FOPE
Federation
Of
Pharma
Entrepreneurs

The Secretary to the GOI,
Ministry of Chemicals & Fertilizers,
Department of Pharmaceuticals,
Shastri Bhawan,
New Delhi-110 001

13.05.2017

Sub: Financial support for conducting BE / BA studies of oral dosage forms of medicines as per Gazette Notification No. G.S.R. 327(E) dated 03.04.2017 of Ministry of Health & Family Welfare

Sir,

Federation of Pharma Entrepreneurs (FOPE) was formed in the year 2006 representing the likeminded entrepreneurs who migrated from different parts of the Country to central excise free zones established by the Government of India in the States of Himachal Pradesh and Uttarakhand for promoting industrial development in these States. The objective of FOPE was to take up the issues relating to pharmaceutical industry, particularly concerning small and medium scale manufacturers, with the Government. Due to laborious efforts of its office bearers, FOPE is now having reorganization across the Country and have more than 400 individual manufacturers as its members in the States of Karnataka, Gujarat, Maharashtra, Rajasthan, Haryana, Punjab etc.

This is to state that recently under Gazette Notification No. G.S.R. 327(E) dated 03.04.2017 of the Ministry of Health & Family Welfare, Drugs & Cosmetics Rules have been changed and a clause of "biopharmaceutical classification system' has been added. All the drugs have been classified in four categories and submission of bioequivalence studies has been made mandatory for the drugs falling in category II & IV of the said classification.

We have been informed by our members that most of the common drugs being manufactured and marketed by them since long fall under category II and IV thus requiring bioequivalence studies for continuity in production. Bioequivalence study of a single drug costs between a few lac rupees to crore of rupees depending upon the formulation. The small and medium segment of the industry has no resources to pay crores of rupees for a basket of drugs in their manufacturing range for conducting bioequivalence studies and in absence of which licenses may not be renewed leaving only a few large manufacturers and MNCs in fray. The resultant affect will be shortage of affordable medicines across the country causing hardship to the patients.

It may be seen that in order to remain in the business of manufacturing drugs falling under biopharmaceutical classification system huge investment will be required for conducting bioequivalence studies which

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is out of the scope of small medium scale manufacturers.

For the other category of products the requirement is for conducting stability studies. This also required huge investment in equipments such as temperature and humidity control chambers, HPLC etc. in multiple numbers for conducting accelerated stability studies, real life stability studies and stability of products to be exported according climatic zone of the importing country. The investment in equipments may range from Rs. 2.5 crore to 3 crore depending on the scale of operations in addition to the cost of highly trained operators. The out sourcing of services from accredited laboratories may cost Rs. 75 lacs to Rs. one crore for each drug.

The resultant impact of enforcing the said notification will be shortage of drugs especially those falling under category II and IV and many small and medium scale manufacturers may have to close down resulting in unemployment and labour unrest and above all shortage of drugs. Even Country's exports may also suffer and may not be as competitive once the requirement of bioequivalence studies becomes mandatory as importers may also ask for the same for sourcing medicines from the Country.

Keeping the above facts in view, we have to request that a scheme be evolved under your department so that grant may be provided to small and medium scale manufacturers for conducting bioequivalence and stability studies of the drugs covered under category II and IV as identified by the Health Ministry.

This is a issue for the survival of this segment and also of the availability of affordable drugs produced this segment. we are ever ready to have a detailed discussion on this subject at a time convenient to you.

Thanks & Regards

(Sudesh Kumar)
Executive Secretary (II)

CC: Shri K.L. Sharma, Joint Secretary, Ministry of Health & Family Welfare, Nirman Bhawan, New Dehi-110 011

The Drugs Controller General (India), FDA Bhawan, New Delhi-110 002