

Different liposomal amphotericin B formulations for visceral leishmaniasis

In response to the promising results of a single dose of liposomal amphotericin B (AmBisome) to treat visceral leishmaniasis in Bangladesh, Nilima Kshirsagar (April issue),¹ suggests that an alternative form—Fungisome—might soon qualify for similar use and application.

AmBisome was the first formulation of amphotericin B that maximised efficacy in visceral leishmaniasis while minimising toxic effects. Fungisome is the brand name of a liposomal amphotericin B product developed in Kshirsagar's own laboratory² and marketed by LifeCare Innovations. It cannot be considered a generic of AmBisome because the liposomal compositions are not comparable. To transform multilamellar vesicles into small unilamellar vesicles, Fungisome requires sonication for 45 min before administration, which is technically

very challenging in programmatic settings for visceral leishmaniasis.

Moreover, published evidence on the efficacy and safety of Fungisome in visceral leishmaniasis, either in single-dose or multidose regimens, is very limited.³ The phase 2–3 clinical trials that Kshirsagar mentions were actually in fungal infections.² An ongoing phase 2 trial is assessing single-dose Fungisome for visceral leishmaniasis in India.⁴

Beyond Fungisome, other products could be considered as generics of liposomal amphotericin B. Bioequivalence to AmBisome has to be established then through adapted processes.⁴ Before any generic product can be used for visceral leishmaniasis, liposomal amphotericin B suppliers should submit their products to the WHO Prequalification Programme, the remit of which has been expanded to liposomal amphotericin B,⁵ to determine which medicines are quality-assured and bioequivalent to AmBisome. This is the only safeguard to avoid exposing visceral leishmaniasis patients to products with an unassessed safety and efficacy profile.

We declare that we have no competing interests.

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- 3 Mondal S, Bhattacharya P, Rahaman M, Ali N, Goswami RP. A curative immune profile one week after treatment of Indian kala-azar patients predicts success with a short-course liposomal amphotericin B therapy. *PLoS Negl Trop Dis* 2010; **4**: e764.
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For the ongoing trial of single-dose Fungisome for visceral leishmaniasis in India see <http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=3687>