***Phytopharmaceuticals Drugs***

As per the Gazette notification G.S.R.918 (E), published by Government of India on 30th November 2015, the regulatory provisions for phytopharmaceuticals and regulatory submission requirements for scientific data on quality, safety, and efficacy to evaluate and permit marketing approval for Phytopharmaceuticals drug on similar lines to synthetic, chemical moieties have been made under the Drugs & Cosmetics Act 1940 and Rules 1945 there under. As per the Gazette notification, Phytopharmaceuticals drug is defined as purified and standardized fraction with defined minimum four bio-active or phytochemical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation, or prevention of any disease or disorder but does not include administration by parenteral route. The requirements for phytopharmaceuticals are under the purview of Central Drugs Standard Control Organization (CDSCO) as it differs from Ayurvedic, Siddha or Unani drugs which include all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of (disease or disorder in human beings or animals, and manufactured) exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani and other systems of medicine specified in the First Schedule. However, phytopharmaceutical drugs are fraction of crude extract and are distinctly differentiated by being purified and standardized. A separate category of Phytopharmaceutical Ingredient (PPI) monograph has been included in IP where, an herbal drug/extract/purified fraction has been characterized minimum of four marker compounds. However, such PPI monographs may or may not strictly meet the requirements of definition of phytopharmaceuticals drugs. The inclusion criteria herbal drugs monograph will also

applicable for PPI category monograph besides ensuring minimum four analytical markers. The purpose of the PPIs monograph is to provide the scientific information on the quality standards and characterization of minimum four of its bio markers / analytical markers in order to facilitate appropriate maintenance of the standards by the stakeholders. An example, the existing monograph in IP, namely *Andrographis paniculata* modified to provide for testing qualitatively/quantitatively for four bio / analytical markers such as, Andrographolide, Andrograpanin, Neo - andrographolide and 14-deoxy -11,12 didehydro andrographolide. Such monographs are categorized with the suffix PPI next to the name of the monograph to denote that such ingredients demonstrate potentially meeting the defined criteria for a phytopharmaceutical in IP. However, the Phytopharmaceticals drugs dosage form monograph shall be included in IP only after the approval of CDSCO. It is to be recognised that mere inclusion of a monograph for an herb or extract or PPI in IP does not give it a status of drug and relevant regulations need to be complied with, and approval as a drug is to be obtained from the office of Drugs Controller General (India) after submission of relevant applications