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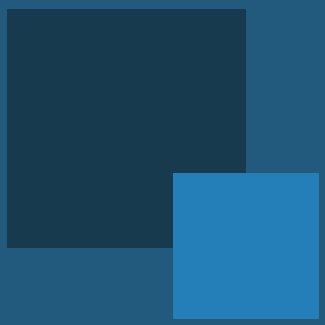
A Profile of the Philippine Pharmaceutical Industry

Celia M. Reyes and Aubrey D. Tabuga



A Profile of the Philippine Pharmaceutical Industry

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Abstract

The efficient production and distribution of good quality, safe, effective, and affordable drug products are key elements towards universal healthcare. The role of the pharmaceutical industry is crucial and the understanding of its performance, structure, dynamics, opportunities, as well as identifying the challenges is rather imperative. This study seeks to provide a profile of the pharmaceutical industry based on the available information from data sources like the Food and Drug Administration (FDA), Securities and Exchange Commission (SEC), Philippine Statistics Authority's Census of Philippine Business and Industry (CPBI), Department of Health (DOH), IQVIA Philippines, MIMS. This study also employs electronic sources of drug price data, among others. Acknowledging that these data sources provide limited information, the study likewise utilizes data gathered from key informant interviews (KIIs) with industry association leaders, and representatives of the regulating agency, drug manufacturers, distributors, retailers, contract research organizations, and private hospitals. The study looks at the industry from various perspectives – assessing the different players such as drug manufacturers, traders, hospitals and retailers as channels of distribution, testing centers or contract research organizations, and the regulator - FDA. It examines industry performance, segmentation, industry dominant players, and extent of consolidation and/or integration. Such analyses are complemented with an assessment of patterns and trends in drug price data. The study finds that majority of the pharmaceutical market is captured by the generics segment particularly branded generics which reflects that Filipinos are now into generics. It is also found that majority of the drug products registered at FDA comprise of imported products with India as the leading source. And although local companies' share is rising, the market is still dominated by multi-national companies. Based on authors' crude estimates using FDA drug registration data, the number of drug manufacturers has gone down roughly by half since 2010. Survey data likewise show that employment levels in these manufacturing establishments have gone down. Interestingly, the paper found some evidence of consolidation and/or integration within the industry. Meanwhile, although average prices have gone down (which is attributed to the presence of generics), the prices of similar molecules vary widely depending on the brand and where they are sold. Lastly, this study identifies several issues and provides some insights for a more informed policy-making.

1. Introduction

Filipino households are investing more on their health. From 1994 to 2017, the share of out-of-pocket expenses to total health expenses went up from 47 to 54 percent.[1] In fact, the Philippines has one of the highest percentages of out-of-pocket health expenditures in the region. A significant proportion of households' health care budget (at 50.1 percent) is spent on medicines. The high importance of medicines in the budget can be observed for most households regardless of income status. On the government's side, the passage of the universal health care bill will have a significant impact on the way the government procures medicines and other health care needs. Therefore, the adequate supply and efficient distribution of medicines are crucial in the promotion of health and the availability and accessibility of good quality, safe, and effective (QSE) medicines. In addition, the performance of the supplying pharmaceutical industry are salient areas of inquiry.

There are only very few existing studies on the profile of the Philippines' pharmaceutical sector. Most works pertain to reports by industry associations,[2] others focus on market research[3] and drug prices.[4] Reyes, et al (2011) conducted a profiling exercise but did not comprehensively examine the value chain as well as the policy issues. This study bridges the gap by examining the structure of the value chain and market segments, trade, key players, employment, drug price trends, extent of (non)concentration, regulation, and more importantly the key challenges and opportunities with an ultimate objective of drawing insights to aid in the policy-making process. It seeks to answer the following questions:

1. How is the Philippine pharmaceutical sector doing in terms of trade and domestic sales?
2. What is the extent of market (non) concentration?
3. Are there challenges in the supply and distribution of affordable generics?
4. What are the key trends in terms of pricing?
5. Are there regulatory bottlenecks? What are the barriers to entry in this business?
6. What are the aspects that require urgent attention in the achievement of adequate and efficient supply of QSE medicines?

Section 2 discusses the data and methodology used for this study. This is followed by Section 3, the main text of the report which is the profile of the Philippine pharmaceutical industry. Section 4 looks at some trends in drug prices, followed by the regulation of the industry in Section 5, and the issues and challenges in Section 6. Lastly, Section 7 provides insights for policy and areas for further research.

2. Data and Methodology

This analysis gathered sales data from the IQVIA Philippines, a human health market research organization, to help draw clearer understanding of pharmaceutical market performance and segmentation. The IQVIA sales data were disaggregated by name of corporation, name of manufacturer, type of manufacturer (i.e. local or multi-national), therapeutic category, channel (i.e. retail or hospital), license type (i.e. originator, branded generic, and unbranded generic), and ethical status (prescription drug, over-the-counter). This study also utilized the raw data on drug registration from the Food and Drug Administration (FDA) as these could provide information with regards to the number of registered drug units based the country of origin, an estimate of the proportion of imported drug products, and pharmaceutical manufacturers, traders, and distributors. Meanwhile, trade data of pharmaceuticals came from the UN-COMTRADE and UNCTAD.

For other information such as number of pharmaceutical establishments, employment level, production workforce, investments on research and development, assets, among others, this study utilized the 2006 and 2012 Census of Philippine Business and Industry (CPBI) conducted by the Philippine Statistics Authority (PSA). The focus of the analyses using the CPBI[5] are the following 2009 (1994) PSIC codes: 1) C21001 (D24241) or manufacturers of drugs and medicines including biological products such as bacterial and virus vaccines, sera and plasma; 2) G47721 (G52311) or retail sale of drugs and pharmaceutical goods; and 3) G46421 (G51381) or wholesale of medicinal and pharmaceutical products.

The paper also used information from the Securities and Exchange Commission (SEC) to complement the profiling of drug manufacturers, traders, and distributors. For the trends on prices, the study used data from MIMS Philippines, Department of Health's Drug Price Watch database (Electronic Drug Price Monitoring System), and other online pharmaceutical platforms like muramed.com, and Rose Pharmacy website. The Family Income and Expenditure Survey (FIES) from the Philippine Statistics Authority (PSA), which has information on household expenditure of medical care including drugs and medicine, was likewise used as reference for the demand for medicines. In addition, IQVIA and MIMS Philippines provided information on the backward (manufacturing) and forward (distribution) linkages among pharmaceutical companies. To be able to examine and obtain data relating to the issues and challenges, the authors interviewed key informants from the industry such as industry association leaders, and representatives of drug manufacturers, traders, retailers, private hospitals, testing laboratories, and the regulatory agency, among others.

For the purpose of this study, the following technical definitions were used:

1. "Drug establishment" is defined as a "sole proprietorship, partnership, corporation, institution, association and organization engaged in the manufacture/repacking, distribution, importation, exportation, sale, offer for sale, donation, transfer, use, testing, promotion, advertising, or sponsorship of drug product including the facilities and installations needed for its activities."

2. "License to operate (LTO)" is an authorization or permission embodied in a document that it grants to any natural or juridical person engaged in manufacture, distribution, importation, exportation, sale, offer for sale, testing and transfer of drug products.

3. "Generic drug" is a drug product which has the same dosage form and identical bioequivalent range with a brand/reference listed drug product, and which contains the same active ingredients content as the original formulation.

Inductive approach was used in this study by first examining patterns and trends from the data, getting the details, and then further narrowing the analysis in areas/segments that are worth examining. The key elements in this profiling exercise are value chain structure, performance of contribution, the dominant industry players, the existing regulations, market segmentation, and linkages among players (Figure 1). This study was conducted prior to 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.

1 Philippine National Health Accounts, Philippine Statistics Authority

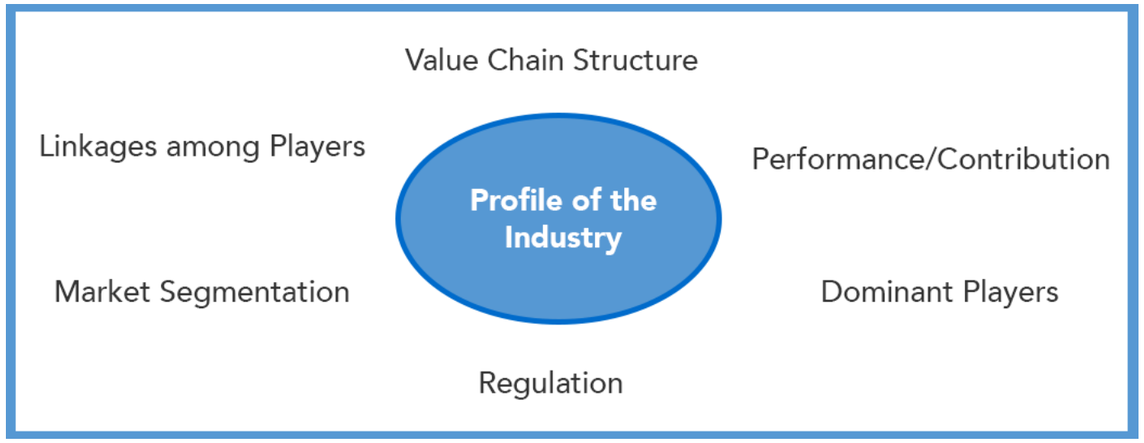
2 See Industry Factbook by the Pharmaceutical & Healthcare Association of the Philippines (PHAP), available at http://www.phap.org.ph/files/downloadables/1_1.pdf Retrieved February 5, 2019

3 Such as those done by marketresearch.com and IMS Health

4 See 1) The Prices People Have to Pay for Medicines in the Philippines by Institute of Philippine Culture, ADMU http://haiweb.org/wp-content/uploads/2015/07/Philippines-Report-2005-Price-Components-Pricing-Surveys.pdf Retrieved February 5, 2019; 2) Haasis, M, A.M. Guerrero, and M. Ladioray. 2015. Developing a Drug Price Reference Index in the Philippines. Journal of Pharmaceutical Policy Practice 8(Suppl 1), p. 7. doi: 10.1186/2052-3211-8-S1-P7, available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4602347/ Retrieved Feb. 5, 2019; and 3) Picazo, O. (n.d.). Review of the Cheaper Medicines Program of the Philippines. Philippine Institute for Development Studies. Available at https://www.dbm.gov.ph/wp-content/uploads/OPCCB/fpb/b_DOH-CheaperMedicines/i-Cheaper%20Medicines%20Program%20Review.pdf Retrieved February 5, 2019

