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EDITORIAL

Promoting local production and active pharmaceutical ingredient (API) industry in low and middle income countries (LMICs): impact on medicines access and policy

Muhammad Akhtar Abbas Khan [a,b] and Asim Rauf [b]

[a]Health Services Academy, Islamabad, Pakistan; [b]Drug Regulatory Authority of Pakistan, Islamabad, Pakistan

ABSTRACT

The success of universal coverage depends on ensuring that patients have access to medicine. Encouraging local production of medicines in developing countries can provide better access to medicines. In addition to determining the quality of pharmaceutical goods, Active Pharmaceutical Ingredients (APIs) also determine their cost. According to market forecasts, the active pharmaceutical ingredients market is expected to increase from USD 193.15 billion in 2023 to USD 285.29 billion by 2028. Pakistan largely depends on India and China for its Active Pharmaceutical Ingredient requirements. It was feared that a shortage of medicines would result from Pakistan's government suspending all trade with India on August 9, 2019. To improve health security in Pakistan, the Government of Pakistan has introduced an API promotion Policy in 2022. Financial and non-financial incentives have helped many countries develop their API industries like China, India, and Bangladesh. The current domestic API market of Pakistan is around 150 million $. After the introduction of the policy, the existing units are increasing their capacity while eight new API units are in the process of establishment. Through local production of APIs and intermediates, Pakistan can improve its health security by learning from the experiences of neighbouring countries, especially China.

KEYWORDS Active Pharmaceutical Ingredient; API; policy; Pakistan; incentives; industry; health security

1. Introduction

For universal health coverage to succeed, it must ensure that patients can access medicines and vaccines (Anderson, 2023). Encouraging local production of medicines in developing countries can provide better access to medicines at a lower cost than medicines imported from developed

CONTACT Muhammad Akhtar Abbas Khan akhtarabbas@hsa.edu.pk Health Services Academy, Chak Shahzad, Islamabad, Pakistan

countries. However, for local medicine production to be efficient, it should be cheaper than importing medicines from the open market (Kaplan & Laing, 2005).

Access to medicines is a crucial concern for policymakers across the world, regardless of their country's income level. This is to ensure that their healthcare systems can effectively meet the needs of their citizens (Obembe et al., 2022). Many developing countries have implemented government policies to exempt pharmaceutical products from import duties (Quick, 2003). However, various factors affect the accessibility and affordability of drugs, including the availability of local pharmaceutical production.

Pharmaceuticals produced locally play a crucial role in enhancing local healthcare system resilience by improving access to needed medicines and decreasing exposure to imports (Tawfik et al., 2022). In addition to determining the quality of pharmaceutical goods, Active Pharmaceutical Ingredients (APIs) also determine their cost. A public health objective is to ensure that final formulators in developing countries have access to high-quality APIs for essential medicines (Bumpas & Betsch, 2009). APIs have become an increasingly important piece of the pharmaceutical supply chain, where they represent the most valuable and clinically effective components.

Active Pharmaceutical Ingredient (API) means

> any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body (US FDA, 2023).

According to market forecasts, the active pharmaceutical ingredients market is expected to increase from USD 193.15 billion in 2023 to USD 285.29 billion by 2028 (Mordor Intelligence, 2023). Globally, 60.5% of API is produced in Asia Far East, 27.9% in Western Europe, 4.6% in North America, and 7% in the rest of the world (European Fine Chemicals Group, 2022). Currently, China and India are the leading suppliers of pharmaceutical raw materials and excipients worldwide.

Medicine manufacturing was dominated by Europe until the 1950s. The production of pharmaceuticals has increasingly been moved to Asia, mainly India, and China, resulting in a very small number of production sites in Europe. There is a growing trend of relocating manufacturing operations back to Europe, including pharmaceutical manufacturing (Fischer et al., 2023). In the next three years, over 60% of European and US manufacturing firms plan to onshore or re-shore parts of their Asian production (BCI Global, 2022). The European governments are providing financial and non-financial incentives, speeding up administrative and regulatory processes. The Austrian and French governments have funded the expansion of local API production (Fischer et al., 2023).

