers may have when deciding to prescribe biological medicines.

Scientific rationale

Organic campaigning capacity in press and social media

press distribution list (1000)

accreditation list for press events (450)

YouTube European Medicines Agency (17,500)

Twitter @EMA_News (117,000)

LinkedIn European Medicines Agency (255,000)

LinkedIn Emer Cooke (Influencer)

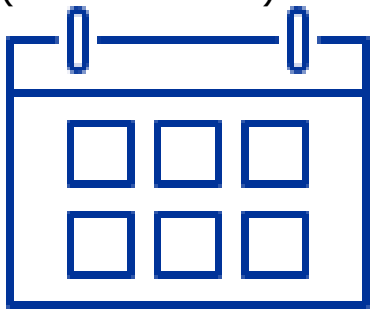
Instagram @one_healthenv_eu with ECDC, EFSA, EMA (8,200)

Joint campaigns?

Starting point: understanding each other's needs and limitations

- Joint message development
- Joint dissemination plan
- Coordinated posting
- Amplification of each other's messages
- Joint evaluation and learning

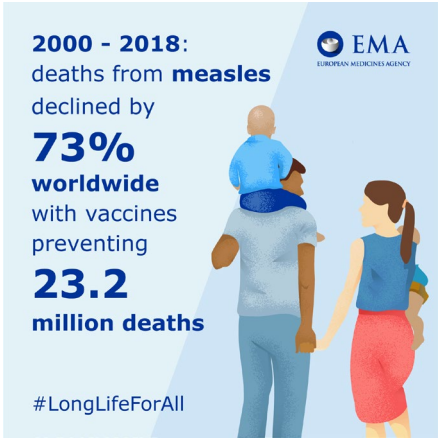
- Planned at EMA for 2023
  - European Immunisation Week (23-29 April)
  - European Antibiotic Awareness Day (18 November)

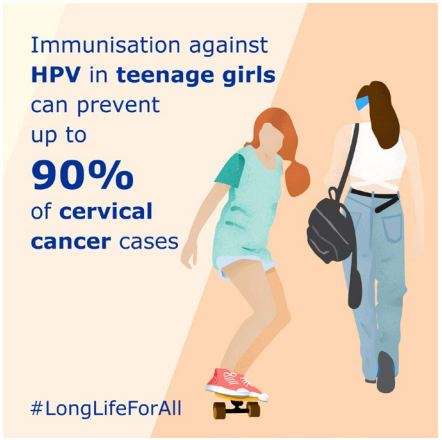


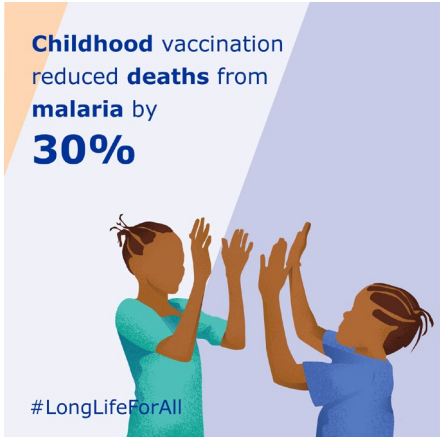
European Immunisation week (23-29 April 2023)

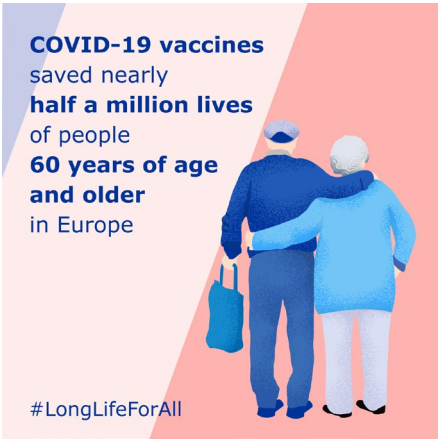
Objective

Improve vaccine uptake in the context of a global backslide in vaccination rates due to the COVID-19 pandemic.









Going forward

- Is there interest in joint campaigning generally?
- Is there interest in joining forces for European Immunisation Week?
- Is there interest in forming a small campaign planning group?
  - Start with EIW 2023?

Any questions?

Further information

monika.benstetter@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
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