5 Excludes research and development for pharmaceuticals as this is lumped in a general category for research and development (M7210)

Figure 1. Elements of the profiling exercise



3. Profile of the Philippine Pharmaceutical Industry

3.1 Performance

The 2015 data from the Philippine Statistics Authority show that the country's population has reached the 100-million mark. The Philippines is now the 13th most populous country in the world and the 2nd most populated among the ASEAN member states. Such growing population amidst a rapidly developing economy offers a bright market outlook for the Philippine pharmaceutical sector. The pharmaceutical market is currently valued at PhP176 billion based on data from the data science company IQVIA.[6] It is a fast-growing market – expanding faster than the country's national output with its average growth rate of 8.3 percent. Seventy-two percent of the market consists of ethical drugs growing at 6.2 percent per year; the other 28 percent is composed of over-the-counter drugs, growing at a double-digit rate of 12.9 percent. Out of the total market sales of PhP173.076 billion in 2016, 87.2 percent is supplied through retail outlets (i.e. drugstores) while the remaining 12.8 percent go through hospitals. Forty-four percent (or PhP74 billion) of the value of sales is captured by the NCR market, while 28.2 percent (around PhP49 billion) comes from the Luzon market outside of NCR. Mindanao gets 14 percent (PhP24 billion) while Visayas has 13 percent (or PhP23 billion).[7]

Majority of the pharmaceutical products being supplied in the Philippine market is imported. As of July 2018, 62 percent of all registered drugs[8] for Philippine consumption are imported; only 38 percent[9] 'originated' in the country. These estimates are based on authors' calculations using FDA's drug registration data which contain for each drug unit registered, the detailed information like origin, name of manufacturer, importer, and distributor, among others. In comparison, the country produced 53.4 percent of all registered drugs in 2011.[10] These estimates do not account for the fact that key raw materials in the manufacturing/formulation are also imported. Industry players and the Philippines' FDA noted that all the active pharmaceutical ingredients (API) used in the production of medicines and other pharmaceutical products are imported; the only materials locally procured are sugar, which is used as an additive in the formulations, and packaging materials. The proportion of medicines originating from the Philippines also includes those which are merely packed, repacked or labeled in the

6 IQVIA data as of February 6, 2018.

7 See Appendix Figure 3 for the detailed information.

8 Drugs registered with validity expiring end of 2017 up to 2022.

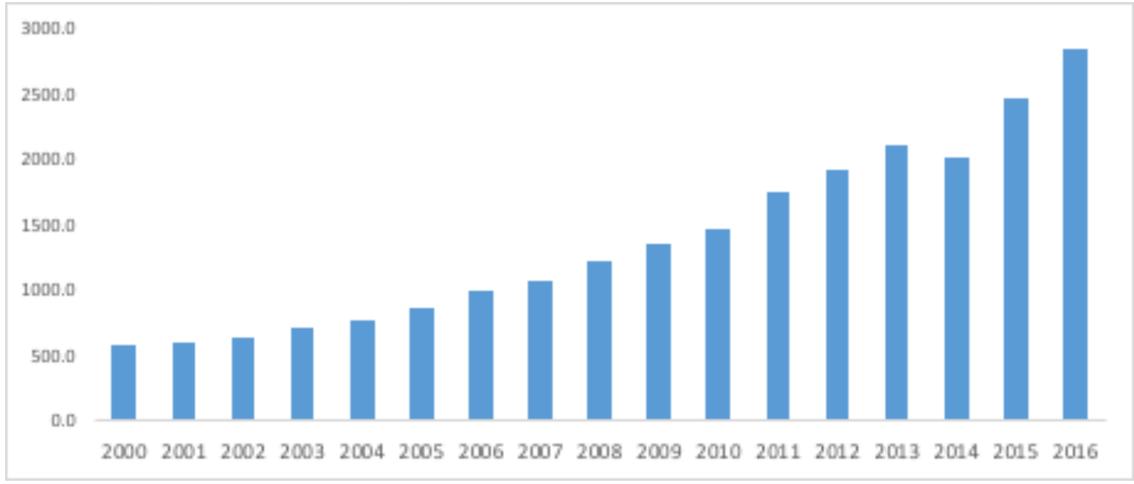
9 Drugs registered with validity expiring end of 2017 up to 2022

10 Drugs with registration validity expiring between 2009 and 2015

country, because such activities are defined by the FDA as 'manufacturing' activity. Therefore, the real proportion of drugs actually formulated and manufactured in the country may be lower.

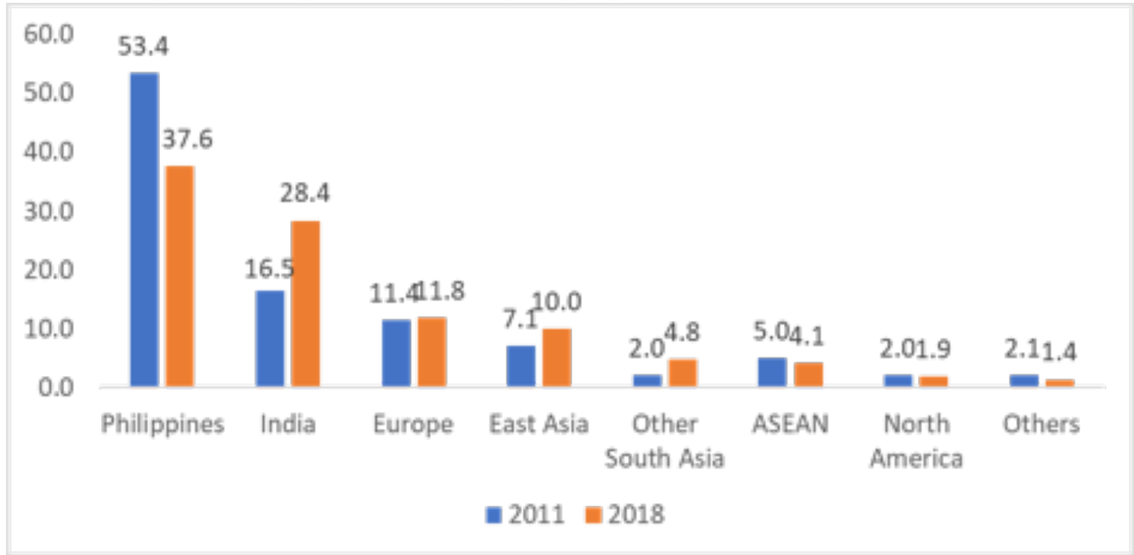
In 2016, total imports reached US$2.8 billion, roughly five times the value in 2000. Import rate is consistently growing by 18.5 percent as of June 2017 based on Philippine Statistics Authority estimates. Medicinal and pharmaceutical products are in fact one of the top 10 imports at US$160.52 million.[11] The country's top 10 sources of imported pharmaceutical products are India, France, Germany, United States, Indonesia, Switzerland, China, United Kingdom, Netherlands and Belgium. India has been the biggest source of pharmaceutical imports, overtaking Germany, since 2015. In 2018, an estimated 28.4 percent of all registered drugs come from India, followed by Europe at around 12 percent, and East Asia at 10 percent. From 2000 to 2016, the compounded annual growth rate (CAGR) of pharmaceutical imports from India is

Figure 2. Imports of medicinal & pharmaceutical products to the Philippines, in US$ million



Source: UNCTAD

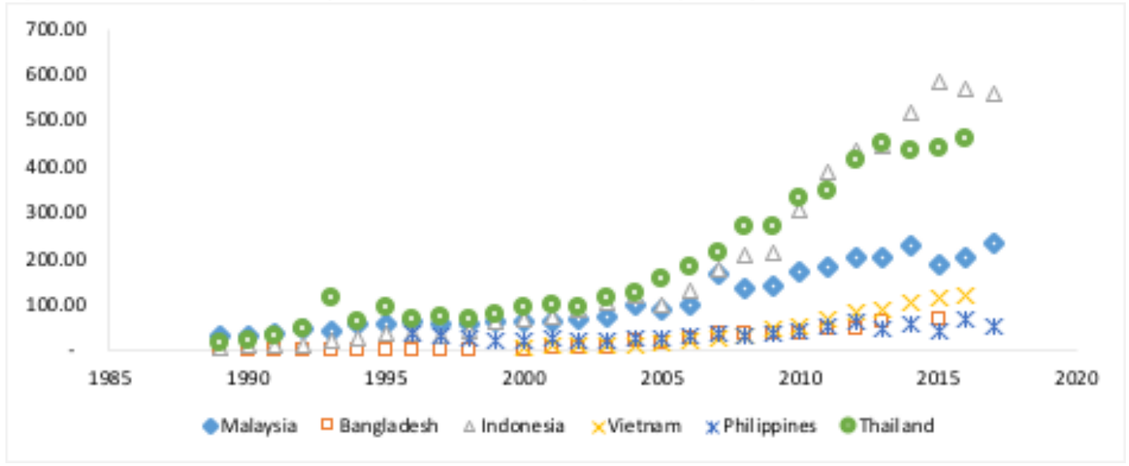
Figure 3. Registered drugs in PH market by origin (percent to total), 2011 & 2018