In order to boost Nigerian pharmaceutical production, Okereke, et al, argue, governments, policymakers,, regulators, pharmaceutical companies, and other stakeholders must eliminate barriers related to politics, socio-economics, finance, and regulation, including extraordinary taxes, increased energy costs, poor infrastructure, insecurity, lack of funding, and unfavourable policy changes (Okereke et al., 2021).

Following India's decision to revoke the special status of Jammu & Kashmir under Article 370, Pakistan's government had on August 9, 2019, suspended all kinds of trade with India (Choudhury, 2019). Later, Pakistan's pharmaceutical industry demanded that the ban be lifted on Indian medicines and medicinal raw materials because the country might face a severe shortage of medicines, especially life-saving drugs. Subsequently, the federal government lifted the ban on the import of medicines and medicinal raw materials from India (Junaidi, 2019). To improve health security in Pakistan, an API policy was introduced in 2022 because of the situation.

2. Pakistan

Pakistan is a lower-middle-income and the sixth most populous country in the world. In 2023, Pakistan's total population has reached 241 million (Pakistan Bureau of Statistics, 2023). The pharmaceutical industry is regulated by the Drug Regulatory Authority of Pakistan (DRAP)**.** The pharmaceutical industry in Pakistan is worth around USD 3.2 billion (The Pakistan Business Council, 2021). More than 650 drug manufacturing licenses (Drug Regulatory Authority of Pakistan, 2023a) and 80,000 product registrations (Drug Regulatory Authority of Pakistan, 2023b) have been granted by DRAP. As the 10th largest pharmaceutical industry in the Asia-Pacific region, Pakistan fulfils 80% of its own medical needs (Jannat et al., 2023). The Pakistani pharmaceutical sector has doubled from 1.64 billion to 3.2 billion USD during the last 10 years. During 2022 Pakistan imported medicines of value more than 90.35 million USD. The total exports are more than 713 million USD (Web Desk, 2022) with the aim to increase them to 1 billion USD (CEO DRAP, 2023).

2.1. Historical context of pharmaceutical industry development in Pakistan

Pakistan gained independence in 1947 with two parts, East Pakistan (now Bangladesh) and West Pakistan (now Pakistan). There were only six factories in the country that produced galenicals and syrups. About 56 factories were operating in the country by the mid-1950s, producing a wide range of fine chemicals, drugs, galenicals, extracts, and tinctures. In and around the Kurram valley, herbs found wild were used to produce Santonine and

Ephedrine. As of the mid-50s, a few pharmaceutical factories produced tablets and injections but not enough to meet demand.

In the 1st five-year plan (1955–1960) the Government planned to invest in a large pharmaceutical factory in erstwhile East Pakistan (Now Bangladesh) and Kurram chemical factory Bannu in West Pakistan (Present day Pakistan). The Government in collaboration with WHO proposed a plant to produce penicillin with the capacity of national demand. A similar plant was also proposed in the East Pakistan. After understanding and acknowledging the importance of this industry Pakistan Government developed two units under the instructions of the Pakistan Industrial Development Board (PIDB) namely Kurram Chemicals Limited Bannu and Antibiotics Private Limited in Mianwali (Government of Pakistan, 1957). In the past few pharmaceutical companies have closed their operations because they could not compete with Chinese and Indian API manufacturers. Antibiotics Pvt. Ltd Mianwali was closed due to privatisation and other similar reasons.

Vaccine manufacturing units were not present in the country at the time of independence. By manufacturing typhoid and cholera vaccines in Karachi, Army Medical Corps personnel became the pioneers of the Biological Industry of Pakistan in 1948. National Institute of Health, Islamabad (NIH) was born out of this unit, which was named Bureau of Laboratories, Karachi (BOL) (NCLB, 2021). Presently National Institute of Health manufacture the Polyvalent anti-snake venom serum, Anti-Rabies serum **ARS, A**nti-Tetanus serum & Anti diphtheria serum (NIH, 2023).

