Comment on the non-biological complex drugs paper

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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/Sandoz’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 glatiramer acetate 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.

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References


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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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