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

11 Based on June 2017 data

Figure 4. Pharmaceutical exports (US$ millions) by country and year



Source of raw data: UN -COMTRADE

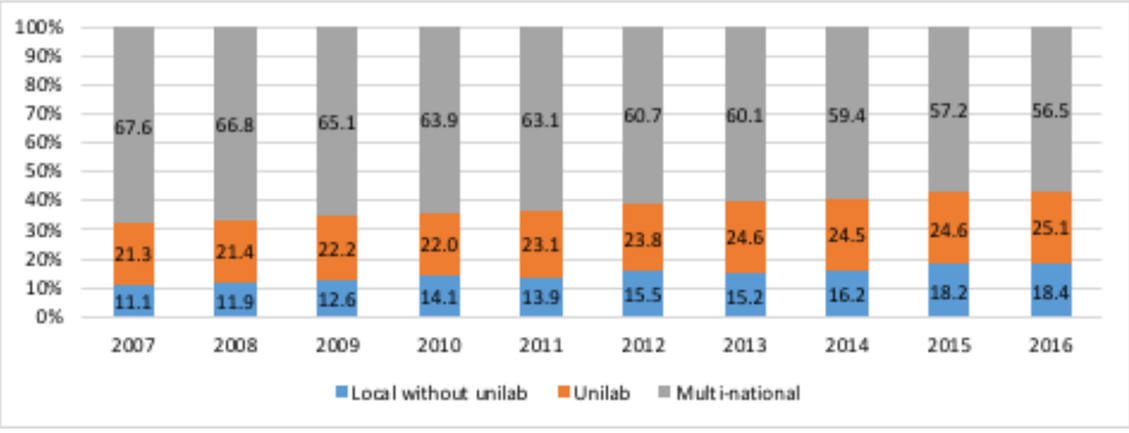
25 percent; 22 percent and 21.5 percent are coming from Indonesia and China, respectively. The CAGR for Germany is around 10 percent, similar to the overall pharmaceutical imports CAGR (10.5%) for the Philippines.[12]

The Philippines' export of pharmaceuticals is very low compared to its imports. In 2017, Philippines' exports value was US$50.6 million. It can be noted that the country was toe-to-toe with Indonesia in 1996, but the latter was able to double its exports in just 5 years. From then on, Indonesia's pharmaceutical exports grew annually at an average of 15 percent while the Philippines' grew only by an average of 4 percent in the comparable period. In 2007, Bangladesh's exports grew faster than the Philippines at 42 percent, while in 2008, Vietnam surpassed Philippines' exports as its export rate grew by 26 percent.

3.2 Segmentation

A significant proportion of pharmaceutical products in the country are supplied by multi-national companies (MNCs) accounting for 56.5 percent of sales value in 2016 (Figure 5). The remaining 43.5 percent was shared by local companies, of which 25.1 percent was captured by the dominant actor – United Laboratories. The share of locals (MNCs) has significantly expanded by 11 percent in the last ten years. The sales of both local companies and MNCs largely come from ethical drugs at 64 and

Figure 5. Total value of sales by type of corporation, Philippines



Source of basic data: IQVIA Philippines

12 See Appendices for the detailed information.

75 percent of total sales, respectively. Sales data from local establishments convey that the share of prescription medicines has increased from 56.5 percent in 2007 to 64.5 percent in 2016, while the share for the MNCs has been relatively stable at 75 percent.

The Philippine domestic 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 Co-trimoxazole is the brand Bactrim by Roche (Table 1). Meanwhile, branded generics, such as Kathrex produced by New Myrex, have the same molecule as the originator. Unbranded generics are those that carry the name of the molecule followed by its manufacturer. RiteMed's Cotrimoxazole is an example. Unbranded generics are sometimes called uni-branded because of the use of just one brand (referring to the maker) for many generic products.

The Philippine market is dominated by the generics sector having 76 percent of the total sales in 2016. Branded generics make the 71 percent and only 5 percent go to unbranded generics. The rest, 24 percent, comes from the sale of originator drugs. In the past decade, the share of branded generics has increased by 4 percentage points while that of the originator went down by around 5 percentage points. The share of unbranded generics has also significantly grown from mere 3.8 percent of the market to 5 percent. There is an increasing role of domestic players in the generics market. The share of local players including that of the biggest player Unilab has doubled from 25 percent to around 57 percent within 2001 to 2016. Interestingly, with Unilab excluded, the share of locals in generics market increased almost 5 times– from 5 to 24 percent within the same period.

Branded generics have the largest market and have grown by an average of 6 percent in the last ten years. In 2016, about 90 percent of the sales made by locals come from branded generic products while around 10 percent are unbranded generics. Local pharmaceutical corporations have very small proportion (i.e., 0.37 percent) of originator products. The supply of unbranded generic drugs is mostly done

Table 1. Examples of varying types of an anti-bacterial drug, Philippines

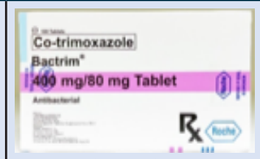
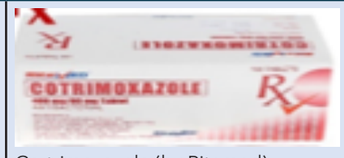
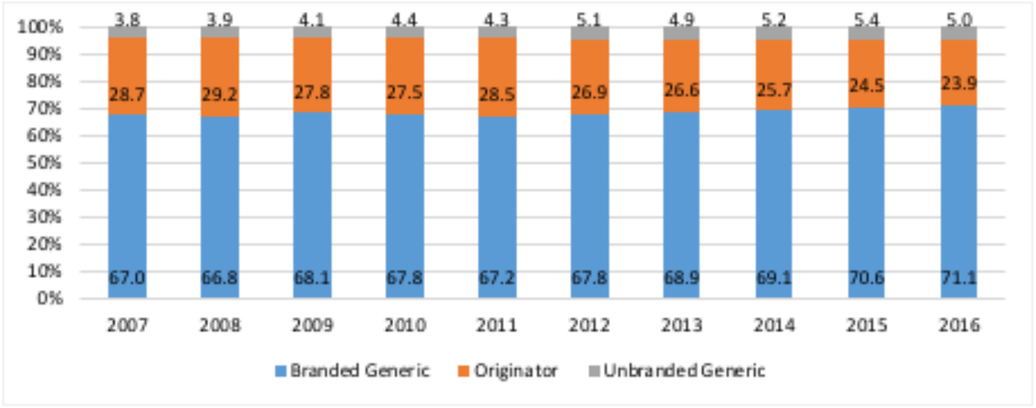
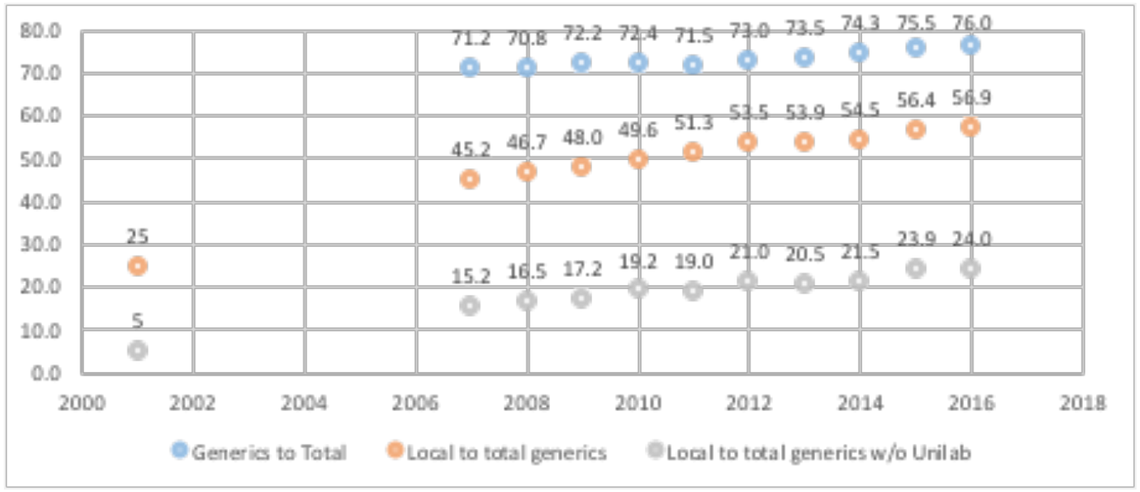
License Type	Definition	Example
ORIGINATOR	Drugs that are first to launch within a single or combined molecule	 Bactrim (by Roche)
BRANDED GENERIC	Brands that have the same molecule as the originator	 Kathrex (by New Myrex)
UNBRANDED GENERIC	Drugs carrying the name of the molecule followed by its manufacturer	 Co-trimoxazole (by Ritemed)

Figure 6. Value of sales by license type, Philippines



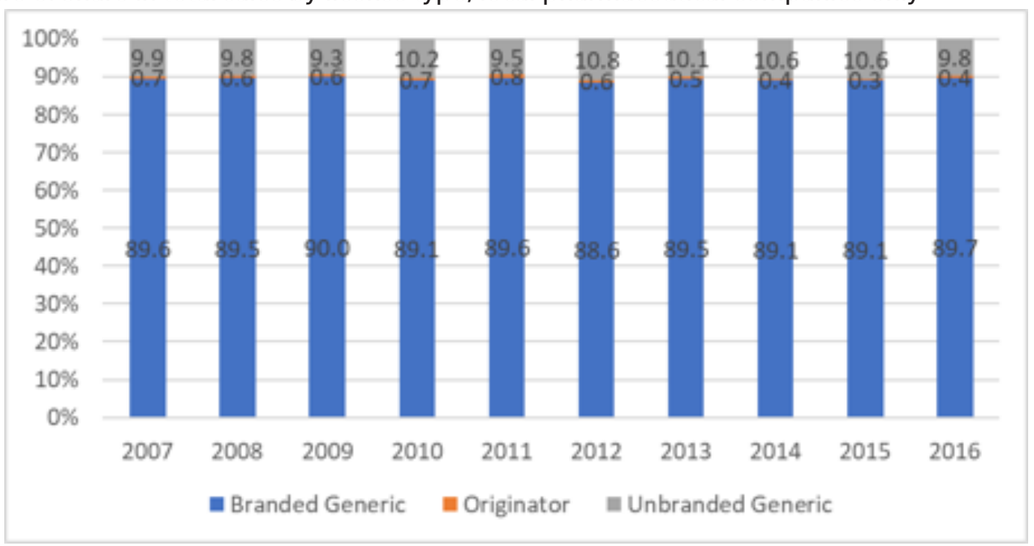
Source of basic data: IQVIA Philippines

Figure 7. Share to total generics market by type of pharmaceutical establishments



