Work plan of the HMA Biosimilar Working Group (BSWG)

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Conclusions of the Stakeholder meeting on biosimilars (during the Finnish EU Presidency 18.9.2019)

- Introduction of biosimilars increases price competition and enhances the availability of expensive biological medicines to patients
- Biosimilar market penetration, market shares and availability varies widely both within and between different MSs
- Only few MSs have currently specific policies for promoting biosimilars
- NCAs need to take stronger positions to increasing trust in biosimilars
- The industry highlighted the need for sustainable policy frameworks
- Medicine regulators may need to take new actions in order to realize the full potential of biosimilars in Europe

The HMA biosimilar pilot group (1)

In the plenary of HMA I Helsinki 9/2019 meeting it was proposed by Fimea to create a HMA Biosimilar Working Group. The plenary preferred to wait for the finalization of the strategy of the European Medicines Agencies Network strategy (EMANS) and suggested to pilot such a group.

The HMA biosimilar pilot group was established 12/2019.

13 NCAs and EMA have participated this pilot group, seven virtual meetings had taken place until 9/2021

Agendas have included sharing of nationally available information packages on biosimilars and national tactics to enhance the uptake of biosimilars

The HMA biosimilar pilot group (2)

An article on interchangeability of biosimilar monoclonal antibodies has been written by a drafting group (FI, DE, BE, GR, IE) and accepted for publication (Kurki *et al*. Drugs 2021)

A survey has been carried (EE) on the information on biosimilars available on the webpages of NCAs

- 29 websites
- in 10 NCAs info on biosimilars was totally missing
- best examples highlighted and shared

Similar findings on the information at the websites of NCAs

Barbier *et al.* 2022 (Regulatory Information and Guidance on Biosimilars and Their Use Across Europe)

40 % of NCAs did not have any info on biosimilars

Less than half NCAs provided info about interchangeability, switching and substitution

https://pubmed.ncbi.nlm.nih.gov/35355594/

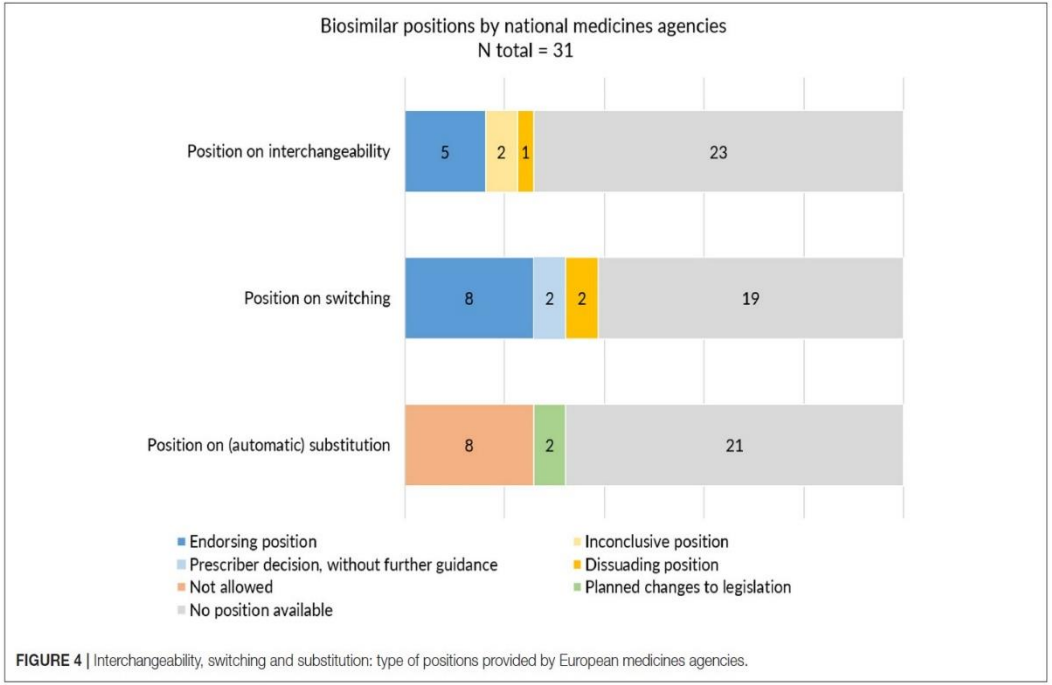

FIGURE 4 | Interchangeability, switching and substitution: type of positions provided by European medicines agencies.

