No. 14-1/2022-PEC
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
TF Complex Sector G-9/4
****

Islamabad, 16th January, 2023

NOTIFICATION

Subject: - **Borrowing of APIs for performing Product Development, R&D & stability Testing Registration Board Decision Thereof.**

I am directed to refer to the subject captioned above. DRAP Authority in its 134th meeting held on 29th April 2022 while discussing the case of "Borrowing of APIs for performing Product Development, R&D & stability Testing", decided as under:

"The Authority deliberated that for product development / stability studies, the manufacturer need to purchase drug substance from a reliable source, however, in extraordinary circumstances beyond the control of manufacturer, the Authority acceded to the request of Pakistan Pharmaceutical Manufacturers Association (PPMA) to allow borrowing, except controlled drugs, the requisite quantity of drug substance for product development / stability studies only to fulfill pre-requisite for submission of Form 5-F (CTD) from a licensed manufacturer having legitimate purchase evidence. However, all requirements of quality and traceability would be applicable in such cases and will be the responsibility of the borrower of the material. Further, the products so manufactured in NO case shall be allowed for commercial sale".

2. Registration Board in its 322nd meeting held on 8th & 10th November, 2022 deliberated that in pursuance of the decision of DRAP Authority, pharmaceutical firms are availing the opportunity of loan of Active Pharmaceutical Ingredients for submission of Form 5F (CTD) applications. In order to further harmonize the submission of data and ensure data integrity, Registration Board decided as under:

Firm shall submit the documents of loan of API to PE&R division within 15 days of such acquisition along with requisite documents and shall secure its receiving from R&I section, DRAP. This receiving shall be presented along with Form 5F at the time of dossier submission. Those firms who have already obtained such materials on loan and their product development studies are in process, are also advised to inform PE&R Division as per aforementioned procedure.

3. For effective implementation of above decision, applicants are hereby advised to submit following documents as an evidence of loan from a licensed pharmaceutical manufacturer within 15 days of such acquisition:

a) Documents for the procurement of Active Pharmaceutical Ingredients with approval from DRAP (in case of import) by the lending company.
b) Letter and agreement of loan between such pharmaceutical manufacturers.

4. Those firms who have already obtained such materials on loan and their product development studies are in process, shall submit the above stated documents within 30 days of this notification and this receiving shall be presented along with Form 5F at the time of dossier submission.

5. Accordingly, above decision of Registration Board is hereby circulated for information and compliance by all relevant stakeholders / applicants.

16/1/2023

(Ch. Zeeshan Nazir Bajar)
Additional Director (PE&R)/ Secretary,
Registration Board

Distribution:

i. Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
ii. Executive Director, Pharma Bureau, Karachi.
iii. Executive Director, PCDA, Karachi.

Through E-Office:

i. Director (PE&R)/Chairman, Registration Board.
ii. Director (MIS), DRAP for uploading on DRAP's website.
iii. Additional Director / Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction.

Additional Director (PE&R)/
Secretary, Registration Board