

Comments on P242 - Foods for Special Medical Purposes Initial Assessment Report

Office of Complementary Medicines, Therapeutic Goods Administration

The Therapeutic Goods administration (TGA) is not in a position to comment on specific aspects of P242 in relation to the most appropriate regulatory model for Foods for Special Medical Purposes (FSMPs), but we would be happy to assist with any advice that would be helpful as this work is progressed.

There are, however, two specific points that we would like to draw to the Australia New Zealand Food Authority's attention. The first is the potential that some of the ingredients in some medical foods may be included in the *Standard for the Uniform Scheduling of Drugs and Poisons*. Selenium could be a case in point. If this were to be the case ANZFA would need to negotiate a clear regulatory approach to this potential problem with the National Drugs and Poisons Scheduling Committee.

The second issue relates to the claims manufacturers of medical foods may seek to make in relation to their products. Clearly, it would be inappropriate for these products to carry therapeutic claims, where they are being regulated as foods. However, it is likely that the manufacturers of at least some of these products may want to mention specific diseases or conditions in describing the use of their products. We would urge ANZFA to work closely with the TGA to define the boundaries for claims on medical foods as your work on this proposal proceeds.