The HMA biosimilar pilot group (3)

Information on the analysis of identification of biosimilars using the EMA adverse drug reaction data base has been shared and a publication has been accepted

Other relevant articles and reviews (e.g. annual IQVIA report) have been shared and discussed

Follow up of development of national legislation (e.g. automatic substitution in Germany and Norway, abbreviated acceptance pathway in the UK) has been carried out

Sharing best practices

Becoming an ”official” group of HMA

The Biosimilar Working group (BSWG) was establised at the HMA I Slovenia meeting 9/2021 and the mandate was endorsed.

BSWG continued with the 13 agencies [AT, BE, CZ, EE, ES, FI, GE (PEI), GR, IE, IT, LV, NO, SL) which originally participated the pilot and EMA later also SE and FR have joined

Esa Heinonen (Fimea), who had chaired the pilot group, has continued to chair the meetings together with Vice-Chair Steffen Thirstrup, Chief Medical Officer of EMA

The BSWG officially started 1/2022, and has had three virtual meetings and one face-to-face meeting in 2022

EMA has provided the secretariat (Charlotte Hallin), the scientific secretariat consists of Ingrid Bourges (BE) and Niklas Ekman (FI).

Mission of the HMA Biosimilar Working group

HMA biosimilar working group generates and disseminates tailored information and contributes to training on the quality, efficacy, safety and immunogenicity of biosimilars to **increase confidence in biosimilars** in order to **enhance healthy competition** on the national markets of biologicals thus increasing the availability of expensive biological medicines to patients.

The working group will **support efforts of the NCAs especially in topics outside the EMA mandate**, e.g. informing on interchangeability/substitution and harmonization of NCA messages on biosimilars.

The group keeps HMA updated on the regulatory development in the field of biosimilars.

Goals of BSWG in the multiannual workplan of the HMA/EMA

"Review existing information materials relating to biosimilars at national and European level and develop a **toolkit** (including materials related to the switching from originators to biosimilars) that can be employed at national level as appropriate

Update **guidance** on data required to support approval of biosimilars and demonstrate comparability with the originator product

Arrange **training** for assessors to facilitate a consistent approach to the review of biosimilars in line with agreed European guidance"

Work plan of the BSWG 2022-2023 (1)

1. Create the TOOL KITS on biosimilars for health care professionals and patients

- Drafting group established: IE (lead), EMA, AT, NO
- First task is to list materials to be included in the TOOL KITs Q4/2022
- Draft information package ready for health care professionals 6/2023
- Draft information package ready for patients 12/2023
- Recommendation on how to use the info packages 12/2023

Work plan of the BSWG 2022-2023 (2)

2. Provide recommendation on the basic information of biosimilars for the websites of the NCAs:

- Drafting group established: EE (lead), FI, IT
- Text recommendation was finalized and endorsed at the HMA I Prague meeting 9/2022
- Commitment from HMA to use the recommended items by each NCA (taking into consideration possible national legal restrictions)

Work plan of the BSWG 2022-2023 (3)

3. Suggest a text on interchangeability of biosimilars at the website of EMA

- drafting group [EMA (lead), PEI, IE, FI] provided a text suggestion together with the BMWP (Biosimilar Medicines Working Party at EMA)
- the text and related scientific rationale was discussed at EMA, CHMP endorsement 9/2022
- EC and industry associations were informed before hand
- the document was published 9/2022;

Work plan of the BSWG 2022-2023 (4)

4. Ensure communication on regulatory and legislative changes on biosimilars between EMA (e.g. changes in regulatory guidelines prepared by the BMWP) and NCAs (e.g. regarding automatic substitution)

5. Further sharing of information within the network

- Sharing relevant articles and other publications (e.g. annual IQVIA reports) at the BSWG meetings
- Sharing best practices (e.g. legislation, tendering, pricing, substitution) to promote the access to biosimilars

Work plan of the BSWG 2022-2023 (5)

6. Support EU Network Training center (EU-NTC)
   - It is in the remit of BMWP to give training to assessors
7. Enhance and support research on biosimilars
   - support academic groups to carry out research on biosimilars
8. Other goals:

- Address specific topics at the request of HMA and draft opinions on biosimilars
- Respond to requests from NCAs on biosimilar questions and contributing to stakeholder meetings at national or EU level
- Draft publications on specific biosimilar topics when needed

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union