POLICY NOTE
No. 2, Series of 2020

Identifying Challenges in the Philippine Pharmaceutical Industry

Celia M. Reyes and Aubrey D. Tabuga[1]

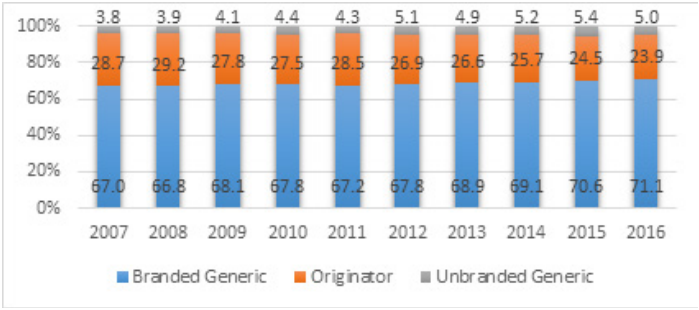
Ensuring a reliable supply of good quality, safe, and effective medicines is a highly salient policy issue due to its crucial role in the promotion of healthcare of the population. This is achieved with the improvement of the pharmaceutical industry's capacity for production and distribution, effective and efficient regulation, and the development of responsive policies. Based on a full report[2] on the pharmaceutical industry, this Policy Note provides a brief profile and summarizes the gaps and challenges that beset the country's pharmaceutical industry with an emphasis on the dimensions of competition, prices, and regulation, to draw insights for immediate action and for policymaking.

The Industry at a Glance

The pharmaceutical industry is robustly growing. Based on 2017 data from IQVIA, the Philippine pharmaceutical market is valued at P176 billion. It is a fast-growing market, expanding at an average of 8.3 percent per year—faster than the country's Gross Domestic Product. The rapidly increasing population amidst a vibrant Philippine economy offers an even brighter market outlook for the Philippines' pharmaceutical sector.

The industry is characterized by increasing share of generics and an improving share of local companies in the market. The Philippines' pharmaceutical market is segmented into three license types - 1) originators, 2) branded generics, and 3) unbranded generics. IQVIA defines originators as those drugs that are first to launch within a single or combined molecule. An example of originator drug for the anti-biotic drug Cotrimoxazole is Bactrim by Roche. Meanwhile, branded generics have the same molecule as the originator. An example is Kathrex by New Myrex. Unbranded generics are those that carry the name of the molecule but without a brand. Instead, the name of the manufacturer acts as the brand in the packaging. An example is RiteMed's Cotrimoxazole. Between 2007 and 2016, the share of generics (branded and unbranded generics) expanded from 71.2 to 76.1 percent of the sector's total sales (**Figure 1**). Similarly, the role of local firms expanded from 32.4 to 43.5 percent of the overall market.

Figure 1. Distribution of pharmaceutical sales by license type



Source of raw data: IQVIA Philippines

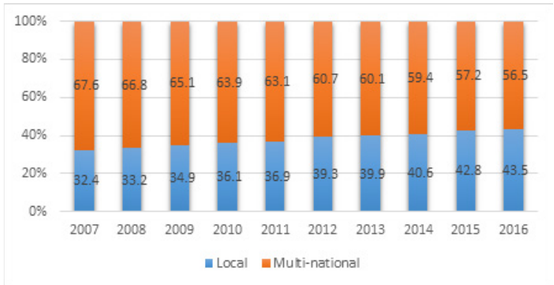
Amidst the increasing role of the generics sector and the expanding participation of the Filipino-owned companies, the market presence of multi-national firms remains large. Multi-national companies still capture the majority of the market at 56.5 percent based on 2016 data (**Figure 2**). This is probably because multi-national companies maintain their portfolio through the years - concentrating mostly on importation of

1 President and Research Associate, respectively, Philippine Institute for Development Studies (PIDS). This policy note was prepared before the issuance of Executive Order No. 104 on Improving Access to Healthcare through the Regulation of Prices in the Retail of Drugs and Medicines in February 2020.

2 The industry scoping study from which this Policy Note was drawn from was commissioned by the Philippine Competition Commission (PCC).

branded generics, which comprises 57 percent, while the originator medicines contribute only 42 percent to their total sales. This composition is relatively similar between 2007 and 2016. Local companies, on the other hand, focus their production on branded generics, with nearly 90 percent of their total sales coming from this segment. Around 10 percent is on unbranded generics, while there is only 1 percent on originator products.

