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## SECTION A: MEDICAL, DENTAL AND VETERINARY SCIENCES

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### A-01: Safety study in humans on the use of combinations of albendazole with ivermectin or diethylcarbamazine (DEC)

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Both DEC and ivermectin have been shown to have microfilaricidal activity against *Wuchereria bancrofti*. Recent studies have shown albendazole to have a filaricidal activity as well. It was considered useful to determine whether combination therapy with albendazole would enhance the filaricidal activity of DEC and/or ivermectin. This is a preliminary communication evaluating the safety of anthelmintic combinations in healthy volunteers prior to testing drug combinations in microfilaraemic subjects.

Tolerability, laboratory and clinical safety of a single dose of 600 mg albendazole with 400 mcg/kg/bw ivermectin or 600 mg albendazole with 6 mg/kg/bw DEC, were studied.

10 amicrofilaraemic healthy male volunteers were randomized to receive each of the single dose combination treatments mentioned above. After initial haematological and biochemical investigations patients were hospitalised and treatment given under personal supervision. Laboratory tests were repeated on days 2, 4, 7 and 14. Pre-and post-treatment ECG's were done.

The subjects tolerated the medications well with no adverse effects like fever, postural hypotension, myalgia, lethargy or anorexia. No significant anomalies were detected in Hb%, blood picture, serum bilirubin, serum creatinine, urine analysis and in the ECG's. Two patients from each group showed a slight elevation of SGOT and SGPT on day 14 which returned to normal in 2 weeks. This elevation was attributed to consumption of ethanol.

The drug combinations were well tolerated with no adverse clinical effects. All laboratory safety tests were normal except for the slight transient

elevation in liver enzymes which were most probably ethanol induced. It appears therefore, that the combinations of albendazole with DEC or ivermectin, in the doses used in this preliminary study are safe.