PHARMAPACT OBJECTIONS TO THE LISTING SYSTEM (Expedited Registration Procedure)
(ST/PP-22/7/99)

PHARMAPACT's objections are recorded in considerable unanswered registered correspondence to the authorities to date. Without elaborating further, these are briefly recorded as follows and more specific technical objections to the procedure are added to outline our principle objections:

-PRIOR MORAL & LEGAL OBJECTIONS-

1) **The totally pre-selective, biased, exclusive, unrepresentative, undemocratic, uncommunicative, non-transparent, illegal and unconstitutional nature of the development of the entire procedure;**

2) **The total absence of any professional expertise on the CMC and Technical Committee;**

3) **The MCC initiated, promoted, logistically assisted and endorsed development of the procedure;**

4) **The 30 - month MCC bias in favour of this procedure to the total exclusion of all other models;**

5) **The financially vested interest homoeopathic pharma-industry driven nature of the procedure;**

6) **The central role of Rene' Doms, as ex head of MCC Inspectorate/industry leader in the process;**

7) **The MCC inaction in reforming the process over and in spite of 30-months of legitimate protest;**

8) **The MCC's repeatedly failed promises to make the procedure available for detailed critique;**

-CURRENT TECHNICAL & LOGISTICAL OBJECTIONS-

a) **The absurdly suppressive regulation of food and its nutritional and related factors as medicines;**

b) **The concept of product registration based on pre-existing lists of so-called approved substances, particularly bearing in mind the financially vested interest nature of the inclusion process;**

c) **The inability to reliably verify the scientific validity of the inclusion of each listed substance and its alleged actions, due to the absence of specific cross-referencing to the cited sources;**

d) **The resulting inability of the authority to make regulatory provisions and decisions having an acceptable degree of scientific certainty or likelihood of scientific validity, due to the arbitrary process of inclusion to the lists, as well as the validity of associated claims and risks, not only of the substances, but also the authorised applications thereof. Who will bear legal responsibility?;**

e) **The failure to apply the modern trend of "evidence-based" criteria to a new regulatory model, which will have the regressive effect of endorsing quackery in the guise of "traditional use".**

PHARMAPACT's model on the other hand specifically embraces "evidence-based criteria" for all medicines, whilst protecting foods and related substances from suppressive regulatory fervour. Our concerns iro medicines quackery are exemplified in our report titled "Homoeopathy: A Critique".

f) **The logistical inability of the indigenous African medicines to be equally and urgently included in the process, let alone the process enforced on this significantly high-risk sector. The gross moral, legal and constitutional implications of ignoring or exempting this sector, which is directly responsible for an estimated 10-20 thousand tragically unnecessary deaths per annum has been detailed in our recent 15,500 word report titled "MCC/DoH Traditional African Medicine Genocide and Ethnopiracy Against the African People".**

PHARMAPACT's model on the other hand not only specifically addresses and accommodates this problem as its regulatory priority, but has the active participation and support of its main ally, the statutory Interim Co-ordinating Committee of Traditional Medical Practitioners of South Africa.

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