INTERPERMUTABILIDADE DE MEDICAMENTOS BIOLÓGICOS E IMPLICAÇÕES PRÁTICAS

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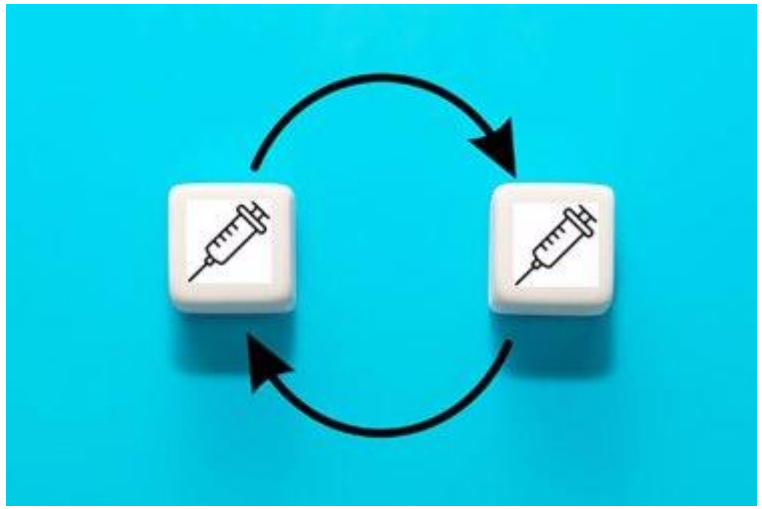

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

19 September 2022
EMA/627319/2022

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

Approved biosimilars have demonstrated comparable efficacy, safety and immunogenicity compared with their reference products (5). Thus, EU experts consider that when approval for a biosimilar is granted in the EU, additional systematic switch studies are not required to support the interchangeability at prescriber level.

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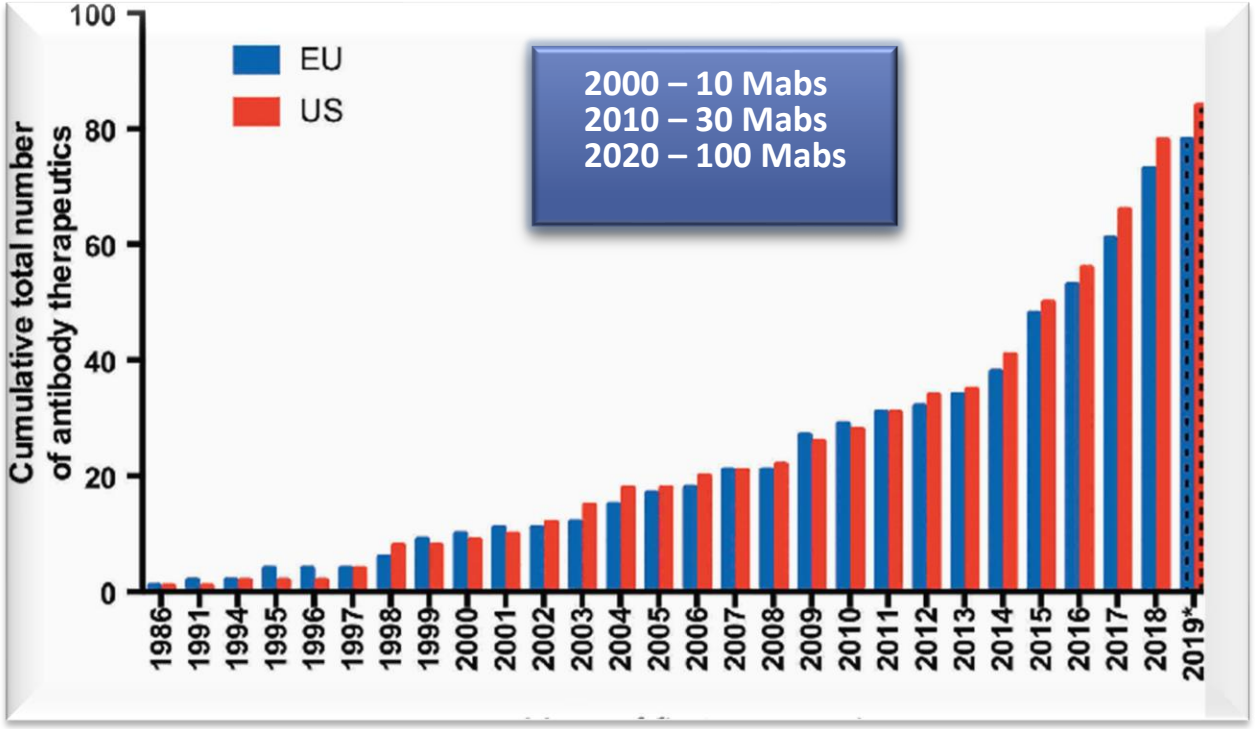
- **EMA tem aprovados 88 biossimilares**
- Apenas 16 biológicos têm biossimilares
- 16 biológicos → 88 biossimilares
- 100 biológicos → **550 biossimilares**
  !



