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Stable Isotope Profiling of Internet-Sourced Viagra® and 'generic-Viagra' Tablets

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Viagra® manufactured by Pfizer was the first prescription drug for the treatment of erectile dysfunction (ED), a condition that is estimated to affect 1 in 10 men at some stage in their lives (1). Viagra® contains the active pharmaceutical ingredient (API) sildenafil, as the citrate salt. Sildenafil, along with Tadalafil and Vardenafil belong to a class of drugs known as phosphodiesterase type 5 (PDE5) inhibitors.

Since its first production in 1998, Viagra® has generated well in excess of $10 billion US dollars in sales (2) and with Pfizers' patent extended to April 2020 (3) it still remains the only sildenafil-based treatment option for sufferers of ED in the US. There are no legal 'generic-Viagra' formulations available in the US. However, formulations containing sildenafil citrate as API are widely available over the internet and often sold as 'generic Viagra'. These cheaper alternatives are often manufactured under less than ideal conditions with little or no QA/QC procedures in place.

The World Health Organisation recognised the scale of the problem in its 2010 bulletin "Growing threat from counterfeit medicines" (4) and quotes a Dutch study cited in the International Journal of Clinical Practice in which from a cohort of 370 seized Viagra® samples, only 10 were genuine.

We sourced a variety of tablets sold for the treatment of ED which claimed to have sildenafil citrate as API. Viagra®, 'generic-Viagra', Kamagra, Silagra and Filagra tablets were ordered via the internet and supplied from both UK-based pharmacies as well as overseas suppliers (Hong Kong, India, Vanuata).

In this small-scale pilot study, we present results from bulk 2H/18O and 13C/15N stable isotope analysis performed on crushed tablets from 23 samples of internet-sourced tablets sold for the treatment of ED and purported to contain sildenafil citrate as API.

References
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3. US Patent & trademark office (www.uspto.gov)
4. WHO bulletin 2010; 88:247-248