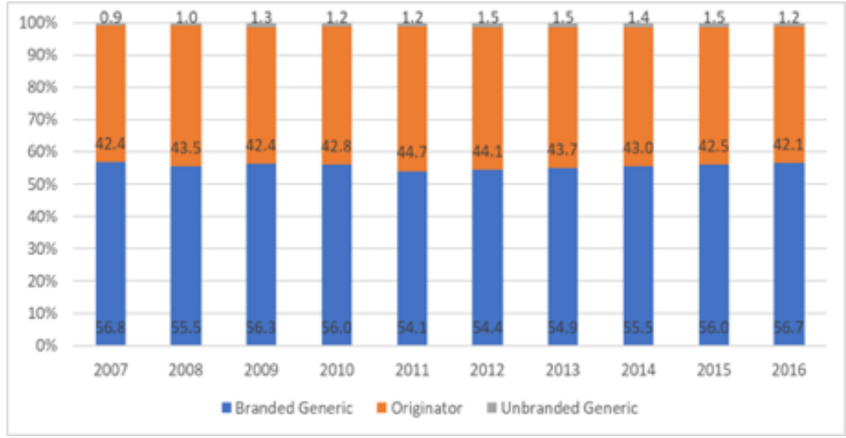
Sources: 2001 – Paper by Kenneth Hartigan-Go; for 2007 onwards, basic data came from IQVIA

Figure 8. Share in total sales by license type, local pharmaceutical companies only



Source of basic data: IQVIA Philippines

Figure 9. Share in total sales by license type, multi-national pharmaceutical companies only



Source of basic data: IQVIA Philippines

by locals with 86 percent of the total sales. Meanwhile, originator drugs and other pharmaceutical products are basically carried by multi-national companies. Nonetheless, multi-nationals also obtain majority (57 percent) of their sales from branded generics; their originator products generate only 42 percent of their revenue. Such has been the case since 2007.

Based on the number of establishments in the IQVIA raw data, there seems to be an increased competition in the market. The number of pharmaceutical companies engaged in the production (manufacturing, importing) of branded generics went up from 460 in 2007 to 557 in 2010 and then to 654 in 2016. The top 20 corporations hold a combined share of 73 percent of the total sales in 2016; back in 2007 the top 20 held 81.2 percent of the total market sales. Meanwhile, the top 50 companies hold a combined share of 88 percent.

The branded generics market is dominated by local corporations with 54 percent market share. The share of United Laboratories, at 31 percent of the total branded generic market, has been relatively stable. On the other hand, the share of the rest of local companies has been increasing through the years at an average of 2.33 percent annually from 2007 to 2016, from only 13 percent in 2007 to 17 percent in 2010, to 23 percent in 2016. In fact, the market captured by locals (excluding Unilab) has been growing at a compounded annual growth rate of 13 percent in the last 10 years. On the other hand, the share of multi-national companies has shrunk from 57 in 2007 to 45 percent

Figure 10. Distribution of branded generic market by type of companies

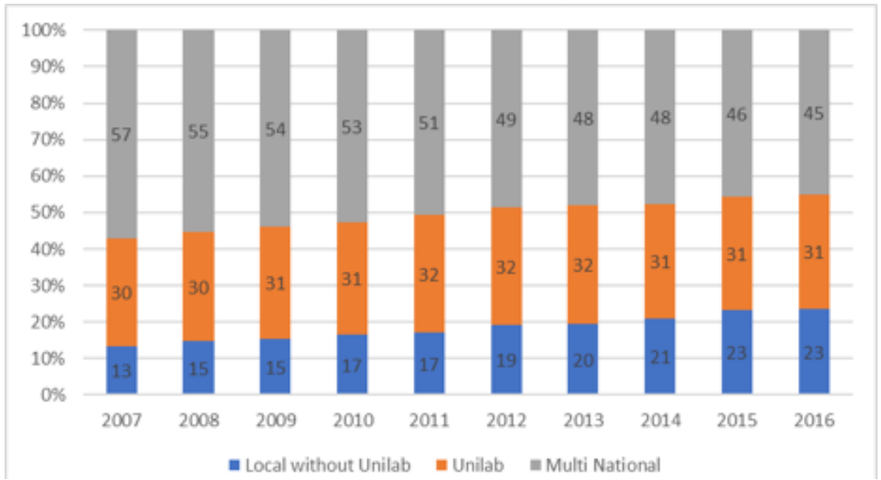
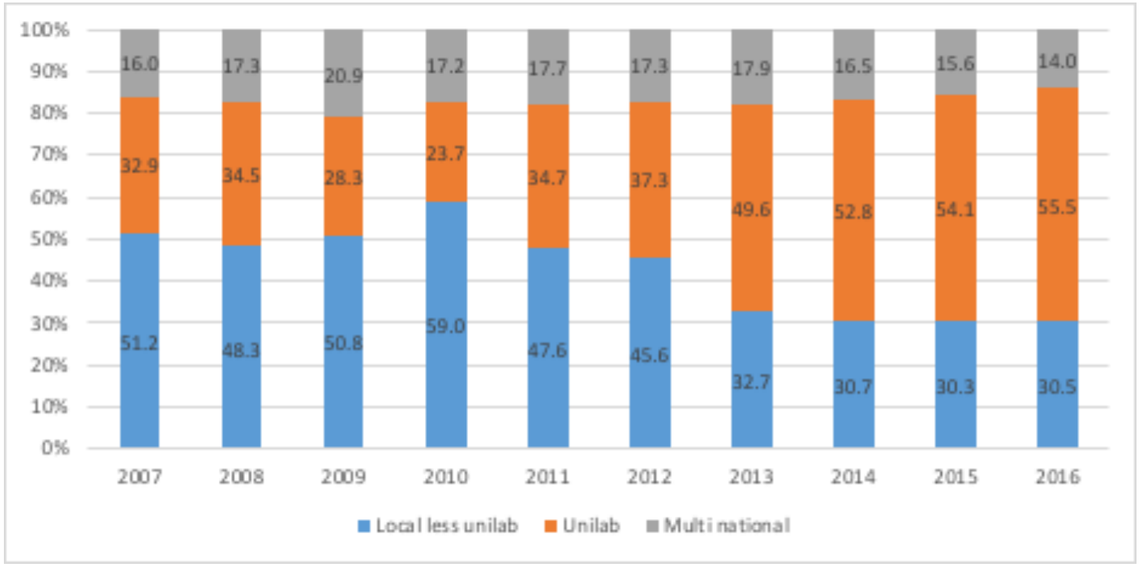


Figure 11. Distribution of unbranded generic market by type of companies



in 2016. Interestingly, even the share of multi-national companies included in the top 20 has gone down. In 2007, the MNCs among the top 20 had a bigger share at 45.4 percent of the total market of branded generics but in 2016 this has been reduced to a lower 33.4 percent. That for the locals in the top 20 has slightly increased from around 36 to 40 percent. Nevertheless, multi-nationals still outnumber locals in the top 20.

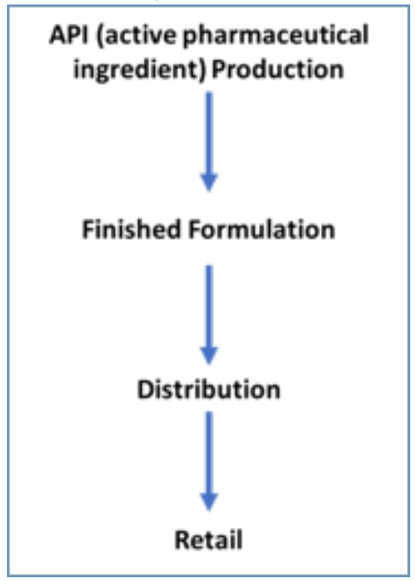
On the other hand, unbranded generic medicines comprise only 5 percent of the total market sales where 89 percent are from the sale of prescription medicines; only 11 percent are made through OTC drugs. The pharmaceutical corporations supplying unbranded generic medicines (i.e. those which have non-zero sales data) have become fewer through the years, from 113 in 2007 to 100 in 2010 to only 78 in 2016. The number of players that dominate the segment is even much lower; the top 20 companies hold 97 percent of the total sales. In 2007, the top 20 companies held a combined share of 95 percent. Local producers have a commanding presence in this segment with a total of 86 percent share while MNCs have only 14 percent.

The dominant player in the unbranded generics segment, United Laboratories, has 55.5 percent share to total sales in 2016. This is high compared to its shares in 2007 and 2010 which are at 32.9 percent and 23.7 percent, respectively. Its leadership has begun in 2013 where it captured 49.6 percent of the total market. During this time, the rest of local producers lost their control as their shares decreased to 32.7 from 45.6 percent in 2012. A closer look at the performance of Unilab shows that the increase was attributed to the rise in the sales of Rite Med (i.e., 43% year-on-year growth in 2012 to 2013). RiteMed is Unilab's key producer of unbranded generics which holds 93 percent of its total sales. Interestingly, in 2016, it has acquired Pharex, the generics unit of its closest competitor - Pascual Laboratories.

3.3 Value Chain & Linkages

The sector's value chain starts with the production of the active pharmaceutical ingredient (API) that is normally done by large-scale production outfits in China, India and some European countries. It entails a chemical process and mostly done in large volumes. These API are utilized by medicine producers in the stage called finished formulation—the heart of the pharmaceutical production process. It is also a phase that is highly regulated. Some research and development are carried out in the finished formulation stage because it is at this phase where the active pharmaceutical ingredients are mixed with other materials to produce biosimilars. From finished formulation, the next stage is distribution followed by trade which is mostly retail (Figure 12).

