INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

December 06, 2013

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

Sub: Comments on Ministry of Health & Family Welfare Notification GSR 702 (E), dated 24th October 2013

Dear Sir,

Ministry of Health & Family Welfare vide gazette notification GSR702(E) dated October 24, 2013 has sought comments on the proposed draft rules pertaining to "Phytopharmaceutical Drugs". We welcome the Ministry's proposal so as to include "Phyto Pharmaceutical Drugs" in drug rules so that they will be adequately regulated by the Ministry.

However, the proposed rules require data to be submitted along with the application at par with the "Chemical Drugs".

Please note that India has rich heritage of numerous "Phytopharmaceutical Drugs". One of the significant exports from India is "Herbal Extracts". Number of Indian manufacturers and Pharmexcil members manufacture and exports "Herbal Extracts" under gambit of "Phytopharmaceutical Drugs" which are sought to be brought under these draft rules.

The data required is exhaustive which may not be available for the ancient "Ayurvedic" / "Herbal Extract" products.

In the part two of the proposed rules extensive data have to be generated by the applicant. This includes Taxonomical Information along with the certificate issued by qualified Taxonomist. The data also requires chromatographic fingerprint of the samples.

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Over and above this, the safety and pharmacological section mandates animal toxicity and safety data like Oral Toxicity, GenoToxicity, Dermal Toxicity and Teratogenicity Study. The data requirement also necessitates different human studies and proof of concept or confirmatory clinical trials.

The draft rule clearly indicates that as per the proposal rules the "Phytopharmaceutical Drugs" are being treated at par with chemical drugs. Please note that due to its complex nature it may not be possible to make available or generate all the data as required in the proposed rules.

We draw attention that Global Regulatory Authorities like Health Canada has a separate division called "Natural Health Product Directorate". Similarly, TGA, Australia also has different guidelines for Herbal products. We suggest that Ministry of Health & Family Welfare should also consider different set of guidelines for "Phyto Pharmaceutical Drugs".

We reiterate that we welcome the initiative to regulate the "Phyto Pharmaceutical Drugs", However, the proposed rule must reflect the present capability of the Indian Industry and should be benchmarked with the current global practices. The adoption of draft rules in the present format will adversely impact the export of "Herbal Extracts" from India. Accordingly, we request you to consider the above comments before finalizing the proposed rules.

We would also request you to permit us for submitting our supplementary suggestions till the first week of January 2014.

Thanking you,

Yours sincerely,
For Indian Drug Manufacturers' Association,

Daara B Patel
Secretary-General