Pakistan Institute of Development Economics

Policy Brief

RASTA

DISSECTING THE EFFECT OF INTERNAL R&D, IMPORTED INPUT VARIETY AND EXTERNAL TECHNOLOGY ACQUISITION ON EXPORT COMPETITIVENESS OF PHARMACEUTICALS IN PAKISTAN

Abdul Rauf, Abdul Jalil, and Ahsan Abbas

(CGP # 06-252)

(This document is unedited author's version submitted to RASTA)

INTRODUCTION

Exports are critical for employment generation, poverty alleviation and sustainable economic growth. It is also a significant source of international technology spillovers through learning-by-exporting. Thus, it is crucial to explore the determinants of firm-level export performance in developing countries. One crucial determinant is technological innovation (TI) which enhances firm capability and export competitiveness. TI directly induces exports as well as it indirectly affects exports via its positive impact on productivity. However, firms in developing countries face several micro level constraints including limited R&D activities, low skill level, lack of firm-specific tangible and intangible resources, lack of motivation for R&D, among others. Several macro-level rigidities including financial constraint, innovation-unfriendly macroeconomic landscape and regulatory hurdles also stifle innovation activities. Further, some sectors, e.g., pharmaceuticals, face extremely stringent product (drug) registration and quality, safety and efficacy compliance requirements from international regulatory bodies which restrict the firm's entry into the export market. The study examines the regulatory issues, R&D rigidities and export constraints of pharmaceutical firms in Pakistan and empirically investigates the impact of indigenous innovation, external technology acquisition and sector/firm-specific factors on firms' export performance.

Pharmaceuticals is a USD 3.45 billion industry in Pakistan. It has seen a CAGR of 17% during FY19-FY24. The sector is among a few leading sectors in large scale manufacturing (LSM) which has seen double-digit (23.19%) growth during FY-2024. The sector fulfils 80% of domestic medication demand and provides employment to approximately half a million people. However, the effect of somehow dynamic growth has not been reflected in the global competitiveness of the sector. Pharmaceutical exports increased at a CAGR of 12% during the period 2019-2023 with exports reaching USD 328 million FY-2023 and projected to reach USD 350 million in 2024, contributing only 1% to overall exports and GDP. Thus, it is critical to investigate the innovation and export challenges of the pharmaceutical firms in Pakistan.

The export competitiveness of Pakistan's pharmaceutical firms is constrained by several regulatory barriers and R&D rigidities at home and abroad. First, the firms face stringent drug registration and mandatory pharmacovigilance requirements in medium to high regulatory standard countries

which are hard to fulfil with their existing level of technology. It restricts firms' entry into stringent regulatory authority (SRA) markets and makes them rely on exporting to semi-regulated markets of the developing countries in Asia and Africa, weakening the learning-by-exporting channel. Second, the domestic drug pricing mechanism and molecule registration criteria are incompetent which encourage more spending on post-production (marketing and distribution) activities and render low funds allocated to R&D activities for drug discovery and high-quality formulations. Third, the Drug Regulatory Authority of Pakistan's (DRAP) human resource capacity and technical capacity concerning new therapeutic avenues of biologicals and AI-based medicine is low which leads to inability of compliance with the required standards and discourage the production of new medicines. Further, there are several legal and operational barriers to contract research and manufacturing services (CRAMS) which restrict drug manufacturing at low R&D cost and knowledge spillovers from innovator firms/countries. Fourth, R&D rigidities pertinent to weak innovation value chain (from drug discovery research to manufacturing and marketing), low technology transfer opportunities and less collaborative industry structure hamper TI which in turn restrict export quality upgrading. Lastly, a narrow product base, high production cost and lack of government support is also detrimental to export.

The study utilizes useful insights from neo-technology models which consider firms' heterogeneity and product differentiation as major drivers of trade and resource-based view (RBV) which postulates that firms' resources drive differences in firms' capabilities which leads to determining their sustained competitive advantage. The study is also linked with capability approach and the dynamic capability view which consider that knowledge spillovers from trade, FDI and government's trade and innovation policies enhance innovation capability of firms. Recently, endogenous growth models associated with new trade theories highlight the role of technology in intra-industry and intra-product trade.

DATA AND METHODOLOGY

The research design of the study is based on primary data. During August to November 2024, we surveyed the pharmaceutical firms located in Punjab, Sindh, KPK provinces and Islamabad Capital Territory. These regions comprise 97% (623 of total 639) of pharmaceutical firms. We utilized the directory of pharmaceutical manufacturing firms as issued by DRAP as sampling frame (DRAP, 2024). We used a stratified random sampling method with strata being the geographical location of a firm based on the information in our sampling frame. Our sample is representative at provincial level and regional/district level.

The data is based on structured questionnaire which collects information on firms' characteristics (size, productivity, absorptive capacity), firms' engagement in innovation activities including sources (internal and external, domestic and foreign) and types (product, process and organisational) of innovation, the factors hampering innovation activities, the factors promoting TI and the supply and demand side determinants of exports. Our sample size is 100, which is 16% of the population. We surveyed all the regional/district-level industrial clusters having more than 15

pharmaceutical firms. The response rate is 51 percent owing to the sensitive nature of the industry. We also executed 12 semi-structured interviews of key stakeholders from manufacturers, pharma association (PPMA), academia and DRAP to refine and consolidate the collected information.

