

### **Product Containing Combination of Amino Acid**

As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2014 – 23 April 2014':

Bioequivalence study is not required for all generic products containing combination of Tryptophan with other amino acid when it is used as supplement, with the indication such as:-

'Prevention and therapy of damages due to faulty or deficient protein metabolism in chronic renal insufficiency in connection with limited protein in food of 40g per day (for adults) and less; i.e. generally in patients with a glomerular filtration rate (GFR) between 5 and about 15ml/minutes.'