Figure 12. The value chain in pharmaceutical industry



Source: Key Informant Interviews (KII)

3.3.1. Production

The production stage entails importation, production of finished formulation including R&D, and packing/repacking/labelling. Some companies do finished formulation along with the different pre-production procurement and tests, while some carry out packing/re-packing only of imported finished products. This study attempts to distinguish these different types.[13] One is the multinational-importer type which imports products from its regional production hub and gets the service of local manufacturer for packing/repacking/labelling. Such services are necessary because of the Philippines' FDA requirement of imprinting in each tablet/capsule the expiry date of the medicines. Some MNCs also use local toll manufacturers for the production of their formulations but the MNC is the marketing authorization holder (MAH). Another type of producer is the toll manufacturer which simply manufactures for a trader using the trader's own formulation; the trader holds the marketing authorization and takes care of registration requirements. A third type is the manufacturer-formulator which formulates its own product, procures own materials, conducts R&D for formulation, and manufactures (including packing and labeling) for itself and for other partner-traders. Manufacturer-formulators are locally-owned establishments that usually conduct or invest in pre-production R&D, have their products undergo tests like the bioequivalence/bioavailability test and/or bio-waiver test, and apply for drug registration. One key informant noted that at the minimum, the initial investment to cover only the physical infrastructure in putting up a manufacturing facility is not lower than US$6 million while the minimum period for training a manufacturing personnel (i.e. chemist) is six months. The fourth type is the purely importer-trader which conducts importation and is responsible for drug registration application of the foreign product. Lastly, there is also an importer/re-packer which imports finished products in bulk, then conducts re-packing/re-labelling.

There are no official estimates as to the number of manufacturers by type because FDA does not distinguish the types of manufacturers. Also, the total number of drug manufacturers per year could not be determined as it has not been provided by the FDA. Although the FDA defines a drug manufacturer as an establishment engaged in any or all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling for purposes of storage, sale or distribution, the term does not apply to the compounding and filling of prescription in drugstores and hospital pharmacies. However, a trader is also categorized as a manufacturer. In Section VI of DOH Administrative Order No. 2014-0034, a manufacturer-trader refers to "any establishment which is a registered owner of a drug product and formulation, and

13 This listing may be not exhaustive.

Table 2. Number of pharmaceutical manufacturing establishments by region and type

Region	With total employment of 20 and over		With total employment less than 20		All types	
	2006	2012	2006	2012	2006	2012
13 – NCR	25	16	3	4	28	20
3 – Central Luzon	10	10	1	3	11	13
4A - CALABARZON	17	18	0	4	17	22
6 – Western Visayas	-	2	-	1	-	3
7 – Central Visayas	3	4	0	3	3	7
10 – Northern Mindanao	-	2	-	1	-	3
11 – Davao	-	2	-	1	-	3
Total	55	54	5	17	60	71

Source: 2006 and 2012 CPBI, PSA

procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or exportation in wholesale of its own drug products and importation of raw materials for the production by its contract manufacturer. In cases where the contract manufacturer procures the raw materials and packing components, a quality agreement must be provided."

In the absence of official data, the crude estimate of the total number of drug manufacturers (i.e. human drugs) in the country as of 2018, based on FDA drug registration data, is 109. This figure, which includes manufacturers of medicinal gases, cosmetic products, and herbal supplements, is almost one-third of the number in 2010-2011 of around 280 establishments. These estimates lump the manufacturer-formulator, toll manufacturers, and packers/re-packers/labelers. An informant from the Philippine Pharmaceutical Manufacturers' Association (PPMA) put the current number of licensed drug manufacturers at 46, only a small fraction of some 126 manufacturers-formulators that exist a decade ago. In terms of importers, the authors' estimates based on the FDA raw data of drug registration, there are some 500 establishments doing drug importation.

The PPMA estimate of drug manufacturers is quite near the estimate based on the 2012 Census of Philippine Business and Industry (CPBI) conducted by the Philippine Statistics Authority (PSA). The data show that the total number of manufacturing establishments regardless of size went up from 60 in 2006 to 71 in 2012. Of the 71, 54 have total employment of 20 persons and above, roughly similar to 2006 estimate of 55 comparable establishments. Fifty-nine percent (42 of 71) of the establishments are in CALABARZON and NCR. The rest are in Central Luzon (13), Central Visayas (7), Western Visayas (3), Northern Mindanao (3) and Davao (3). Between 2006 and 2012, manufacturing establishments were created in some regions outside of Luzon namely – Western Visayas, Northern Mindanao, and Davao.

This section discusses the profile and contributions of drug manufacturers with total employment of 20 and over. In 2012, the pharmaceutical manufacturing sector employs 11,514 employees or an average of 213 per establishment. This is 23 percent lower than the total employment in 2006 at 14,916 or 271 per establishment. There are slightly more male employees, at 54 percent of the total, than female ones. Meanwhile, the sector employs on the average 109 production workers per establishment, or a total of 5,876, which is 4 percent lower than total production employment at 6,123 in 2006. Around 5 in every 10 production workers are in CALABARZON, around 24 percent are in NCR, 14 percent in Central

Table 3. Number of employed in pharmaceutical manufacturing establishments with total employment of 20 and over by region and sex

Region	Total						Average					
	2006			2012			2006			2012		
	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total
Employment												
13 - NCR	2,703	1,736	4,439	1,833	2,140	3,973	108	69	178	115	134	248
3 - Central Luzon	2,302	1,322	3,624	682	518	1,200	230	132	362	68	52	120
4A - CALABARZON	2,336	2,127	4,463	2,564	2,030	4,594	137	125	263	142	113	255
6 - Western Visayas				64	101	165				32	51	83
7 - Central Visayas	1,863	527	2,390	843	320	1,163	621	176	797	211	80	291
10 - Northern Mindanao				186	30	216				93	15	108
11 - Davao				74	129	203				37	65	102
Total	9,204	5,712	14,916	6,246	5,268	11,514	167	104	271	116	98	213
Paid employees												
13 - NCR	2,699	1,730	4,429	1,831	2,137	3,968	108	69	177	114	134	248
3 - Central Luzon	2,302	1,322	3,624	682	518	1,200	230	132	362	68	52	120
4A - CALABARZON	2,325	2,066	4,391	2,564	2,030	4,594	137	122	258	142	113	255
6 - Western Visayas				64	101	165				32	51	83
7 - Central Visayas	1,863	527	2,390	843	320	1,163	621	176	797	211	80	291
10 - Northern Mindanao				186	30	216				93	15	108
11 - Davao				74	129	203				37	65	102
Total	9,189	5,645	14,834	6,244	5,265	11,509	167	103	270	116	98	213
Unpaid employees												
13 - NCR	4	6	10	2	3	5	0.2	0.2	0.4	1	1.5	2.5
3 - Central Luzon	0	0	0	0	0	0	0.0	0.0	0.0	0	0	0
4A - CALABARZON	11	61	72	0	0	0	0.7	3.6	4.2	0	0	0
6 - Western Visayas				0	0	0				0	0	0
7 - Central Visayas	0	0	0	0	0	0	0.0	0.0	0.0	0	0	0
10 - Northern Mindanao				0	0	0				0	0	0
11 - Davao				0	0	0				0	0	0
Total	15	67	82	2	3	5	0.3	1.2	1.5	0.15	0.25	0.38

Source of basic data: CPBI 2006 & 2012, PSA

Table 4. Number of production workers in pharmaceutical manufacturing establishments with total employment of 20 and over by region and sex

Region	2006			2012		
	Male	Female	Total	Male	Female	Total
13 - NCR	122	568	1,525	922	480	1,402
3 - Central Luzon	591	228	819	481	319	800
4A - CALABARZON	700	1,412	3,079	1,653	1,148	2,801
6 - Western Visayas				23	5	28
7 - Central Visayas	578	122	700	499	80	579
10 - Northern Mindanao				178	25	203
11 - Davao				43	20	63
Total	3,793	2,330	6,123	3,799	2,077	5,876
	Average					
13 - NCR	38	23	61	58	30	88
3 - Central Luzon	59	23	82	48	32	80
4A - CALABARZON	98	83	181	92	68	156
6 - Western Visayas				12	2.5	14
7 - Central Visayas	193	41	233	125	20	145
10 - Northern Mindanao				89	13	102
11 - Davao				22	10	32
Total	69	42	111	70	39	109

Source of basic data: CPBI 2006 & 2012, PSA

Luzon, and the remaining 15 percent are located outside of Luzon.

A total of 15.7 million hours of work by production workers was recorded. Forty-five percent of which pertains to those working in CALABARZON. Production workers are defined in the CPBI as workers directly engaged in the production process including working foremen. These exclude apprentices and other learners receiving regular pay or not directly engaged in production process; managers, executives, administrative and technical personnel above foreman level; accounting and personnel staff, and unpaid production workers.

In terms of gross wages and salaries per worker, the sector of drug manufacturers contributes a total of PhP7.2 billion or PhP624,500 per worker in 2012. Gross wages and salaries refer to payments in cash or in kind prior to any deductions for employee's contributions to SSS/GSIS, withholding tax, etc.[14] It excludes cost of uniform/working clothes, reimbursable transportation and representation allowances. Meanwhile, the estimate for total employers' contribution to social security[15] in 2012 is PhP599.8 million or 42 percent higher than in 2006 (PhP422 million). In total, the contribution of the sector in terms of employees' compensation is PhP7.791 billion, 56 percent higher than in 2006 (PhP5 billion).

Manufacturing establishments with total assets amounting to PhP74.4 billion gained a total of PhP67 billion in 2012; 69 percent of this comes from its biggest market – the NCR. Of the 54 establishments with employment 20 and over, 61 percent are operating at a capacity utilization rate of 70 and above; 22 percent of these have an average capacity utilization rate of 50 to 69 percent. The rest (17%) are operating below 50 percent utilization. The manufacturing sector contributed at least PhP5 billion pesos in taxes in 2012.

Changes relating to the operations of establishments that were present in both the 2006 and 2012 rounds have been noted to analyze trends in order to define the dynamic nature of the sector. For instance, between 2006 and 2012, some 25 establishments, or almost half of the total number, may have ceased to operate[16] while some 24 establishments were created (Figure 13).