Figure 2. Distribution of pharmaceutical sales by type of ownership



Source of raw data: IQVIA Philippines

There is evidence of concentration, consolidation, and integration. The top 20 pharmaceutical corporations capture a combined share of 73 percent of the market, with one local company enjoying a quarter of the total market. Furthermore, the number of domestic pharmaceutical manufacturers has been significantly reduced through the years, resulting in a reduction in employment. In the absence of official data, the authors' crude estimate of the total number of manufacturers of human drugs in the country as of the end of 2018 is 109. This estimate, which is based on FDA raw drug registration data, is nearly one-third of the 280 establishments recorded in 2010. These estimates lump the manufacturer-formulator, toll manufacturers, and packers/re-packers/labelers. A representative of manufacturing companies' association puts the current number of licensed drug manufacturers operating locally at 46, a small fraction of the estimated 126 manufacturers-formulators that exist a decade ago. Since many establishments are actually subsidiaries of more prominent pharma companies, determining the actual figure could be tricky. Although there seems to be a lot of pharmaceutical manufacturers listed, close scrutiny of data from the Securities and Exchange Commission (SEC) showed that the owners of these companies do overlap. If establishments that have similar owners are pooled, some 31 pharmaceutical establishments will consolidate into only 5 companies.

Furthermore, there is an emerging pattern of integration by producers – doing end-to-end services from manufacturing to distribution to marketing and even bioequivalence[3] tests for generic medicines and hospital service. Meanwhile, retail companies are coming up with their own labels of generic medicines. This emerging trend needs to be monitored to prevent anti-competitive behavior and ensure that small manufacturers have access to the market.

Local manufacturers/traders note their difficulty in competing with bigger ones. Only a few products manufactured locally have economies of scale. Smaller manufacturing companies face more significant cost of production because they could not afford bigger volumes of active pharmaceutical ingredients (API). Based on a report by the Philippine Pharmaceutical Manufacturers Association, the cost of 10 kilograms of Amlodipine is PhP14,153 per kilogram. However, a bulk purchase of 1,000 kilograms is only PhP7,215.00 per kilogram, roughly half the price for the 10-kilogram purchase. Furthermore, small companies have difficulty paying for bioequivalence tests—sometimes paid on an installment basis. Smaller companies also lack marketing capacity, constraining their ability to supply medicines to hospitals and major drugstores.

Informants from both the industry and the regulator emphasized the challenge of getting qualified people. A testing center claimed that once trained, many of its people are enticed to join lucrative pharmaceutical companies. An FDA informant also noted that it is challenging to get people with technical skills who can work in the evaluation of drug registration applications. Moreover, it would take up to 6 months to train a chemist in the production of medicine. Retailers, too, have difficulty in hiring pharmacists.

The slow drug registration process constrains the ease of entry in production. While big pharmaceutical manufacturers can spread the costs emanating from the delays, smaller ones have a lower capacity to recover from business losses. The slow registration process originates from several critical factors. FDA has limited plantilla positions. Although applications for registrations are continuously increasing, the workforce is not growing as much.

Furthermore, its electronic submission system cannot process the large volume of application documents coursed through it. These constraints have been exacerbated by the increased registration requirements, particularly the bioequivalence test required for a significant number of generic oral formulations. To address these issues, the FDA implemented a program called "Project: Backlog" where it hired several technical and administrative staff. They were assigned under the direct supervision of then FDA head Nela Charade Puno to process applications.

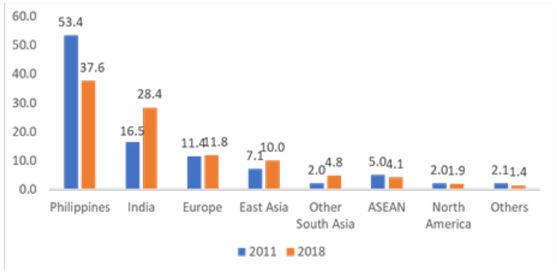
Interviews with informants reveal that there is a lack of avenues for communication and dialogue between the industry and the regulatory agency. Currently, FDA's system of formal communication and coordination is through the FDAC (Food and Drug Action Center). This is the same facility that it uses for receiving applications for drug registration and licensing, where all applicants are required to register in its password-protected online platform. It is also the same facility where the FDA also provides the outcome of the application process. The facility strictly follows a queueing system. Therefore, those with inquiries to the FDA course their concerns through the FDAC. Such a process takes time because interests are not immediately conveyed, and thus responses are delayed. In response, the FDA commenced its regular session of dialogue between the industry and the regulator, called "Kapihan" where industry issues are discussed.