2.2. Current situation of API manufacturing in Pakistan

According to research, API and raw material availability issues lead to the unavailability of many essential medicines (Malik et al., 2020). There are thirteen basic pharmaceutical units for API manufacturing in Pakistan. Pakistan largely depends on China and India for the import of pharmaceutical raw materials (Atif et al., 2017). Pakistan's current market of domestically produced APIs is around 175 million $. Seventy-three APIs are enlisted for production in Pakistan while local firms are producing 32 APIs. This only fulfils the 10% needs of Pakistan, and the rest of the APIs are imported. The Drug Regulatory Authority of Pakistan (DRAP) has issued a policy to enhance API manufacturing in Pakistan (Drug Regulatory Authority of Pakistan, 2022). Financial and non-financial incentives have helped many countries develop their API industries. There is a huge potential for investment in the Pakistani API industry.

The current API policy has introduced incentives including a reduction in customs duties on starting and intermediate materials, machinery for five years, levying of regulatory duties (antidumping duty), tariffs against the

import of materials manufactured in Pakistan, and financial incentives like soft loans and keeping 15% of export earnings as short-term incentives. A linkage between academia/research organisations and the basic manufacturing industry for funding shall be established. The policy proposed the establishment of API mega parks in the long run (Drug Regulatory Authority of Pakistan, 2022). Recently the Minister for Health announced that Pakistan is working on establishing a Pharma Park for the API units with the help of a public-private partnership (Raheela Nazir, 2023).

Federal Board of Revenue has increased the import duties on the locally produced APIs. A dedicated Cell was established by DRAP as part of the implementation of the policy to deal with matters related to indigenous Active Pharmaceutical Ingredient (API) manufacturers on priority. To expedite licensing issuance, this cell will work closely with the relevant ministries. By taking these steps, DRAP is demonstrating its commitment to enhancing efficiency and innovation in the pharmaceutical sector which would result in a reduction in API imports.

There is a growing trend in the region for clinical trials to be conducted in Pakistan. For all clinical trials approved by the Clinical Studies Committee of DRAP, United States National Trial Registry has been adapted as an international registry. Currently, 91 clinical trial sites and 5 centres for BA/BE studies has been approved by DRAP. DRAP has approved more than 20 CROs and 61 clinical trials.

After the introduction of the policy, the existing units are increasing their capacity while eight new API units are under the process of establishment. Through local production of APIs and intermediates, Pakistan can improve its health security by learning from the experiences of neighbouring countries, especially China.

3. China

As a result of infrastructure investment, large-scale manufacturing capacity, cost efficiency, technical capability, and supportive government policies, China maintains its dominant position in the global market. The policies adopted by China to become a dominant force in bulk drugs are policy and infrastructure reforms, to provide impetus and scale to its pharmaceutical and associated raw material industry. That involves encouraging innovation across the value chain, shortening approval processes, optimising efficiencies, and providing the necessary utilities at discounted rates (GME, 2023). The government has been investing heavily in biologics and biosimilars, the next-generation drugs. It has recently invested around USD 1.6 billion in new drug development. China has created a 'Thousand Talents Plan' to attract 50,000 PhDs internationally through research funding and created a collaborative research ecosystem, where returning talent creates major

alliances between multinational firms, universities, and other companies (PwC, 2020).

The clusters have proximity to ports and airports for better logistics support. The industry was state-owned, and the Government provided significant incentives for development, including establishing special industrial zones that included provision for low-cost land purchase and infrastructure development. That industry largely focused on the production of basic chemicals and active pharmaceutical ingredients (APIs), and China has emerged as the leading supplier of APIs by volume to the global market. The Chinese government is encouraging R&D in the pharmaceutical sector, with special attention to the biotechnology sector and the development of 'biosimilar' product capacity. Financial, tax and related incentives are important elements of promoting pharmaceutical manufacturing, and the establishment of industrial zones where common infrastructure, environmental support, transport, and other elements may be jointly used by manufacturers is likely to be a useful model for other settings (The World Health Organization, 2017).

