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Comment on the non-biological complex drugs paper

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Comment on the Special Report by Professor Gerrit Borchard: Complexity in the making: non-biological complex drugs (NBCDs) and the pharmacopoeias, published in GaBI Journal, 2016;5(1):36-41.

Keywords: Glatiramer acetate, multiple sclerosis, non-biological complex drugs

We thank you for publishing the manuscript entitled 'Complexity in the making: non-biological complex drugs (NBCDs) and the pharmacopoeias' by Professor Gerrit Borchard [1]. The manuscript highlights interesting aspects of the issues associated with NBCDs.

Sandoz, Inc (a Novartis Division, Princeton, NJ, USA), in collaboration with Momenta Pharmaceuticals (Cambridge, MA, USA) manufactures and markets Glatopa® (20 mg/mL daily injection). Glatopa® is the first FDA (US Food and Drug Administration) approved generic glatiramer acetate (GA) injection for multiple sclerosis (MS), which was approved on 16 April 2015.

The manuscript by Borchard G highlights certain aspects of Glatopa® that require corrections or update, see below:

1. Page 39, 2nd column, line 15 – in the para of the Citizen's Petition Letter by Teva … error in stating 'Momenta/Sanofi's Glatopa®'. This should be corrected to 'Momenta/Sandoz's Glatopa®' [2].
2. Page 39, 2nd column, line 15 – when referring to Glatopa, FDA and physicians interpret it as generic glatiramer acetate, not a 'follow-on glatiramoid' as indicated in the manuscript. The words 'follow-on glatiramoid' should be changed to 'generic glatiramer acetate". The reason is that glatiramoid has been used as a blanket term for all polypeptides containing the four amino acids (G, L, A, T) regardless of their effect as disease-modifying therapy for MS [3]. The term 'generic glatiramer acetate' is reserved for FDA approved generic version of GA that has been established as equivalent [4].
3. Page 39, 2nd column, line 23 – in the para of the FDA approved Glatopa, error in stating 'On 15 April 2015 ...'. This should be corrected to 'On 16 April 2015...' [5].
4. Page 41, reference 17 – Error in stating 'On 16 April 2016 ...'. This should be corrected to 'On 16 April 2015 ...' [5].

We are excited about the special report on generics and biosimilars, and want to ensure the accuracy of the materials presented in the manuscript. We hope that by bringing these errors to your attention, the clarity and impact of the manuscript will be enhanced through the release of a corrigendum, accompanying the manuscript.

Competing interests: Dr Karthik Bodhinathan is the Medical Science Liaison (Neurology) of Trinet Pharma, providing services for Sandoz.

Provenance and peer review: Not commissioned; internally peer reviewed.

References

1. Borchard G. Complexity in the making: non-biological complex drugs (NBCDs) and the pharmacopoeias. Generics and Biosimilars Initiative Journal (GaBI Journal). 2016;5(1):36-41. doi:10.5639/gabij.2016.0501.009
2. US Food and Drug Administration. Department of Health & Human Services. ANDA 090218. Glatopa (Glatiramer Acetate) Injection, 20 mg/mL, 1 mL prefilled syringe [homepage on the Internet]. [cited 2017 Nov 13]. Available from: http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/090218Orig1s000ltr.pdf
3. Varkony H, Weinstein V, Klinger E, Sterling J, Cooperman H, Komlosh T, Ladkani D, Schwartz R. The glatiramoid class of immunomodulator drugs. Expert Opin Pharmacother. 2009;10(4):657-68.
4. US Food and Drug Administration. Draft guidance on glatiramer acetate injection [homepage on the Internet]. [cited 2017 Nov 13]. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM495029.pdf
5. US Food and Drug Administration. FDA approves first generic Copaxone to treat multiple sclerosis [homepage on the Internet]. [cited 2017 Nov 13]. Available from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm443143.htm

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Editor-in-Chief's comment

The reference quoted as support for the claim that this product was 'proven' to be a generic is actually a guidance, not even a rule. Contrary to what is claimed in the letter, acceptance by FDA does not mean the product was 'proven' to be identical. It means only that FDA decided that the product is 'similar enough' to be sold as a generic version. This approval is in part because FDA does not distinguish between NBCDs and simple chemical generics.

Erratum

The *GaBI Journal* apologizes that information mentioned in the Letters to the Editor in page 154 of GaBI Journal, 2017, Issue 4 concerning the manuscript entitled 'Complexity in the making: non-biological complex drugs (NBCDs) and the pharmacopoeias' by Professor Gerrit Borchard, published GaBI Journal, 2016;5(1)36-41, require updating.

These were all updated on the manuscript published on the *GaBI Journal* website, see link: http://gabi-journal.net/complexity-in-the-making-non-biological-complex-drugs-nbcds-and-the-pharmacopoeias.html

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