Out of the 24 manufacturing outfits established during the said period, 13 are from Central Luzon and CALABARZON, some 4 were established in NCR, 2 each in Western Visayas, Northern Mindanao, and Davao, and 1 in Central Visayas. There are 2,346 employees in these new establishments including 1,545 production workers and 47 R&D personnel. On the other hand, of the 25 manufacturing establishments that may have ceased operation during the period and were no longer counted in the 2012 census, the majority were from the NCR, and the rest (48 percent) were from Central Luzon and CALABARZON regions. These 25 establishments comprise of 4,085 employees including 1,317 production workers.

There are only 30 establishments which were present in both 2006 and 2012 Censuses. In these 30 manufacturing outfits, the change in number of employed workers ranges from a reduction of 1,254 to an increment of 140, or a net decrease of 1,663 workers, which is the outcome of a loss of 1,802 male workers and an increment of 139 female workers. The establishments which have experienced growth in the level of employment were mostly smaller establishments while those which had reduced their workforce were mostly larger companies (Figure 13), resulting to a net decrease in workforce.

14 These include total basic pay, overtime pay, vacation, sick and maternity leave pay, bonuses, food, housing and cost of living allowances, commissions paid for salaried employees, commutable transportation and representation allowances, separation, retirement/terminal pay; gratuities, etc.
15 Refers to contributions to SSS/GSIS, Employees Compensation Commission, PhilHealth, PAG-IBIG, etc.
16 Establishments no longer in the CPBI means that they may have ceased to operate. However, it is possible that these may have re-registered under different names or addresses.

It seems that bigger companies have downsized in response to the challenges in the market. The new entrants may consist of packaging/re-packaging while those that have shut down may pertain to more capital-intensive manufacturing outfits that have greater number of workers given the scale of their operations. While such argument is not supported by solid empirical data, it is consistent with the reports from

Figure 13. Number of drug manufacturing establishments included in the CPBI 2006 and 2012

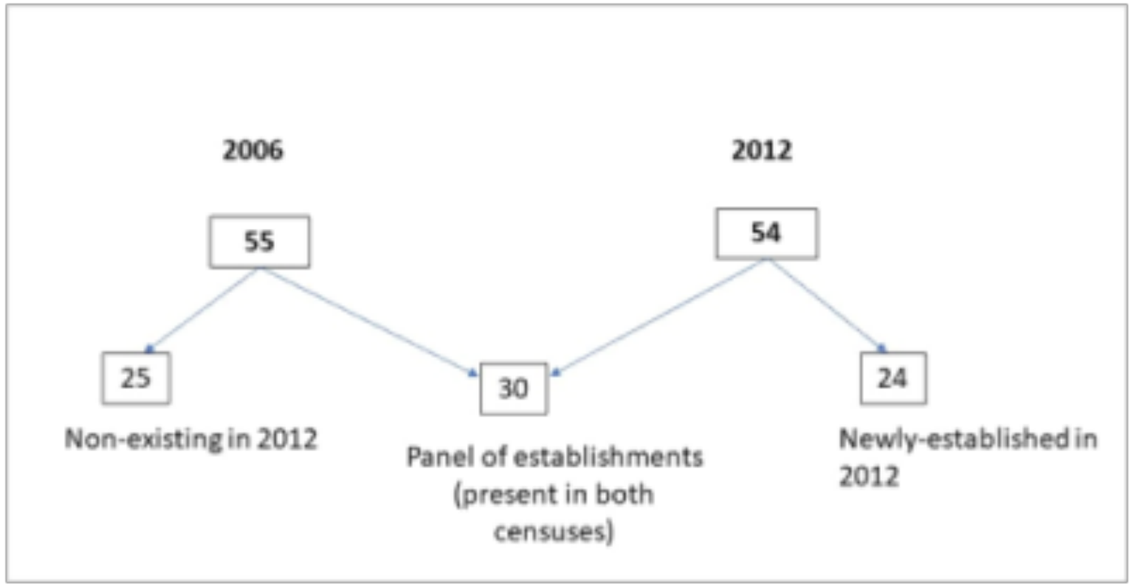
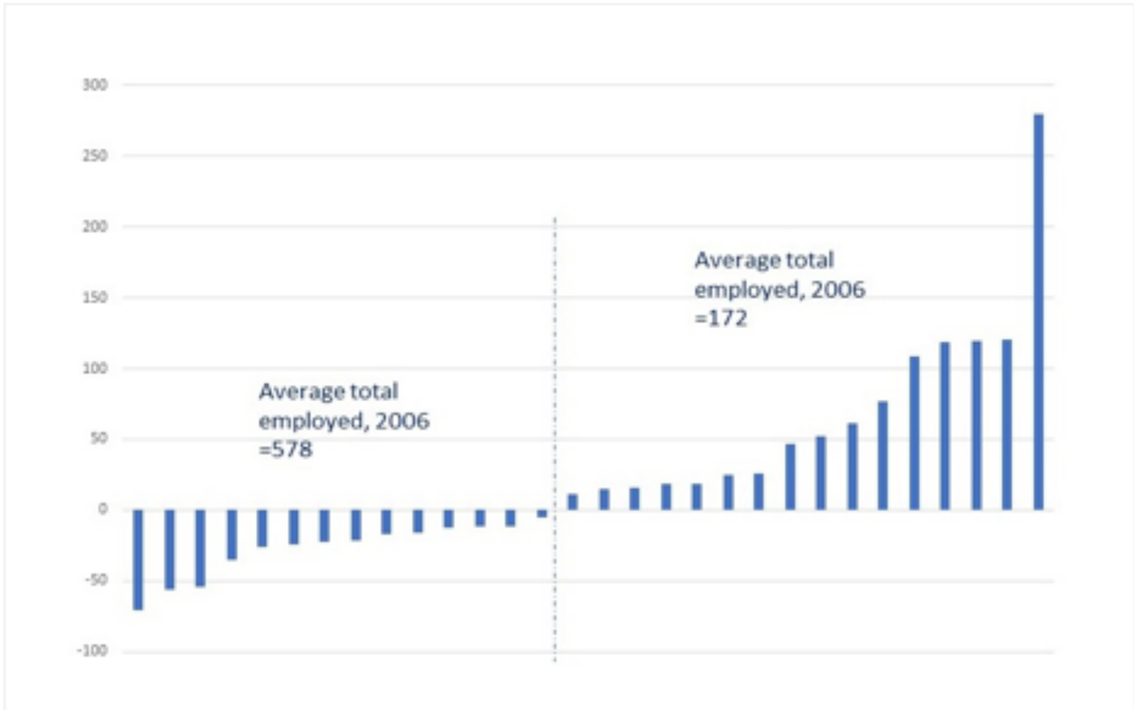


Figure 14. Percent change in the total workers employed by drug manufacturers between 2006 and 2012 (n=30)



industry stakeholders stating that some pharmaceutical local manufacturing facilities have already shut down as these could not compete with cheaper imported medicines.

3.3.2. Distribution

Local companies distribute their products through their divisions, subsidiaries, or other local distributors, while almost all multi-nationals use Zuellig as their distributor. Zuellig has 99.99%[17] foreign investment paid up capital and manpower complement of 1,800. Zuellig is the second largest company after United Laboratories in terms of assets (i.e. PhP22.4 billion) and profits at PhP753 million, next to Unilab and Pfizer.[18]

Official data describing the number of drug distributors is not available at the FDA website, so the FDA uses the DOH Administrative Order No. 2014-0034 as reference for the following:

1. Drug distributor-exporter – any establishment that exports raw materials, active ingredients and finished products for distribution to other drug establishments outside the country

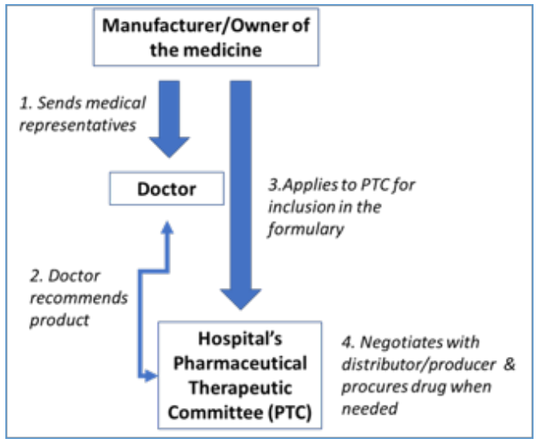
2. Drug distributor-importer – any establishment that imports raw materials, active ingredients and/or finished products for wholesale distribution to other local FDA-licensed drug establishment

3. Drug distributor-wholesaler – any establishment that procures raw materials, active ingredients and/or finished products from a local FDA-licensed drug establishment for local distribution on wholesale basis.

3.3.3. Distribution through hospitals

Hospitals distribute 13 percent of the pharmaceutical products while drugstores distribute the bulk.[19] Information from key informants are used to examine how private hospitals decide on the list of medicines that go into their formulary. The formulary is created by a body within the hospital called the Pharmaceutical Therapeutic Committee (PTC). The PTC is composed of hospital's chairman, medical director, supply chain manager/purchaser, doctors, and pharmacist. The rule of thumb is that there should always be an innovator drug combined with two to three generic counterparts. The hospital doctors make the crucial recommendation to the PTC. Although marketing strategies of the manufacturers through their medical representatives greatly influence the approval of the generic brands for the formulary. The manufacturer/producer of the drug applies for inclusion in the hospital's formulary upon approval of the concerned doctor. Negotiation with the distributors like Zuellig and Metro Drug, as well as with individual principals like United Laboratories and Natrapharm happens after the approval by the PTC.

Figure 15. How private hospitals select medicines for their formulary



Source: KII

Figure 15 shows that only the 'promoted' products penetrate the formulary of private hospitals. Registered generic products, which may be more affordable, but are not promoted or those which are supplied by producers that do not have marketing capacity (i.e., cannot afford to pay for the services of medical representatives) are therefore unable to penetrate private hospitals.

