

**PHARMAPACT REGULATORY PROPOSALS FOR  
NATURAL HEALTH AND THERAPEUTIC SUBSTANCES**

(Official Release Version,ST/PP-22/7/99)

**-FOOD-**

**---JURISDICTION---**

**-MEDICINE-**

<u>FOOD CONTROL DIRECTORATE</u> ACT 54/1972 (FCD) <u>Natural Health Substances</u>		<u>JOINT AUTHORITY</u> (COMMITTEE) <u>Controversial Intermediaries</u>	<u>MEDICINES REGULATORY AUTHORITY</u> ACT 132/1998 (SAMMDRA) <u>Natural Therapeutic Substances</u>	
<u>HEALTH FOODS &amp; BEVERAGES (HFB)</u> <u>TRADITIONAL REMEDIES</u>  Vegetable/mineral/animal with <u>structure - function</u> claims & / or <u>improving all conditions of ill-health</u> . <u>Unlimited disease risk-reduction claims.</u> (substance-specific)	<u>DIETARY SUPPLEMENTS (DS)</u> <u>TRADITIONAL REMEDIES</u>  Vegetable/mineral/animal with <u>structure - function</u> claims & / or <u>improving self-limiting conditions</u> . <u>Self-limiting condition risk-reduction claims.</u> (substance-specific)	←→ <u>CATEGORIES</u> ←→ <u>SUBSTANCES</u>	<u>COMPLEMENTARY MEDICINES (CM)</u> <u>TRADITIONAL MEDICINES</u>  Chemical, phyto-chemical, mineral & animal, with <u>self &amp; non self -limiting disease treatment claims</u> . <u>Life-threatening diseases strictly only as adjuvant.</u> (product-specific)	<u>ORTHODOX (OND) NATURAL DRUGS</u> <u>TRADITIONAL MEDICINES</u>  Chemical, phyto-chemical, mineral & animal, including <u>treatment of life-threatening &amp; emergency medicine</u> . <u>Fast-track compassionate &amp; investigational new drugs.</u> (product-specific)
<u>Nutritional, phyto-chemical, psychological (placebo).</u>  <u>Incidental pharmacologically related health claims</u> strictly limited to indisputable traditional foods/beverages.	<u>Nutritional, phyto-chemical, psychological (placebo).</u>  <u>No incidental or deliberate pharmacologically related health claims whatsoever.</u> Strictly reserved for C M.	<u>Predominant Physiological Action</u>  Claim & risk <u>limitations</u>	<u>Pharmacological, phyto-chemical, nutritional, psychological (placebo).</u>  Substances <u>scheduled on the basis of high risk of adverse reactions</u> , irrespective of the absence of any health claims.	<u>Pharmacological, phyto-chemical, nutritional, psychological (placebo).</u>  Substances <u>scheduled on the basis of significantly high risk of life-threatening adverse reactions</u> . Banned substances.
Scientific evidence-based. <u>Limited Clinical Trials, Experimental Laboratory or Epidemiological Data.</u> Evidence to exceed placebo.	Scientific evidence-based. <u>Limited Clinical Trials, Experimental Laboratory or Epidemiological Data.</u> Evidence to exceed placebo.	<u>Efficacy Qualifying Criteria</u>	Scientific evidence-based. <u>Limited Clinical Trials, Experimental Laboratory &amp; Epidemiological Data.</u> Evidence to exceed placebo.	Scientific evidence-based. <u>Randomised Clinical Trials &amp; Experimental Laboratory Data. Compassionate trials.</u> Evidence to exceed placebo.
<u>Food Safety Standards.</u> Not to exceed that applicable to the most similar foods & appropriate to suggested use.	<u>Food or Pharmaceutical Safety Standards.</u> Appropriate to the substances, degree of processing & dose.	<u>Safety Criteria</u>	<u>Food or Pharmaceutical Safety Standards.</u> Appropriate to the action, degree of processing & dose.	<u>Pharmaceutical Safety Stds.</u> Current standards applying to full registration. (LD/TD50) All products to be re-evaluated.
<u>Food Quality.</u> Appropriate to the substances & the degree of processing. Expiry dates if appropriate. Not to exceed that applicable to the most similar foods.	<u>Food &amp; or moderate Pharmaceutical GMP.</u> Appropriate to the substances & the degree of processing. Also claim related expiry dates, stability tests, if appropriate.	<u>Quality Criteria</u>	<u>Food GMP up to high Pharmaceutical GMP.</u> Appropriate to the substances & the degree of processing. More stringent expiry dates, stability tests, if appropriate.	<u>Pharmaceutical GMP.</u> Appropriate to the substances & the degree of processing. Highly stringent expiry dates, stability tests, if appropriate. All intravenous & injectables.
To Dietary Supplements if <u>HFB</u> parameters exceeded to infringe on delineated <u>DS substance parameters</u> . →	To Health Foods & Beverages if abandon <u>DS</u> & meet <u>HFB</u> delineated parameters. Requires <u>complete product name-change</u> . ←	<u>Product Reclassification (1 stage)</u>	To Orthodox Natural Drugs if above-mentioned parameters exceeded to infringe on <u>OND</u> delineated parameters. →	To Complementary Medicine if not for above-mentioned use, & claims or risks do not exceed <u>CM</u> or meet <u>OND</u> parameters. ←
To Complementary Medicines if specifically <u>pharmacological</u> in action, or <u>high adverse reaction risk</u> . →→	To Complementary Medicines if <u>DS</u> parameters exceeded to infringe on <u>CM</u> parameters. →→	<u>Product Reclassification (2 stage)</u>	To Dietary Supplements if abandon <u>CM</u> & meet <u>DS</u> delineated parameters. Requires <u>complete product name change</u> . ←←	To Dietary Supplements if abandon <u>OND</u> & <u>CM</u> delineated parameters. Requires <u>complete product name change</u> . ←←
To Orthodox Natural Drugs if <u>significantly high life-threatening adverse reactions risk</u> . →→→	To Orthodox Natural Drugs if <u>significantly high life-threatening adverse reactions risk</u> . →→→	<u>Product Reclassification (3 stage)</u>	To Health Foods & Beverages if abandon <u>CM</u> & meet <u>HBS</u> delineated parameters. Requires <u>complete product name change</u> . ←←←	To Health Foods & Beverages if abandon <u>OND</u> & meet <u>HBS</u> delineated parameters. Requires <u>complete product name change</u> . ←←←

