

PEER-REVIEW REPORT

Name of journal: World Journal of Clinical Cases

Manuscript NO: 39028

Title: Biosimilars: Review of current applications, obstacles, and their future in medicine

Reviewer's code: 02446483

Reviewer's country: Canada

Science editor: Ze-Mao Gong

Date sent for review: 2018-03-27

Date reviewed: 2018-03-27

Review time: 10 Hours

SCIENTIFIC QUALITY	LANGUAGE QUALITY	CONCLUSION	PEER-REVIEWER STATEMENTS
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	<input type="checkbox"/> Accept	Peer-Review:
<input checked="" type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language	(High priority)	<input checked="" type="checkbox"/> Anonymous
<input type="checkbox"/> Grade C: Good	polishing	<input checked="" type="checkbox"/> Accept	<input type="checkbox"/> Onymous
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade C: A great deal of	(General priority)	Peer-reviewer's expertise on the
<input type="checkbox"/> Grade E: Do not	language polishing	<input type="checkbox"/> Minor revision	topic of the manuscript:
publish	<input type="checkbox"/> Grade D: Rejection	<input type="checkbox"/> Major revision	<input type="checkbox"/> Advanced
		<input type="checkbox"/> Rejection	<input type="checkbox"/> General
			<input type="checkbox"/> No expertise
			Conflicts-of-Interest:
			<input type="checkbox"/> Yes
			<input type="checkbox"/> No

SPECIFIC COMMENTS TO AUTHORS

Biosimilars are a drug class designed to be used interchangeably with biologics and are very important right now because of the increasing costs of healthcare in several countries. Biologics are created in living cells and are typically large, complex proteins that may have a variety of uses. Within the field of gastroenterology alone, biologics are



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used to treat inflammatory bowel diseases, cancers, and endocrine disorders. The editorial is well written and very instructive for clinical gastroenterologists!

INITIAL REVIEW OF THE MANUSCRIPT

Google Search:

- ☐ The same title
- ☐ Duplicate publication
- ☐ Plagiarism
- ☐ [Y] No

BPG Search:

- ☐ The same title
- ☐ Duplicate publication
- ☐ Plagiarism
- ☐ [Y] No

PEER-REVIEW REPORT

Name of journal: World Journal of Clinical Cases

Manuscript NO: 39028

Title: Biosimilars: Review of current applications, obstacles, and their future in medicine

Reviewer's code: 00073640

Reviewer's country: Slovenia

Science editor: Ze-Mao Gong

Date sent for review: 2018-03-27

Date reviewed: 2018-03-30

Review time: 2 Days

SCIENTIFIC QUALITY	LANGUAGE QUALITY	CONCLUSION	PEER-REVIEWER STATEMENTS
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	<input type="checkbox"/> Accept	Peer-Review:
<input checked="" type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language	(High priority)	<input checked="" type="checkbox"/> Anonymous
<input type="checkbox"/> Grade C: Good	polishing	<input checked="" type="checkbox"/> Accept	<input type="checkbox"/> Onymous
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade C: A great deal of	(General priority)	Peer-reviewer's expertise on the
<input type="checkbox"/> Grade E: Do not	language polishing	<input type="checkbox"/> Minor revision	topic of the manuscript:
publish	<input type="checkbox"/> Grade D: Rejection	<input type="checkbox"/> Major revision	<input type="checkbox"/> Advanced
		<input type="checkbox"/> Rejection	<input type="checkbox"/> General
			<input type="checkbox"/> No expertise
			Conflicts-of-Interest:
			<input type="checkbox"/> Yes
			<input type="checkbox"/> No

SPECIFIC COMMENTS TO AUTHORS

The title/subject is interesting and topical, the manuscript is well structured and well written. I have only 2 comments: - In the abstract there is sentence "Currently, five biosimilars have been approved by the FDA" in the discussion section and the Table - "Currently there are seven biosimilars approved...." - please correct appropriately -



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Table 1 – legend: please explain what means N/A in the Table 1

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- ☐ No

PEER-REVIEW REPORT

Name of journal: World Journal of Clinical Cases

Manuscript NO: 39028

Title: Biosimilars: Review of current applications, obstacles, and their future in medicine

Reviewer's code: 01429143

Reviewer's country: Italy

Science editor: Ze-Mao Gong

Date sent for review: 2018-03-27

Date reviewed: 2018-04-01

Review time: 5 Days

SCIENTIFIC QUALITY	LANGUAGE QUALITY	CONCLUSION	PEER-REVIEWER STATEMENTS
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	<input type="checkbox"/> Accept	Peer-Review:
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language	(High priority)	<input type="checkbox"/> Anonymous
<input checked="" type="checkbox"/> Grade C: Good	polishing	<input type="checkbox"/> Accept	<input checked="" type="checkbox"/> Onymous
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade C: A great deal of	(General priority)	Peer-reviewer's expertise on the
<input type="checkbox"/> Grade E: Do not	language polishing	<input checked="" type="checkbox"/> Minor revision	topic of the manuscript:
publish	<input type="checkbox"/> Grade D: Rejection	<input type="checkbox"/> Major revision	<input type="checkbox"/> Advanced
		<input type="checkbox"/> Rejection	<input type="checkbox"/> General
			<input type="checkbox"/> No expertise
			Conflicts-of-Interest:
			<input type="checkbox"/> Yes
			<input type="checkbox"/> No

SPECIFIC COMMENTS TO AUTHORS

I read with interest the review by Flynn Kaida-Yip et al. It is well written and informative.