17 See Appendix Table 5
18 FDA has not provided the official figures of industry players.
19 IQVIA Philippines

Table 5. DOH's winning bidders in direct negotiation

YEAR	MODE OF PROCUREMENT DIRECT CONTRACTING	PROJECT	WINNING BIDDER
2015	DC No. 2015-021	Human Recombinant Tissue Type Plasminogen Activator (Alteplase)	Metro Drug Inc. Joint Venture with Interpharma Holdings and Management Corp.
2014	DC No. 007-2014	Azithromycin as Dihydrate 500mg (Pack of 3)	Pfizer, Inc. -Philippines
2014	DC No. 2014-006	Azithromycin 500mg	Zuellig Pharma Corporation
2013	DC No. 2013-015	Troclosene Sodium 67mg	Barr-Xsel Pharma Trading
2013	DC No. 2013-017	Survantant (Beractant)	Zuellig Pharma Corporation

Source: DOH

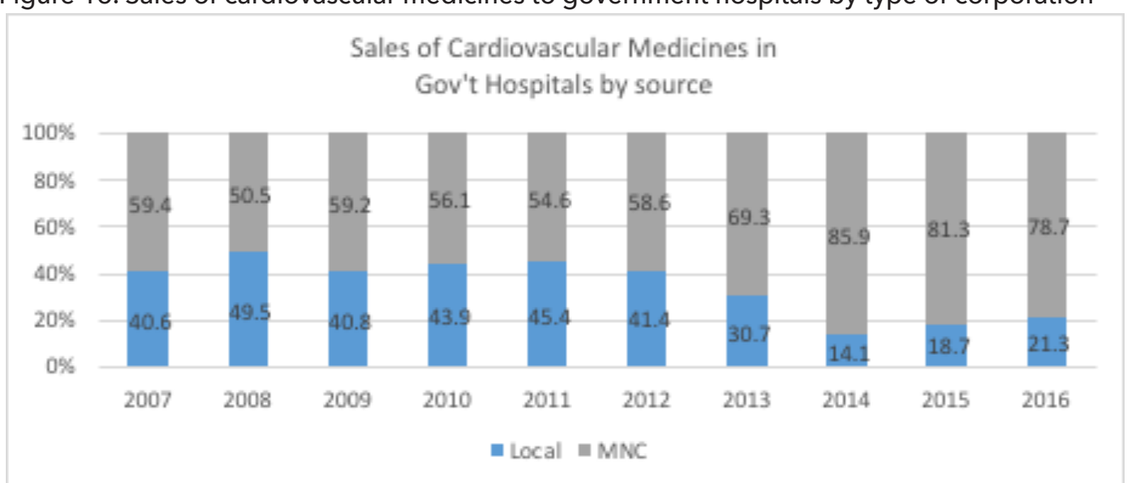
On 01 March 2018, a directive from the Philippine Health Insurance Corporation (PhilHealth) made it mandatory that only the drugs listed in Philippine National Drug Formulary as per Section 37 of Republic Act 7875 as amended by RA 9241 and RA 10606 shall be paid for claims reimbursement and performance monitoring hospital admissions.

Procurement in the government only allows medicines in the PNDF. Data from the DOH implies that government bidding is participated by big companies such as Zuellig, Metro Drug, and Pfizer, who mainly supply Azithromycin, Beractant, and Troclosene sodium (Table 5). Additionally, the United Laboratories, which has not participated in public bidding for twenty-five years recently joined for anti-tuberculosis medicine supply.

3.3.4. Distribution through drugstores

Drugstore/pharmacy/botica, including hospital pharmacy and institutional pharmacy is defined as "drug establishment where registered drugs, chemical products, dental, medicinal and household remedies are dispensed directly to the general public on a retail basis.[20] Botika ng Barangay and its variants that sell the same shall be reclassified and required to secure LTO as a drugstore.

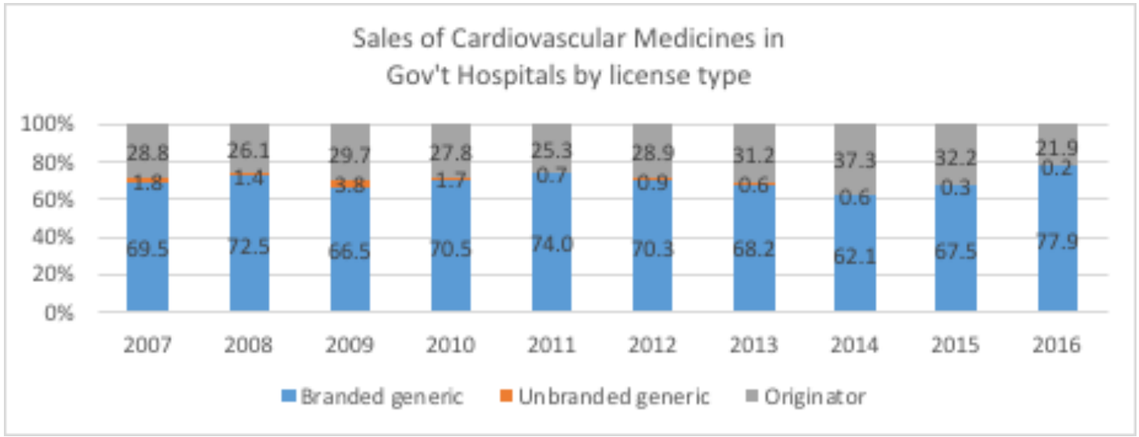
Figure 16. Sales of cardiovascular medicines to government hospitals by type of corporation



Source of basic data: IQVIA Philippines

20 Administrative Order No. 2014-0034

Figure 17. Sales of cardiovascular medicines to government hospitals by license type



Source of basic data: IQVIA Philippines

Before the products reach the drug stores, the process starts with the producer (manufacturer or importer) who markets/ promotes its products (e.g. new molecule) to the retailer and provides relevant drug-related information including costs. The retailer would then decide whether to sell it or not.

Despite having its own label, a retailer also accepts other generic brands into its store. It also acquires medicines with patents that are not about to expire yet. However, it carries only a handful of such medicines in store. On the other hand, the medicines that carry their own label are sold only in their branches nationwide. It was also found that a retailer conducts distribution and retail and does not import or produce/manufacture its own products. It does not have license to manufacture or import. Its partner, either a multi-national importer or local manufacturer, procures or produces the product and delivers it, in its final packaging complete with labels and logo, to the retailer. The retailer would then distribute its products to its branches or franchises all over the country.

3.3.5. Wholesale and retail trade

Figures gathered from the 2012 Census of Philippine Business and Industry (CPBI) show that there are 7,022 traders in 2012. There are 6,068 that operate at the retail level while 954 are wholesalers. Three out of 10 traders are in the National Capital Region, while 18 percent are in CALABARZON. Majority or 65 percent of traders are in Luzon, 17 percent are in Visayas, and around 18 percent are in Mindanao. In terms of employment, the sector of pharmaceutical traders contributes around 49,000 in total employment. Interestingly, 76 percent of the total, are women. In terms of total compensation, traders pay PhP9.4 million while at least PhP986 million goes to taxes.

The following data does not describe the whole picture of the wholesale and trade sector. Further study of the lead players is needed to provide gainful insights.

The above empirical data does not provide a clear picture of the state of competition in the wholesale and retail trade sector. A close look at the market's leaders, particularly of the retail sector, may provide some insights. In the past, there was only one dominant retailer – Mercury Drug, and there were numerous small actors. At present, Mercury Drug still dominates with its 1,100 branches nationwide but the entry of chain drugstores like The Generics Pharmacy (TGP), Watsons, South Star Drug, Generika, and even MedExpress can be considered a game-changer.

TGP is now the biggest chain drugstore in the country with its 2,000 branches nationwide. Started as an importer and wholesaler of medicine, Pacific Insular Co. – the precursor of TGP was established in

Table 6. Estimated number of wholesale and retail traders of pharmaceutical products by region, 2012

Region	Wholesale	Retail	Total
Total	954	6,068	7,022
13 - NCR	512	1,430	1,942
14 - CAR	0	84	84
1 - Ilocos	26	424	450
2 - Cagayan Valley	5	163	168
3 - Central Luzon	36	404	440
4A - CLABARZON	49	1,224	1,273
4B - MIMAROPA	3	11	13
5 - Bicol	38	147	185
6 - Western Visayas	6	339	345
7 - Central Visayas	139	614	753
8 - Eastern Visayas	22	110	132
9 - Zamboanga Peninsula	18	146	165
10 - Northern Mindanao	18	199	217
11 - Davao	63	520	583
12 - SOCCKSARGEN	0	157	157
16 - CARAGA	20	78	98
15 - ARMM	0	18	18

Source of basic data: PSA CPBI 2012

Table 7. Estimated number of employees in wholesale and retail trade of pharmaceutical products, 2012

Employee	Wholesale			Retail		
	Male	Female	Total	Male	Female	Total
Paid Employees	12,121	13,050	25,171	10,891	36,452	47,343
Unpaid Workers	28	27	55	591	1,004	1,595
Total Employment	12,150	13,077	25,227	11,482	37,456	48,938

Source of basic data: PSA CPBI 2012

1949. Recognizing the need for affordable quality medicines, TGP shifted its focus on generic medicines in 1983. The company first ventured into retail in 2001 and set up what is now known as TGP with only one branch and opened its first franchise only in 2007. In 2012, it reached its target of 1,400 outlets making itself the biggest drugstore chain in the country. In 2016, TGP partnered with Robinsons Retail Holdings.

Another generic-focused retailer – Generika Drugstore was established in 2004 and was opened for franchising only in 2008. In 2015, Ayala Corporation acquired 50 percent of Generika through AC Health. Ayala's business expertise, Generika is "poised to become bigger in the pharmaceutical retail space."[21] Presently, Generika has less than 200 branches nationwide.

Meanwhile, Henry Sy's Watsons has more than 623 stores.[22] The partnership between SM Prime Holdings Inc. and Hong Kong-based A.S. Watsons began in 2002. Watsons now operates in SM malls nationwide. On the other hand, Robinson's South Star has now nearly 400 stores.[23] Prior to its

21 https://www.generika.com.ph/page/about Retrieved August 22, 2018
22 https://www.watsons.com.ph/company-information Retrieved August 22, 2018
23 https://www.southstardrug.com.ph/about-us Retrieved August 22, 2018

partnership with Robinsons Retail Group in 2012, South Star was already a growing company. From being a Chinese herbal pharmacy in the quiet town of Naga in 1937, then Southern Drug expanded to other parts of Bicol and started offering Western Medicine in the 50's and became new South Star Drug. Between 2010 and 2011, it further expanded to Visayas and Central Luzon. South Star also celebrated its 75th anniversary as it entered into a partnership with Robinsons Retail in 2012. It is the longest-established drugstore chain in the country.