For concreteness, we develop two single-equation empirical models including innovation equation and export equation. The objective is twofold: first, to empirically assess the factors which significantly induce firms' innovation performance; second, to systemically estimate the impact of diverse channels of TI and other crucial factors on firms' export performance. To tackle the issue of small sample size, imbalance in data points and the risk of separation, which may arise due to strong linear association among variables, we utilize the Firth Logistic (FL) regression for estimations because the abovementioned issues render standard logistics regression inconsistent.

FINDINGS

The empirical results of the innovation equation show that external (embodied and disembodied) technology acquisition and knowledge spillovers from FDI induce pharmaceutical firms' decision to innovate, suggesting the important role of the import of machinery and equipment, technology licensing and FDI in firm-level innovation. The results reveal that firms' characteristics, including firms' productivity, absorptive capacity and organizational innovation, are significant determinants of firms' propensity to innovate. It not only reveals the importance of skill, human capital and internal and external training of workers for innovation but also it highlights the significance of implementing modern organizational methods and business practices for firm's innovation decision. Furthermore, research collaboration and knowledge spillovers from CRAMS activities are critical for a firm's involvement in innovation activities. The results advocate the significance of contract research organisations (CROs) and toll/contract manufacturing services for firm's probability to innovate. The findings of the study also suggest that research collaborations among firms through strategic partnerships and joint ventures are critical drivers of firm's innovation decisions. It also highlights the critical importance of the university-research institution-industry linkages for a firm's engagement in innovation activities.

The empirical results of export equation show that internal R&D and external technology acquisition are two crucial channels for firms' export propensity. It reveals the importance of R&D induced decrease in average cost and improvement in quality and reliability of products for firm's global competitiveness. It also highlights the significance of international technology spillovers through import of machinery and equipment and licensing of technology for export. The results confirm the neo-technology models which explain the role of R&D in production and trade structure. The empirical results also show that firm size, process innovation and innovation variety are critical for firm-level export, suggesting that large firms with improved production processes or distribution method and those involved in variety of technological and non-technological innovation activities are more likely to enter the export market. Further, empirical results of the study show that product diversification and the development of infrastructure are critical for firm's probability to export. It reveals that the products focusing emerging therapeutic avenues are

critical for global competitiveness. In the context of Pakistan, it broadly involves the production of high-quality generics and simpler biologicals such as vaccines and others. Findings advocates that the establishment of drug testing laboratories and Bioequivalence/Bioavailability (BE/BA) study centres are crucial for export propensity of firms. The estimates of the study also show that the firms' membership of international regulatory bodies (e.g., US FDA) and the membership of the drug regulatory body (e.g., DRAP) of PICS countries is critical for entry into the export market. Lastly, findings confirm that incentives provided by government for local production of APIs, import of machinery and equipment, export rebates, financial support for BE/BA studies and GMP inspections and facilitation for drug registration are critical for firm's entry into the export market.

RECOMMENDATIONS

- The study recommends a three-pronged R&D strategy involving: First, R&D for the production of high-quality generics and capturing off-patent market; Second, basic research for drug development through university-research group-industry linkages; and Third, R&D to enhance the production of biologicals. To this end, firms are required to enhance R&D intensity, large firms to establish R&D consortia and the government to utilize the Central Research Fund (CRF).
- Firms should focus on accelerating indigenous innovation activities and relying on external technology acquisition for technology upgrading leading to plant accreditation. Further, there is a need to upgrade to electronic/digital and AI based machinery and equipment. Government should facilitate technology upgrading activities at the firm level.
- The study recommends that firms should be involved in toll/contract manufacturing to save on drug discovery cost. Further, we recommend the establishment of CROs, analytical labs and BE/BA study centers to become the source of pre-clinical and clinical trials and BE/BA studies.
- The study recommends a change in curriculum pertinent to understanding the global standards and pharmacovigilance system. Also, there is a need to develop a viable university-industry linkage where the problem identification and implementation into the curriculum will be smooth. The study proposes an increase in the biotechnology schools and research labs in order to gain the capability to move to new therapeutic avenues.
- As for DRAP, the human resource capacity enhancement and capacity development for guidelines and its implementation of AI-based/biological drugs is critical at this stage. Further, DRAP should materialize the use of CRF, seek amendments in the Drug Act 1976 where necessary and expedite the process of PICS membership. Further, DRAP should revise the toll manufacturing policy to enhance low-cost manufacturing. Also, there is a need to devise a criterion to limit the registration of a single molecule by so many firms to avoid more spending at the post-production stages.
- The study recommends that drug price decision should not go to the cabinet. The Federal Government should establish a dedicated price board who have a close eye on the cost of production and other related factors. The Federal government should revise the existing

APIs policy based on the available experience and setting up a task force to examine its implementation.

We suggest an increase in the USD retention limit of the exports proceeds of pharmaceutical firms.