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Biosimilar medicines clinical use: an experience based-EU perspective

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Washington D.C. ,USA

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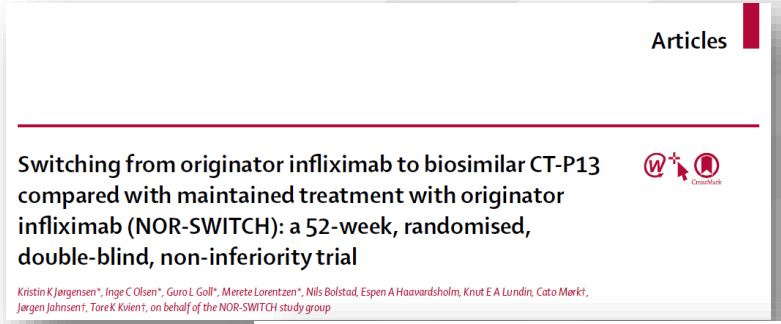
Large Body of Confirmatory Evidence
11 Years of Biosimilar medicines Clinical Use

Real-world experience

700 million
patient days[1]

"Over the last 10 years, the EU monitoring system for safety concerns has not identified any difference in the nature, severity or frequency of adverse effects between biosimilars and their reference medicine" [2]

Controlled experience



Articles

Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial

Kristin K Jørgensen*, Inge C Olsen*, Guro L Goll*, Merete Lorentzen*, Nils Bolstad, Espen A Haavardsholm, Knut E A Lundin, Cato Mørkt, Jørgen Jahnsent, Tore K Kvient, on behalf of the NOR-SWITCH study group

Clinical and epidemiological research
Concise report

A nationwide non-medical switch from originator infliximab to biosimilar CT-P13 in 802 patients with inflammatory arthritis: 1-year clinical outcomes from the DANBIO registry

Bente Glintborg[1, 2], Inge Juul Sørensen[3, 4], Anne Gitte Loft[5], Hanne Lindegaard[6], Asta Linauskas[7], Oliver Hendricks[8], Inger Marie Jensen Hansen[9], Dorte Vendelbo Jensen[2, 3], Natalia Manilo[10], Jakob Espesen[11], Mette Klarlund[12], Jolanta Grydehøj[13], Sabine Sparre Dieperink[3], Salome Kristensen[14], Jimmi Sloth Olsen[15], Henrik Nordin[16], Stavros Chrysidis[17], Dorte Dalsgaard Pedersen[18], Michael Veedfald Sørensen[19], Lis Smedegaard Andersen[20], Kathrine Lederballe Grøn[3], Niels Steen Krogh[21], Lars Pedersen[22], Merete Lund Hetland[1, 4] On behalf of all departments of rheumatology in Denmark

[1] Medicines for Europe information based on EMA Post-authorisation Safety Update Reports (PSURs)
[2] EMA – European Commission: Biosimilars in the EU – Information guide for healthcare professionals, 2017 (link)

