INDIAN DRUG MANUFACTURERS' ASSOCIATION

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INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

20 January 2015

Dr. G.N. Singh,
Drugs Controller General (India)
Central Drugs Standard Control Organization,
FDA Bhawan, Kotla Road
NEW DELHI

Dear Sir,

Subject- Drugs and Cosmetics Act, 1940 and Rules thereunder –
Active Pharmaceutical Ingredients not complying with IP Specifications- reg.

With reference to the above, we wish to inform you that the Indian Pharmacopoeia (IP) 2014 has been released and it came into effect from 01.1.2014. Thereafter 1st addendum to IP 2014 has also been released and it is effective from 1-4-2015. It is an official book of standards for drugs in India. It supersedes the IP 2010.

As per the provisions of the Drugs & Cosmetics Act , 1940 & the Rules 1945, the laws governing the activities of Import, Manufacture, Sale and Distribution of drugs in India, the standards of identity, purity and strength prescribed in the IP 2014 apply to all drugs involved in the above said activities in India. For drugs not included in the IP 2014, but included in the IP 2010, the standards prescribed in that book apply. In short, the drugs made available to the consumers in the country by whatever process as the case may be, are to conform to the standards prescribed in the IP 2014 or in IP 2010 as described above.

Only in the case of drugs not covered by these two books of standards other standards apply, which includes other official pharmacopoeias or in the case of 'new drugs', the norms applicable to them. Failure to comply with the standards set out in the IP could result in supply of drugs that are legally not of standard quality.

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The fundamental purpose of a pharmacopoeial standard is to control the quality of ingredients and of finished products and so to contribute to the efficacy of and safety in the use of medicines. Pharmacopoeial monographs control many parameters, including purity, potency (amount of active ingredient present) and performance characteristics of the medicine.

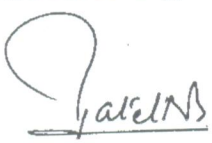
Despite the clear position related to compliance with the prescribed standards of drugs, it has been brought to the notice of our association that some of the manufacturers of API continue to manufacture APIs that do not comply with the standards prescribed in the applicable monograph of the current edition of IP and continue to claim IP standards.

A case in example is API Aceclofenac. This API is being manufactured in India since last few years and it appeared for the first time in IP 2010 and the specifications (pertaining to impurities) were modified in IP addendum 2012 and the same is continued in IP 2014. While some manufacturers have taken steps to improve the process to meet the Pharmacopoeial Specifications, others have not done so restricting themselves to the old specifications.

Therefore we urge your goodself to direct the officers of CDSCO and State Licensing authorities to enquire into the matter and to take necessary steps under the provisions of law against the concerned manufacturers in the interest of the consumers in general and quality manufacturers of Active Pharmaceutical ingredients in particular.

Thanking you,

Yours sincerely,



Daara B. Patel
Secretary-General