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Auto - Administração

Preparação e administração por profissional saúde

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Hospital Garcia de Orta

Pharmacy Department
Hospital Garcia de Orta
Almada - Portugal

Infliximab biosimilar: Cost-Efficacy Analysis

Alcobia, A.[1] ; Bento, R. [2] ; Camões Domingos, S.[1] ; Silva, M. [2] ; Soares, A.[1]

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Material and methods

All new patients treated with infliximab between January 2014 and October 2015 were considerer for our study. The criteria used to evaluate treatment efficacy were: for psoriatic and rheumatoid arthritis, the number of tender joints and the number of swollen joitns; for ankylosing spondylitis, the BASDAI and BASFI scales; for patients with Crohn's disease and ulcerative colitis, biochemical and clinical development before and after treatment with infliximab.

Results

46 patients

23 patients

23 patients

According to the medical records, there was similar efficacy between the reference and the biosimilar infliximab.

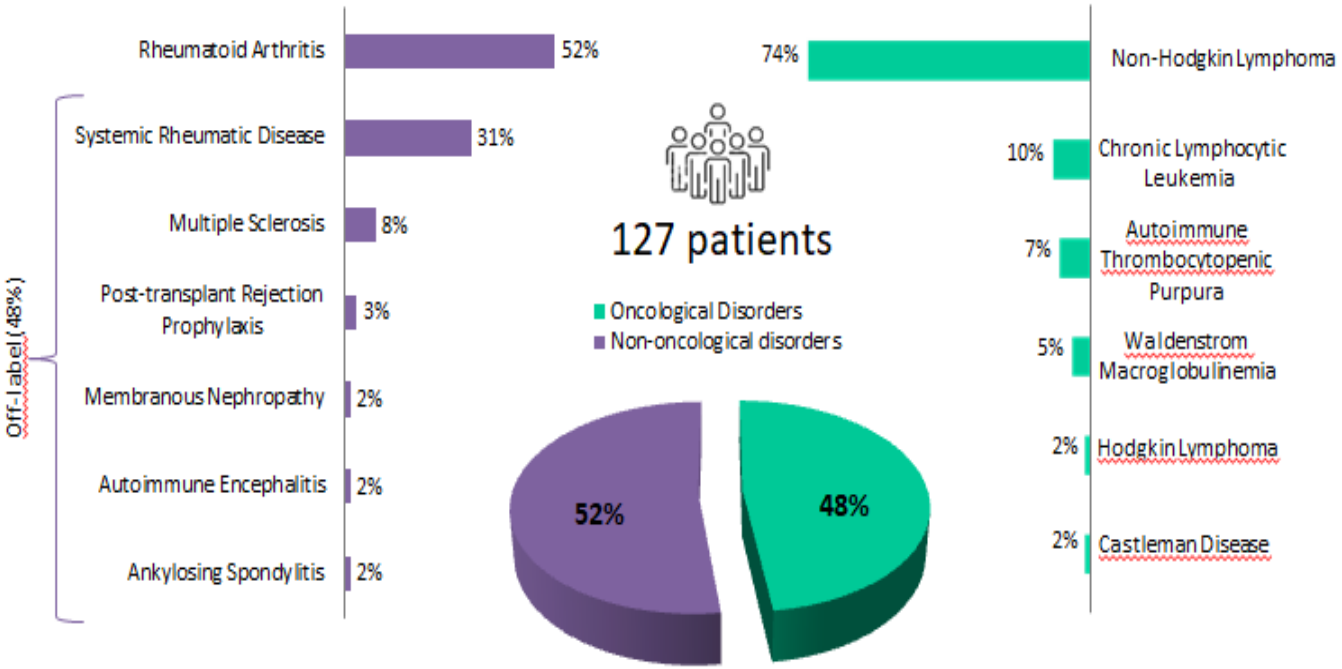
84,6% efficacy

Biosimilar	Reference
19 responders	18 responders
3 inefficacy	5 inefficacy
1 toxicity	-

78,3 % efficacy

The economic impact of switching all patients to a bisiomilar could result in a 27% saving in annual spending on infliximab. During the time of follow- up (22 months) it was saved approximately 45.848 €.