4. India

Among the world's largest suppliers of generic medicines, India ranks third in terms of volume of medicines produced (Cherian et al., 2021). The Indian API industry has progressed from being known for producing simple API molecules to becoming the preferred destination for high-value and complex API (Confederation of Indian Indsutry, 2020; Singh & Popli, 2021). With around 1,500 units, India's API industry is highly fragmented. During 2018–19, the top 14–16 companies accounted for 16–17% of the total market share (Confederation of Indian Indsutry, 2020). As a result of the adoption of international standards and the establishment of big plants, the industry has grown rapidly. With 665 plants approved by the US FDA, India has the highest number of abbreviated new drug applications in the world (GME, 2023).

As part of its efforts to promote API manufacturing in the country, India has taken several steps. The federal government and state governments have created excise duty-free zones to support pharmaceutical manufacturers in their production. As a result, Pharma companies have been encouraged to produce a wide variety of pharmaceutical products (Chander et al., 2016). Furthermore, the government is promoting domestic manufacturing of APIs to reduce reliance on imports (Zhang & Bjerke, 2023). Overall, India has taken various measures to promote API manufacturing, reduce import dependency, and ensure the ethical promotion of medicines. These initiatives aim to strengthen India's pharmaceutical industry and enhance its self-reliance in the production of essential medicines.

5. Bangladesh

The Drugs (Control) Ordinance, of 1982 is credited with the development of the industry in Bangladesh. Another historic event occurred in Bangladesh in 2008 when the product patent system was abolished. Changes in the patent regime have had the same effect on patented products as the 1982 Ordinance did for generics. In Bangladesh, a total of eight firms are API manufacturers.

Through the Bangladesh Small & Cottage Industries Corporation under the Ministry of Industry, an API Park was approved in 2008 on 200 acres of land in Munshiganj near Dhaka by the National Drug Policy 2005. A common effluent treatment plant and waste disposal yard shall be set up by the Bangladesh Association of Pharmaceutical Industries (Mosharraf et al., 2019). 2018 marked the introduction of the National API and Laboratory Reagents Production and Export Policy. It is estimated that the domestic API market will reach 1.4 billion by 2025, with a current market size of USD 730 million (Bangladesh Investment Development Authority, 2021).

Bangladesh Economic Zones Authority has announced several incentives for unit developers and manufacturing unit investors. From tax exclusions to capital expenditure reductions, zone developers benefit from these incentives. Foreign Direct Investment ceiling, issuing work permits, and recommendation for residence/citizenship are some of the non-fiscal incentives for investment, including exemption of tax, customs, and excise duties. (Bangladesh Economic Zones Authority, 2023).

As part of the government's effort to cut reliance on imports and bolster exports, manufacturers of raw materials used to make medicines will receive tax exemptions until 2032. The tax benefit would be available retrospectively to API and laboratory reagent manufacturers that already make the raw materials. Firms need to make at least five APIs and laboratory reagents annually from July 2022 to qualify for the tax holiday. A 7.5% tax will be payable for drug makers who will produce three new APIs and reagents every year from July 2022. Besides, API molecules and reagent makers will have to spend at least one percent of their annual turnover on research and development and increase their involvement with academic and research organisations gradually. The privilege would continue until 2032 as the government aims to ensure a strong footing for the pharmaceutical industry and boost export receipts by taking advantage of the patent waiver under the Trade-Related Aspects of Intellectual Property Rights (TRIPS). Local manufacturers were able to make 41 API molecules and reagents in 2017. The government aims to raise it to 370 by 2032, according to the national policy on API and reagent production and export framed by the commerce ministry in 2018 (The Daily Star, 2021).

6. Conclusion, implications for policy and practice

It's a moot question whether producing an active pharmaceutical industry in a country will promote access or otherwise. The countries and manufacturers would always procure active ingredients from other countries if cheaper. However, producing API could provide a sense to meet health security challenges and or be the part of industrial policy of the country.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Authors' contributions

MAAK conceptualised the idea, conducted the literature review, and wrote the initial draft. AR synthesise data and revise the manuscript. All contributors checked and accepted the final version of the manuscript.

ORCID

Muhammad Akhtar Abbas Khan http://orcid.org/0000-0001-7129-4075

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