INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

8 January 2014

Dr. Arun Kumar Panda,
Joint Secretary to the Government of India,
Ministry of Health and Family Welfare,
Nirman Bhavan
New Delhi

Subject: **Proposed Amendments to GSR No. 702 dated October 24, 2013 regarding Phytopharmaceutical Drugs**

Ref: **Our Representation dated 6 December 2013**

Dear Sir,

In continuation of our submission as above (copy enclosed) on the proposed inclusion of a new category of "Phytopharmaceutical Drugs" in the Drugs and Cosmetics Rules, 1945, we submit our **Supplementary Suggestions** as below:

1. It is heartening to note the recognition by the Ministry of Health to an opportunity that is being granted to enable Indian Pharmaceutical companies to introduce not only Indian herbs but also herbs used in the other International Systems of Medicine into mainstream allopathic drug therapy. This would result in a large number of new compounds from herbal sources being used in allopathic drug therapy as in the western countries (eg. Germany doesn't discriminate between pharmaceuticals and phytopharmaceuticals). Hence, by the creation of this new class of drugs in the Drugs and Cosmetics Rules, the intention of use of these herbal formulations (as phytopharmaceutical drugs) from the various international herbal systems of medicines will allow pharmaceutical companies to help bring the benefits of these herbals products to the population in India and facilitate the use of these beneficial herbal drugs in the allopathic system of medicine.

2. **Proposed Rule 2 clause (eb) - Insertion of 'Phytopharmaceutical drug':** As the purpose of the amendment has been to facilitate the approval of finished herbal formulations and herbal extracts for use in the manufacture of these Phytopharmaceutical drugs, we strongly suggest

that 'Unprocessed Standardised Materials' should be deleted from the definition.

3. The insertion of Phytopharmaceutical drug in Rule 122-E is also welcome.

4. (a) In **Appendix 1-B,** under Schedule-Y, the detailed description is good and encouraging however, the word 'traditional' may be deleted.

   (b **Section 3.8 - Quality specification**: Details of contaminants are not defined, and that is mandatorily required. The limit should be based on daily consumption instead of per dosage content. This exactly refers to the WHO 2008 circular based on which AYUSH has defined limit on the heavy metals, pesticides, solvent residue, pesticides, aflatoxins etc.

   (c) **Section 8.2 - Animal Toxicity:** We appreciate this inclusion, as all plant based products may not be safe. However, safety study may be exempted in the following instances:

   - In case of extracts from 100% water.
   - In case extracts are standardized for known markers where safety study is available for single marker in peer reviewed journals.
   - In case extracts are standardized for known markers where safety study is available in peer reviewed journals for polyherbals, then safety study may be limited with acute toxicity.
   - Safety study should be extended only when the solvent used is other than water.

   (d) The Office of the DCG(I) has approved a few herbal formulations (Guggulipid tablets in 1985-1987, Gingko-biloba tablets in 1992, Silymarin Capsules in 1997 and Ivy Leaf Extract in 2005 etc) from the western system based on the data submitted by some pharmaceutical companies in India. It may, however, be difficult to see the approval of many more herbal products coming through due to the requirements in **Sections 9 (Human Studies) and 10 (Proof of Concept or Confirmatory Clinical Trials) of Appendix I-B.** This must be reconsidered and reviewed keeping in mind the current status of the Clinical Drug Testing Industry in the India. Also in view of the history of use of these herbal products, only additional clinical trials to demonstrate safety maybe requested for obtaining approval, **if it is a serious demonstrated / substantiated concern.**

5. We would also like to bring to your attention that companies manufacturing extracts as per Western Pharmacopoeias for herbal formulation manufacturers based in the western countries were often

left in the lurch. While they may have been granted a drug license to manufacture an extract for export purposes only as per the specifications in the international pharmacopoeias, their Advance License applications to import the Crude herb would be delayed indefinitely, as the request for an expert opinion from the Department of Ayush by the Director General of Foreign Trade would remain unanswered. This may be due to the policy of the Dept. of Ayush, to respond only if the herb is used in an Indian System of Medicine and to facilitate and regulate the use of drugs used as per the traditional Indian Systems of Medicine (AYUSH systems). The recognition of this new class of drugs will highlight the difference between the various systems of Medicine and facilitate quicker clearances by other Government Departments such as DGFT depending on the intention of use of these extracts, as it had been done in the past before the creation of the Department of Ayush.

We thank you for your indulgence and the opportunity to represent the concerns of our members and look forward to amendments that will facilitate the growth of the Herbal Drug Manufacturing Industry in India. We also suggest that our suggestions made vide our submission dated 6th December 2013 and our Supplementary Suggestions as above may be considered while notifying the amendments to include 'Phytopharmaceutical drug' in Drugs & Cosmetics Rules.

Thanking you,

Yours sincerely,

S V Veerramani
President

Encl: as above