R11/1304o Mark George? 14/8/2001

EVALUATION OF A COMPLEMENTARY MEDICINE SUBSTANCE

REQUIREMENTS FOR COMPOSITIONAL GUIDELINES

DRAFT – IN PREPARATION 14/8/01

1. Purpose

The purpose of a Compositional Guideline is to define the substance to the extent necessary to justify its entry onto the ARTG. The CG should reflect the substance for which quality, safety and efficacy have been reviewed.

2. Content - general

2.1 A CG should include descriptions, tests and acceptance criteria that can be applied to the substance to independently verify its identity and quality. It should be specific enough to enable the substance to be distinguished from closely related materials.

2.2 Acceptance criteria should take into account any relevant official standards and should be based upon batch histories.

2.3 Tests should be validated according to international (ICH) requirements. Use of pharmacopoeial tests, or other recognised procedures eg AOAC, is preferred.

3. Content – examples of tests

3.1 Full name of the substance, together with any commonly used names. For botanicals, the Latin title and authorities, part used and any particular harvesting or treatment requirements.
3.2 Physical description
3.3 Organoleptic properties
3.4 Identification tests (TLC, IR etc.)
3.5 Impurities (solvents, related compounds, toxic metals, pesticides)
3.6 Physico-chemical characters (boiling point/range, melting point/range, refractive index etc.)
3.7 Purity tests (optical rotation, absorbance etc.)
3.8 Assay(s) (actives, markers, water etc.)
3.9 Chromatographic profile