DAILY DAWN
23.10.2009

PUBLIC NOTICE

50% SUBSIDY ON BIO-EQUIVALANCE/BIO-AVAILABILITY STUDIES ON THE PHARMACEUTICAL PRODUCTS

PREAMBLE

TRADE POLICY 2009-10 ANNOUNCED 50% SUBSIDY TO THE PHARMACEUTICAL COMPANIES FOR BIO-EQUIVALENCE/BIO-AVAILABILITY (BE/BA) STUDIES ON THE LOCALLY MANUFACTURED PHARMACEUTICAL PRODUCTS AS REQUIRED BY THE REGULATORS IN IMPORTING COUNTRIES. TESTS ARE REQUIRED TO BE CONDUCTED IN THE WHO APPROVED LABORATORIES WITH A TRACK RECORD OF APPROVALS BY ALL MAJOR REGULATORY AGENCIES INCLUDING (USA) FDA, UK (MHRA), GCC, EUROPEAN UNION (EMEA), SOUTH AFRICA (SA MCC) ETC.

ELIGIBILITY CRITERIA FOR APPLICANT COMPANIES

This facility will be available to:

All national pharmaceutical manufacturing companies who intend to obtain registration of their generic products in the semi developed and developed foreign countries are eligible to apply.

ELIGIBILITY CRITERIA FOR BIO-EQUIVALENCE LAB

Labs must be included in the approved W.H.O list of BA/BE centers. The Laboratory should have a track record of approvals by all major regulatory agencies including MHRA, SA MCC, USA (FDA) etc.

PRODUCTS COVERAGE

Allopathic, medicinal products, in Oral forms (Tablet, Capsule, Syrup, Suspension, Cream & Ointment as well as Eye/Ear drops) only for human use is covered for carrying out Bio-equivalence/Bio availability studies under this Public Notice.

SUPPORT LEVEL

TDAP shall provide 50% subsidy on Bio-equivalence/Bio-available studies to the pharmaceutical companies with suitable capping after the completion of BA/BE studies.

PROCEDURE

- Companies must seek prior approval from the TDAP which will decide the merit of such applications and after obtaining the approval, companies are required to initiate the process for carrying out BA/BE studies with the concerned lab.
- Companies are required to submit legalized contract agreed between the Company and Lab CRO (Clinical Research Organization) through which they intend to carry-out the Bio-equivalence and Bio-availability studies.
- Companies are also requird to submit the documents validating the proof of the registration process of their generic products with the concerned Regulatory Authority.
- Any other relevant document(s) if requird by the Technical committee.

A technical committee comprising TDAP officials and a representative of PPMA will administer this scheme.

Interested companies wh intend to avail this facility may apply to:

Muhammad Rashid
Director General (Engineering)
Trade Development Authority of Pakistan
MINISTRY OF COMMERCE
GOVERNMENT OF PAKISTAN
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