Press Release

IMA lauds mandatory bioequivalence studies for drugs

Move will ensure that the manufactured drugs are safe and effective

New Delhi, April 28, 2017: In what can be called a long overdue move, the Ministry of Health and Family Welfare, has made bioequivalence studies compulsory for all drugs before they are launched in the Indian market. The draft amendments were first advertised in early February for public comment. Following this, the Drugs and Cosmetics Rules, 2017 were formally amended through a notification on April 3 to incorporate the change.

Bioequivalence studies are conducted to establish that both the original patented drug and a generic version of it have the same biological equivalence. This means they should work the same way, to the same extent, and for the same purpose. Welcoming this move, Padma Shri Awardee Dr K K Aggarwal, National President Indian Medical Association (IMA) and President Heart Care Foundation of India (HCFI) and Dr RN Tandon – Honorary Secretary General IMA in a joint statement, said, "For a long time, doctors have been prescribing generic drugs with no data on how these would perform. Until recently, only new drugs which have been in India for less than four years were required to undergo bioequivalence studies if they were in use in developed markets like the US and Europe. Many domestic manufacturers waited till the fifth year and got approval to manufacture and sell generics without conducting bioequivalence studies. However, IMA has always stood for conducting bioequivalence studies and the health ministry needs to be lauded for this decision."

Bioequivalence studies are mostly conducted on a smaller group of healthy volunteers. On the other hand, clinical studies are conducted on patients who suffer from a said disease. The cost of a bioequivalence study is therefore only a small fraction of clinical trials. The amendment introduces a biopharmaceutical classification system, classifying drugs into categories based on solubility and permeability: i) category I- high solubility and high permeability; (ii) category II- low solubility and high permeability; (iii) category III- high solubility and low permeability; and (iv) category IV- low solubility and low permeability. Manufacturers will now need to conduct bio-equivalency studies on category II and IV drugs to obtain a manufacturing license from the state licensing authority.
Adding further, Dr Aggarwal, said, "This decision is definitely a step in the right direction. It not only aligns the Indian framework with global standards but also ensures that the drugs manufactured are safe and effective. It assumes greater significance in light of the fact that doctors today are being asked to mandatorily prescribe generic drugs to consumers."

The cornerstone for a vibrant public health framework is access to affordable and safe medicines. Future challenges may include ensuring that clinical research organizations conducting bioequivalence studies do not commit fraud.

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About IMA: Indian Medical Association is the only representative, national voluntary organization of Doctors of Modern Scientific System of Medicine, which looks after the interest of doctors as well as the well-being of the community at large. It has its Headquarter in Delhi and State / Terr. Branches in 30 States and Union Territories. It has over 2,60,000 doctors as its members through more than 1765 active local branches spread across the country.

For further information please contact:
Sanjeev Khanna - 9871079105
Md Adib Ahmad – 9873716235
mediaimahq@gmail.com
IMA Public & Media Advocacy Cell