Switch Rituximab



Oncological Disorders

- **Therapeutic Switch** 9,8%
- **Naïve Patients** 90,2%
- **Switch Time** 34 days [21-58 days]
  - Mean time between the last administration of rituximab and the first administration of biosimilar rituximab

3 severe first IRR (4,9%) that led to biosimilar rituximab **suspension**
- **2** successful re-challenge
- **1** permanent discontinuation

The rate of first IRR was 6.5% in oncological disorders

Non-Oncological Disorders

- **Therapeutic Switch** 39,4%
- **Naïve Patients** 60,6%
- **Switch Time** 13,6 months [0,9-48 months]

No severe first IRR
- **1** successful re-challenge

The rate of first IRR was 2,9% for Rheumatoid Arthritis (RA)

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HOSPITAL Garcia de Orta E.P.E.

A referência a Sul

Hospital Garcia de Orta EPE Almada, Portugal

BEVACIZUMAB BIOSIMILAR USE IN OPHTHALMOLOGY

Mestre, H.; Lobanov, M.; Barreira, T.; Canário, C.; Camões, S.; Alcobia, A.

5PSQ-077

INTRODUCTION

Bevacizumab is an anti-VEGF antibody currently used in ophthalmology as an off-label treatment for age-related macular degeneration, diabetic macular oedema, and oedema secondary to retinal vein occlusion. Despite is off-label use, various studies had shown similar results between bevacizumab and other anti-VEGF treatments. With the availability of a biosimilar with same presentation and excipients a switch program was implemented.

AIM AND OBJECTIVES

Compare the effectiveness of Bevacizumab Avastin® versus Biosimilar MVASI® in Ophthalmology Department.

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METHODS

A retrospective observational study analyzed 122 patients (65 were male and 57 female) who underwent the first intravitreal administration (IVI) between January 2020 and March 2021. Data from best corrected visual acuity (BCVA) and central subfield thickness (CST) were collected. Exclusion criteria were the absence of registration of Optical Coherence Tomography (OCT) and BCVA or failure to comply to 3 loading dose injectiOns. The patients were divided into 3 groups: group 1, 63 patients (3IVI of Avastin), group 2, 30 patients (3 IVI of biosimilar), and group 3, 29 patients (3 IVI, transitioning from Avastin® to the biosimilar, either with 1 or 2 Avastin® administrations. Manova test was used to determine statistically significant differences among the groups, taking into account the values of BCVA and CST, patient's age, and the number of days between the last registration prior to the first IVI and the first posterior to the third IVI, without any corrections for differences between groups. T-tests were used to obtain graphic representations of the results.

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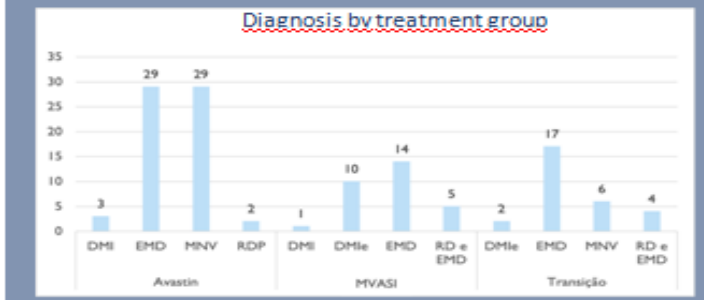
RESULTS

The analyzed sample had a mean of ages of 71.56 years. After three IVI, in group 1, there was 82% of improvement for CST; in group 2 there was 92% and for group 3 there was 84%. MANOVA test was performed showing **no statistical significance in BCVA and OCT central thickness difference between three groups** [Wilk's Lambda (p=0.238)] neither between MVASI group with the Avastin® group [Hotelling T-square Test (p=0.114, equal covariance)].