There is a need for greater vigilance in the registration of pharmaceutical products by the FDA. The FDA notes that counterfeit drugs exist in the market, and the real magnitude is unknown. In January 2018, some US$3 million worth of fake medicines were seized in Manila. The Philippine President ordered the crack-down of all facilities that are involved in the production of counterfeit drugs. The percentage of counterfeit drugs is more significant in less developed countries than in more developed ones like the United States (Blackstone, Fuhr, Jr., & Pociask, 2014). The lack or absence of protection from counterfeit drugs discourages innovation. Counterfeit medicines do not only have significant health implications but also economic repercussions. Therefore, the government must improve all its efforts against counterfeit medicines. Likewise, it must ensure that stringent policies are implemented for all products applying for registration. For instance, its system on tagging the facility that actually manufactures the product is an essential safeguard against fake drugs and counterfeit pharmaceutical products. This must be adhered to by all who apply for registration in the Philippine market to ensure that products are safe, of good quality, and effective.

There is increasing reliance on imported pharmaceutical products. Based on data as of July 2018, 62 percent of all registered drugs[4] in the Philippines' FDA are imported; only 38[5] percent is said to have 'originated' in the country (**Figure 3**). These estimates are based on the authors' calculations using FDA's drug registration data.

In comparison, the country produced 53.4 percent of all registered drugs in 2011.[6] Note that these estimates do not account for the fact that vital raw materials in manufacturing are also imported. Industry players and the FDA note that 100 percent of active pharmaceutical ingredients (API) are imported from abroad. The only materials commonly procured locally are packaging materials and sugar, an additive in the formulation. Medicines packed/repacked or labeled in the Philippines are also classified as manufactured medicines, as defined by the FDA. Therefore, the real proportion of drugs actually formulated and manufactured in the country may be lower.

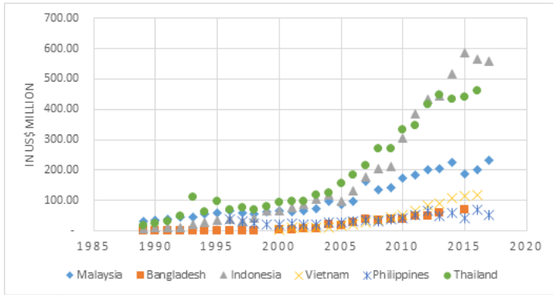
Figure 3. Estimated share[7] in registered drugs in PH market by origin, % to total



Source of raw data: Food and Drug Administration (FDA)

Neighboring countries outperform the Philippines in pharmaceutical exports. The Philippines' pharmaceutical exports value in 2017 is US$50.6 million, comparable with Indonesia's performance in 1996. Indonesia later doubled its exports within 5 years and pharma exports expanded at an average growth rate of 15 percent per year, compared to the Philippines' average 4 percent annual growth during the same period. Bangladesh's and Vietnam's exports have also been growing quite rapidly. **Figure 4** shows how these neighbors now outshine the country in pharmaceutical exports.

Figure 4. Pharmaceutical exports by country



Source of raw data: UN -COMTRADE

Prices of some originator drugs in the Philippines are higher than in other countries (e.g., Indonesia, India). But within the country, there is a substantial variation in the prices of the medicines that were examined. The cost of Ponstan (Mefenamic Acid) in the country, for instance, is 14 times that in India, and 4 times that in Indonesia.[8] There are, however, many options to this brand that offer prices that are only 17 to 72 percent of the cost of the originator. Making these affordable generic brands accessible and available to all consumers is therefore crucial.

Interestingly, the price of the same brand depends on who sells it or where it is sold. Based on DOH's Drug Price Watch, some medicines made by a manufacturer can be marketed and priced differently depending on the trader or marketing authorization holder, the drugstore, or the hospital. Another surprising cost pattern is the pricing of generic brands in the hospitals that is similar to the price of the originator. In these situations, consumers do not enjoy the full benefit of the cheaper generic brand. The actual reasons behind the price differences and the implications of such are important areas that require more in-depth research.

Lastly, the pharmaceutical industry is vast, complex, and to no small extent, opaque because of the lack of easily accessible data for analyzing the sector. There are manufacturer-formulators, importers, packers/re-packers, distributors/traders, exporters, and testing facilities. Official data, however, do not provide disaggregated information and time-series data on the number of these industry actors. There is also no distinction between the manufacturer-formulators and the packers/re-packers. These are challenges in analyzing the characteristics and direction of the pharmaceutical industry.