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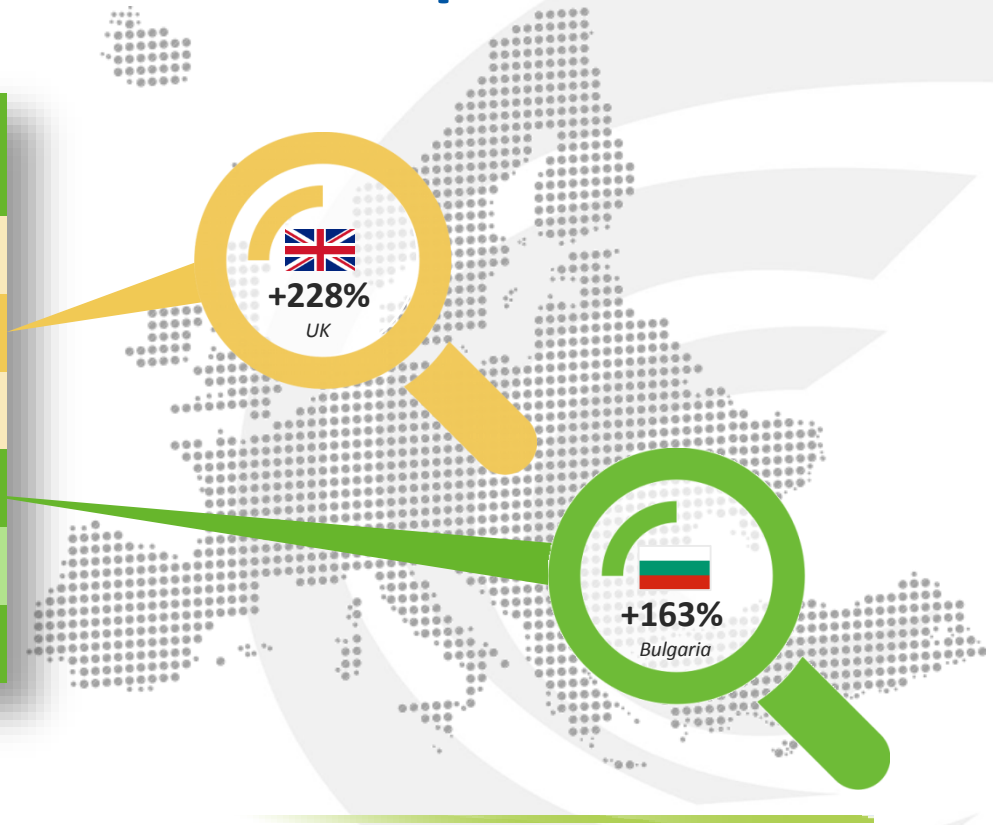
Biosimilar medicines increase patient access

Change in # of treatment days (2016 vs. year before biosimilar entrance)	
Epoetin	+66%
G-CSF (filgrastim)	+122%
Growth hormone (somatropin)	+41%
Anti-TNF (infliximab & etanercept)	+19%
Fertility (follitropin alfa)	+16%
Insulins	+19%



Source: QuintilesIMS (2017) The Impact of Biosimilar Competition in Europe

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THE BENEFITS OF BIOSIMILAR MEDICINES

LAUNCH OF BIOSIMILAR MEDICINES

REDUCTION OF TREATMENT COST

MORE PATIENTS TREATED

MORE TREATMENT OPTIONS

MORE AUTONOMY TO PRESCRIBE

MORE INVESTMENT FOR:

- HOSPITAL INFRASTRUCTURE
- CAPACITY BUILDING
- HEALTHCARE SERVICES

IMPROVED CARE AND HEALTH OUTCOMES FOR PATIENTS

+

ENSURED SUPPLY CHAIN SECURITY

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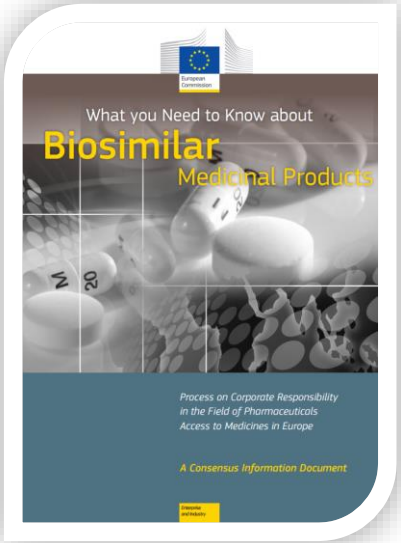
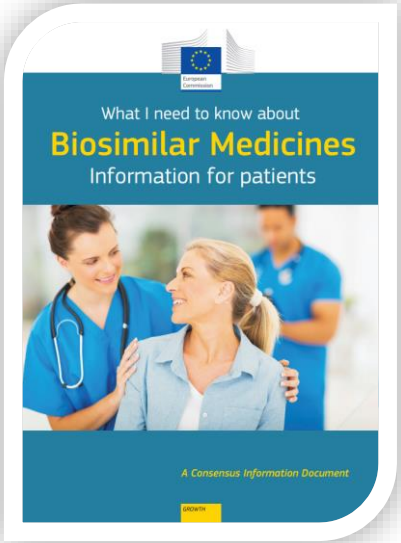
References (1)



What you need to know about biosimilar medicinal products
European Commission, 2013
(link)



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(link)

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(link)

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- **Biosimilars: what clinicians should now** (link)
  Weise et al, Blood 2012
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