I have just some minor comments: Abstract - "While they are still created within living systems, they may differ slightly in manufacturing process to decrease costs" - The cost reduction is surely not mainly due to different manufacturing process but rather the



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reduced need of clinical trials. Introduction - "Therapeutic proteins, also known as biologics, are pharmaceutical agents created in a laboratory setting to mimic the effects" It is not just mimicking but also as the case of anti TNF to antagonize proteins or block receptors. Introduction - "To address this growing issue, biosimilar drugs were developed." Indeed biosimilars are developed because of originator patent's expire. Chapter on IBD - Wgen referring to PLANETAS AND PLANETAR please refers also to published eol and swithc study up to 2 years of treatment. Chapter on IBD - rather that the experience of 25 gastroenterolosist in Germany I would mention the ECCO survey J Crohns Colitis. 2014 Nov;8(11):1548-50 and J Crohns Colitis. 2016 Nov;10(11):1362-1365 Chapter Limitations - I would add that one of the main concern of the physicians is the possible occurrence of multiple switches (from originator to biosimilar and back and more importantly among different biosimilars of the same originators). The possible consequence of these scenarios are completely unknown.

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BPG Search:

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PEER-REVIEW REPORT

Name of journal: World Journal of Clinical Cases

Manuscript NO: 39028

Title: Biosimilars: Review of current applications, obstacles, and their future in medicine

Reviewer's code: 02941507

Reviewer's country: Greece

Science editor: Ze-Mao Gong

Date sent for review: 2018-03-27

Date reviewed: 2018-04-04

Review time: 7 Days

SCIENTIFIC QUALITY	LANGUAGE QUALITY	CONCLUSION	PEER-REVIEWER STATEMENTS
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	<input type="checkbox"/> Accept	Peer-Review:
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language	(High priority)	<input type="checkbox"/> Anonymous
<input checked="" type="checkbox"/> Grade C: Good	polishing	<input type="checkbox"/> Accept	<input checked="" type="checkbox"/> Onymous
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			Conflicts-of-Interest:
			<input type="checkbox"/> Yes
			<input type="checkbox"/> No

SPECIFIC COMMENTS TO AUTHORS

- The main focus of the paper should be on the use of biosimilars in gastroenterological situations and not generally in medicine The journal in which this editorial is going to be published is "The World Journal of Gastroenterology."
- The available clinical trials on the use of biosimilars in Gastroenterology and their results on efficacy, side effects etc,

should be summarized in a separate table. • The results of another study not included in the reference list of the article (Gecse KB, Lovász BD, Farkas K, Banai J, Bene L, Gasztonyi B, Golovics PA, Kristóf T, Lakatos L, Csontos ÁA, Juhász M, Nagy F, Palatka K, Papp M, Patai Á, Lakner L, Salamon Á, Szamosi T, Szepes Z, Tóth GT, Vincze Á, Szalay B, Molnár T, Lakatos PL. Efficacy and Safety of the Biosimilar Infliximab CT-P13 Treatment in Inflammatory Bowel Diseases: A Prospective, Multicentre, Nationwide Cohort. *J Crohns Colitis*. 2016 ;10:133-40. doi: 10.1093/ecco-jcc/jjv220. Epub 2015 Dec 10), should be added. • The way of switching from an original biological agent to a biosimilar should be noted in the discussion section bearing in mind the following references (Schmitz EMH, Boekema PJ, Straathof JWA, van Renswouw DC, Brunsveld L, Scharnhorst V, van de Poll MEC, Broeren MAC, Derijks LJJ. Switching from infliximab innovator to biosimilar in patients with inflammatory bowel disease: a 12-month multicentre observational prospective cohort study. *Aliment Pharmacol Ther*. 2018;47:356-363. doi: 10.1111/apt.14453. Epub 2017 Dec 5). (Switching from Innovator to Biosimilar (Subsequent Entry) Infliximab: An Updated Review of the Clinical Effectiveness, Cost-Effectiveness, and Guidelines [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2017 Jan.). • The Nocebo effect should be mentioned in the discussion section using the following reference (Rezk MF, Pieper B. Treatment Outcomes with Biosimilars: Be Aware of the Nocebo Effect. *Rheumatol Ther*. 2017 Dec;4(2):209-218. doi: 10.1007/s40744-017-0085-z. Epub 2017 Oct 14).

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