Recommendations

1. The presence of concentration, consolidation, and integration in the industry suggests that there is a need to examine more deeply any policy, process, or phenomenon that inhibits greater competition. Furthermore, the significant reduction in the number of local manufacturers indicates the inability of some companies to compete under the current policy and regulatory environment. This

3 A bioequivalence test is conducted to test if two chemically or pharmaceutically equivalent products, for instance, a generic drug and the originator, have the same efficacy and/or toxicity (www.ncbi.nlm.nih.gov)

4 Drugs registered with validity expiring end of 2017 up to 2022.
5 This estimate may include production by packers/re-packers of imported finished products.
6 Drugs with registration validity expiring between 2009 and 2015.
7 Based on authors' estimate using FDA drug registration data.
8 As of July 2018

is something that requires more considerable attention because one of the pillars of the Philippine National Drug Policy is the development of self-reliance in the local pharmaceutical industry. A continued decline in domestic manufacturing would run against this pillar. To arrest the fall, the government must explore avenues on how to boost the capacities of smaller industry players. Furthermore, close monitoring of current practices of retail drugstores in generic labeling of medicines could help deter anti-competitive behavior.

2. Ensuring the adequacy of technical workforce (i.e. chemists, pharmacists) is essential not only in the production, retail, and research but also, and perhaps more importantly, in the regulation or evaluation of pharmaceutical products for human consumption regardless of origin. The government must, therefore, create an environment that draws young people into the relevant fields of study.

3. Efforts must be prioritized to resolve FDA's human resource and infrastructural predicaments to avoid further delays in drug registration and renewal. Procrastination can have more significant adverse effects to smaller players if their essential products are not registered on time. Such delays also deny the Filipino consumers timely launching of potentially important medicines for the treatment of illnesses. While addressing these constraints may take time, the regulatory agency can explore other means to avoid further delays. It may consider extending the validity of new and renewed registration from the current 5 and 2 years, respectively, to more extended periods. Such a move will reduce the administrative burden of having to undergo these processes frequently.

4. There is a need to improve interaction between the industry and the regulator. A regular dialogue between the two parties, together with other stakeholders, is essential so that issues and grievances are clarified and addressed in a timelier manner. Policy directives must also be adequately coordinated and communicated with the industry and other stakeholders. In a stringent regulatory environment, dialogue and clarity of guidelines are very crucial so that misunderstanding and confusion are avoided.

5. The increasing share of imports among registered pharmaceutical products requires a more significant focus on the evaluation of imported pharmaceutical products to ensure that these are safe, effective, and of good quality. Ensuring that standard metrics are used for both imported medicines and locally-produced medicines is crucial. Also, the government must carry out practical efforts to eradicate counterfeit medicines in the market and to ensure that all pharma products being sold in the market are duly registered by the FDA.

6. The ability of local manufacturers to export pharmaceutical products signifies that the quality of locally manufactured products is at par with other global producers. The slow growth of our exports relative to our neighboring countries and that of the domestic market suggests that more can be done in terms of improving our competitiveness. The government, in close collaboration with the industry and other stakeholders, must address any gap that hinders the ability of Philippines-based companies to export.

7. It is crucial to examine why some brands of medicines remain to be significantly more expensive in the Philippines despite the presence of generic products in the domestic market. In light of this, improving consumer awareness on the availability of good quality generic alternatives is a must. The huge expense in medicines implies lack of awareness on the efficacy of generic medicines as compared with that of the originators. It is also possible that these alternatives do not find their way in popular retail stores. The challenge, therefore, is in ensuring the people, especially those in rural and underserved areas, can gain access to the range of more affordable choices available in the market. Authorities must also investigate any violation of the generics law that hampers people's enjoyment of the more affordable generic medicines.

8. The government's monitoring capacity must be improved. The regulatory agency must come up with a comprehensive and accessible database that provides the number of industry actors indicating their individual profile. Information found on their website should be disaggregated by geographic location and other pertinent categories. Its drug registration database must also have unique identification for establishments involved in the production, importation, and distribution of drugs. The presence of a detailed and comprehensive database is very crucial not only in monitoring the trends but also in the decision-making process within the agency. An unprecedented increase, for instance, in the number of imported products calls for more resources towards the evaluation of imported products and the deployment of more foreign auditors. Likewise, the Department of Health's EDPMS is a vital tool for monitoring the prices of medicines, and its coverage must be enhanced to include all drugstores and hospitals in the country.

9. The Philippine pharmaceutical industry is a vast and complex industry with numerous players and products. Hence, a roadmap must be developed to address the gaps and challenges that the industry currently faces. The roadmap will identify industry-level development objectives and delineate roles of various stakeholders in achieving such goals. In the development of a roadmap, the abovementioned issues must be examined more deeply so that practical and feasible solutions can be developed. ■