

PHARMAPACT REGULATORY PROPOSALS FOR NATURAL HEALTH & THERAPEUTIC SUBSTANCES

(ST/PP-22/7/99)

--MAIN PRINCIPLES--

And God said, "See, I have given you every herb that yields seed which is on the face of all the earth, and every tree whose fruit yields seed; to you it shall be for food". Genesis 1:29. Holy Bible, New King James.

- 1) **Foods, their nutrients and related constituents are rarely, if ever, truly classifiable as medicines.**
- 2) **If these factors positively influence conditions, then their action is food corrective, not medicinal in action. Only non-food remedies to which resistant conditions alone will yield, are medicinal.**
- 3) A remedial claim for a food cannot render a food a medicine, but the claim may be challenged.
- 4) Foods may bear risks as well as benefits. It is the right of consumers to know and to choose.
- 5) Food altered from its natural form may become more suspect in terms of both risk and benefits.
- 6) Processed foods may bear risks and benefits. It is the right of consumers to know and to choose.
- 7) Dietary supplements are processed/synthesised foods and may bear risks and benefits. As with natural and processed foods, it is the right of consumers of supplements to know and to choose.
- 8) Traditional remedies, which may variably more or less resemble foods or dietary supplements, may also bear risks as well as benefits. It is the right of consumers to know and to choose.
- 9) **Dietary supplements and traditional "remedies" loosely interface between foods and medicines. Besides their food or ritualistic placebo benefits, claimed further benefits may be challenged.**
- 10) **Traditional and complementary "medicines" cross the interface into the paradigm of medicines.**
- 11) Traditional and complementary medicines may, as with foods, supplements and traditional remedies, possess some of the risks and benefits of these, but are chosen as medicines because they bear special benefits additional to foods, supplements and more traditional remedies.
- 12) If traditional and complementary medicines bear additional benefits, they may bear additional risks. As with foods, supplements and traditional remedies, it is the right of consumers of traditional and complementary medicines to know these risks and benefits and to choose.
- 13) **At the medicinal stage, the traditional or complementary practitioner enters the equation, if the consumer so chooses, prior to which the consumer retains responsibility and the right to know and choose. Only should the consumer choose to delegate this right to the practitioner, does the consumer relinquish their responsibility and becomes a consumer-patient. Not knowing and choosing the risks and benefits, the patient now becomes vulnerable and needs to be protected.**
- 14) **It is the mandate of the medicines control authority to protect the consumer who chooses to self-medicate with traditional or complementary medicines within the confines of that which is safe and effective for that purpose. It is further the mandate of the medicines regulatory authority to protect the patient who has delegated their care to a traditional or complementary medicine practitioner, by ensuring that the risks and benefits of those medicines to be used exclusively by that practitioner are safe and effective for that purpose. This mandate is irrespective of culture. We demand that the medicines and food authorities stop suppressing health substances and instead attend to their urgent mandate of protecting the consumers of both foods and medicines.**