	Avastin *			Mvasi*			Transition		
	Average	IC95%	n	Average	IC95%	n	Average	IC95%	n
Age	73,65	[71,36;75,94]	63	63,8	[63,73;71,87]	30	73,24	[68,93;77,55]	29
Evaluation Days	117	[110,7;123]	63	121	[112,3;129,4]	30	128	[120,7;136]	29
AVD	3,73	[3,06;4,4]	43	3,39	[2,52;4,25]	22	3,34	[2,29;4,25]	16
AVD	3,59	[2,92;4,27]	43	4,46	[3,5;5,1]	22	3,59	[2,41;5,41]	16
Δ AVD	-0,14	[-0,78;0,5]	43	1,07	[0,26;1,88]	22	0,25	[-0,32;1,88]	16
ECC	3,73	[345;403]	63	348	[309;391]	28	404	[355;460]	28
ECC	305	[281;330]	63	315	[281;352]	29	336	[295;382]	29
Δ ECC	81,80%	[0,748;0,894]	63	91,90%	[0,83;1,017]	27	83,60%	[0,761;0,919]	28

Table 1. Clinical data evaluated
AVD: Snellen visual acuity, on the decimal scale; ECC: sub-centre field thickness, in µm



Figur1 1. Diagnosis by treatment group
DMI – Age-related macular degeneration; DMIe – Age-related macular degeneration, wet choroidal neovascularization; MNV – Myopic choroidal neovascularization; EMD – Diabetic Macular Edema; RD – Retinal detachment; RDP – Proliferative retinal detachment

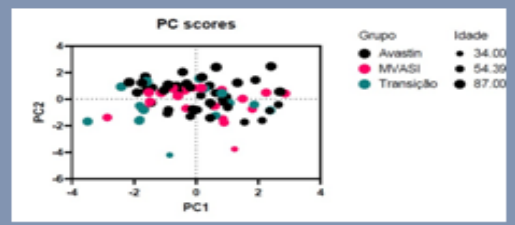


Figure 2. Analysis of the main componentes: age, number of days between assessments, initial ADL, final ADL, initial ECC and final ECC

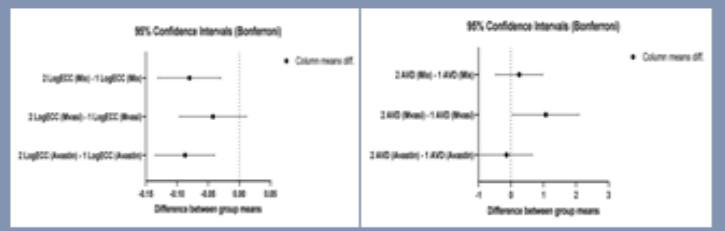


Figure 3. T Tests for paired differences

Switch Bevacizumab

- AGENZIA ITALIANA DEL FARMACO DETERMINA 15 giugno 2020 Inserimento del medicinale per uso umano «Mvasi» nell'elenco dei medicinali erogabili a totale carico del Servizio sanitario nazionale, ai sensi della legge 23 dicembre 1996, n. 648, per il trattamento della compromissione visiva dovuta a edema maculare diabetico. (Determina n. 66073). (20A03240)

- Art. 2 1. I medicinali di cui all'art. 1 sono erogabili a totale carico del Servizio sanitario nazionale per il trattamento della compromissione visiva dovuta a edema maculare diabetico, limitatamente ai pazienti con acuita' visiva non peggiore di 20/40, nel rispetto delle condizioni per esso indicate nel secondo e terzo comma e nell'allegato 1, che e' parte integrante della presente determina. 2. L'erogazione del medicinale bevacizumab (Avastin e biosimilare Mvasi) deve essere effettuata secondo le seguenti condizioni, finalizzate alla tutela del paziente nell'uso del suddetto farmaco per un'indicazione non autorizzata:

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Demasiada pressão nos biossimilares?

0,72€/mg

Outros biológicos?

24€/mg

- Pode reduzir o nº fornecedores
- Pode aumentar o risco de rupturas
- Pode manter os monopólios
- Não incentiva os “biobetters”

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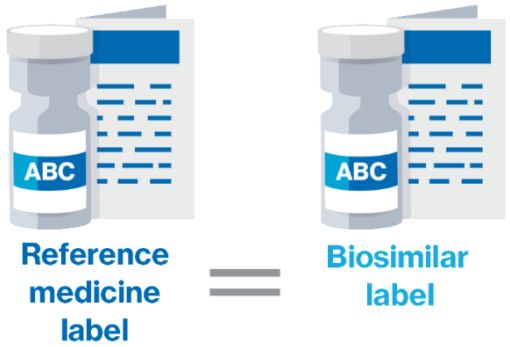

<u>Substituição Automática</u> nos biossimilares com longa experiência de utilização e comprovada segurança (como decorre com o filgrastim)

Incentivos para os biobetters

Potenciar melhoria da estabilidade

Identificação com QR Code

Personalização dos regimes terapêuticos

Obrigado pela vossa atenção

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