It can be inferred from the above discussions that new players were able to penetrate the retail market despite its biggest player, Mercury Drug by partnering with retail giants like SM, Robinsons and Ayala.

MedExpress claims to be the first and only 3-in-1 service drugstore in the country since its establishment in 2005. Information from its official website provides that patients can walk into their branches to buy medicines, drive-thru to pick up the medicines, or call for a delivery. MedExpress has been managing the clinic pharmacy of PLDT nationwide since 2006 and San Miguel Corporation since 2007 while serving the medicine requirement of over 150 companies.[24] MedExpress now partners with 30 key hospitals nationwide – including Makati Medical Center, St. Luke's Medical Center, Chinese General Hospital and Medical Center, Capitol Medical Center, Manila Doctors, and De La Salle University Medical Center, among others. Nevertheless, it seems like others pharmacies like MedExpress have to come up with a new model in pharmaceutical retail to stay in the game.

3.3.6. Linkages among pharmaceutical establishments

The extent of collaboration between multi-national companies with local producers is a salient issue. Technology transfer and building tacit knowledge alliances between foreign companies and local producers enhance local production of medicines and improve access in several countries such as Bangladesh and Indonesia (United Nations, 2011). In Bangladesh, for instance, technology transfer has been extremely instrumental to"(i) establish production capacity, expand product portfolios include several new product categories, and (iii) technological upgrading of the kind required to produce good-quality medicines at reasonable cost…the drugs manufactured…are significantly cheaper than the generic versions of drugs that can be obtained from multinational companies" (UN, p. 81 citing Ahmed, 2009).

This study examined the linkages among local and multi-national pharmaceutical companies. However, the data is limited to information gathered from MIMS Philippines and IQVIA Philippines. A link, denoted by a line connecting two points, is established if one company currently manufactures/ trades/distributes the product of the other or vice versa. The network data which consist of pairs of companies that are linked, are then drawn as a graph using the software package UCInet (version 6). Each company is denoted in the graph as a node. The objective is not to compute for connectedness and centrality measures which are typically done in network analysis. Such is not advisable because the network under consideration is not the whole network (as it misses some companies due to data limitations). Instead, the objective is to examine the links, initially, of top 20 companies or of certain categories like local and multi-national companies examining tendencies for homophily within such groups and associating the networks they have with their performance and competitiveness.

Network graph of top 20 corporations

The ego-centric network graph of the top 20 pharmaceutical companies in the country is shown in Figure 18. It represents both backward (manufacturing) and forward (distribution and marketing) linkages.[25]

24 MedExpress website
25 Source of links is MIMS Philippines, data retrieved on May 2018. Data on the linkages may not be exhaustive.

Nodes correspond to corporations which are either manufacturers or traders. The figure below is not a complete network graph as it contains only alters (nodes directly connected to a node) of the top 20. There are more than 20 nodes in this graph because all firms connected to the top 20 companies are included. The node size is proportional to the degree or the number of direct alters or connections, so the bigger the node, the greater the number of firms connected to it.

One can easily interpret that the ego-centric network illustrates degree of segregation. There are about four main clusters: (A) Unilab group; (B) Cathay Drug; (C) Ambica's group; and (D) multi-nationals. Unilab is separate from the rest; it uses its own manufacturing and distribution outfits. On the other hand, most of the top multi-national companies use Zuellig for their distribution but rely on their own facilities (some in foreign locations) for manufacturing. Ambica, which is represented by the biggest node in the graph that has the most number of alters or direct links, is linked with so many smaller companies. Meanwhile, Cathay Drug which used to be the exclusive distributor of Merck Sharpe & Dohme from 1952 to 2000[26] is a local marketing and distribution firm that caters to a number of suppliers.

The graph has been colored to illustrate its attribute in terms of ownership and rank in the market share. In Figure 19, the green nodes refer to locally-owned establishments while the pink nodes refer to multi-national companies. Those which are neither green nor pink are establishments that do not have data. The direction of arrows signifies product movement from the manufacturer to the trader, then to distributor for those which use entities for manufacturing and distribution other than themselves. Note that for purposes of simplicity, only the Top 20 have larger nodes; all other companies which they are linked to are represented by nodes of equal size.

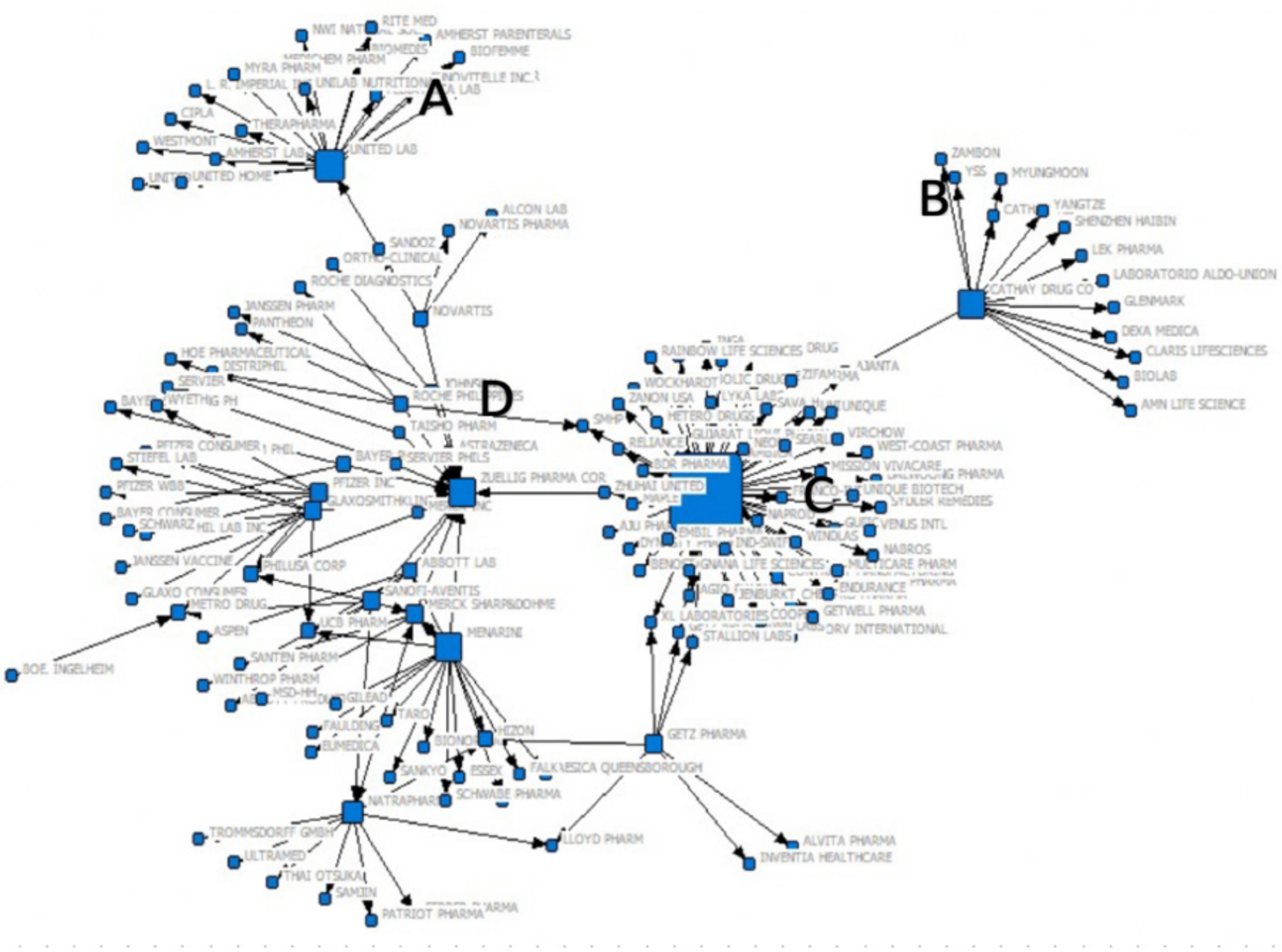
Interestingly, top multi-national companies (MNCs) utilize mainly their own manufacturing outfits and have very minimal, if at all, links with local firms. For instance, Pfizer's supply is manufactured by Pfizer WBB and Pfizer Consumer. GlaxoSmithKline uses seven manufacturers but only one of these is a local firm that manufactures a mere 4 percent of the GlaxoSmithKline's market share: Duncan Pharma. Abbott Laboratories, Sanofi-Aventis, Roche, Merck Inc, Servier, Bayer, and Astrazeneca obtain their drug products from their own manufacturing outfits abroad. Novartis, Merck Sharpe & Dohme, and Johnson & Johnson also exclusively utilize multinational companies for manufacturing. All the top MNCs use Zuellig as their main distributor. Notice that those in cluster D converge at a central node, Zuellig Pharma Corporation.

In contrast to the grouping of multi-national corporations, it is evident that United Laboratories, a local company and the one with the highest share (and biggest node), is separate from the rest of the top firms. Unilab mainly uses its own divisions/subsidiaries for manufacturing and distribution (see part A of the graph). It is linked to the rest of the network only via Novartis as there is a distribution link between Novartis and Unilab. Meanwhile, the role of Cathay Drug (shown in cluster B), Ambica (C), and Menarini (E) is quite interesting in that they seem to play the role of a consolidator. These three companies are also large distributors except that their clients are varied and much smaller in terms of market share.

Since 16 of the top 20 pharmaceutical companies are directly linked to Zuellig Pharma, it is important to examine this network more closely. Figure 20 shows an expanded version of the sub-network. This sub-network exhibits a wheel or a star network wherein the nodes around Zuellig Pharma are not necessarily linked with one another but mainly through Zuellig or its subsidiary, Metro Drug. The spokes around Zuellig are also the main suppliers

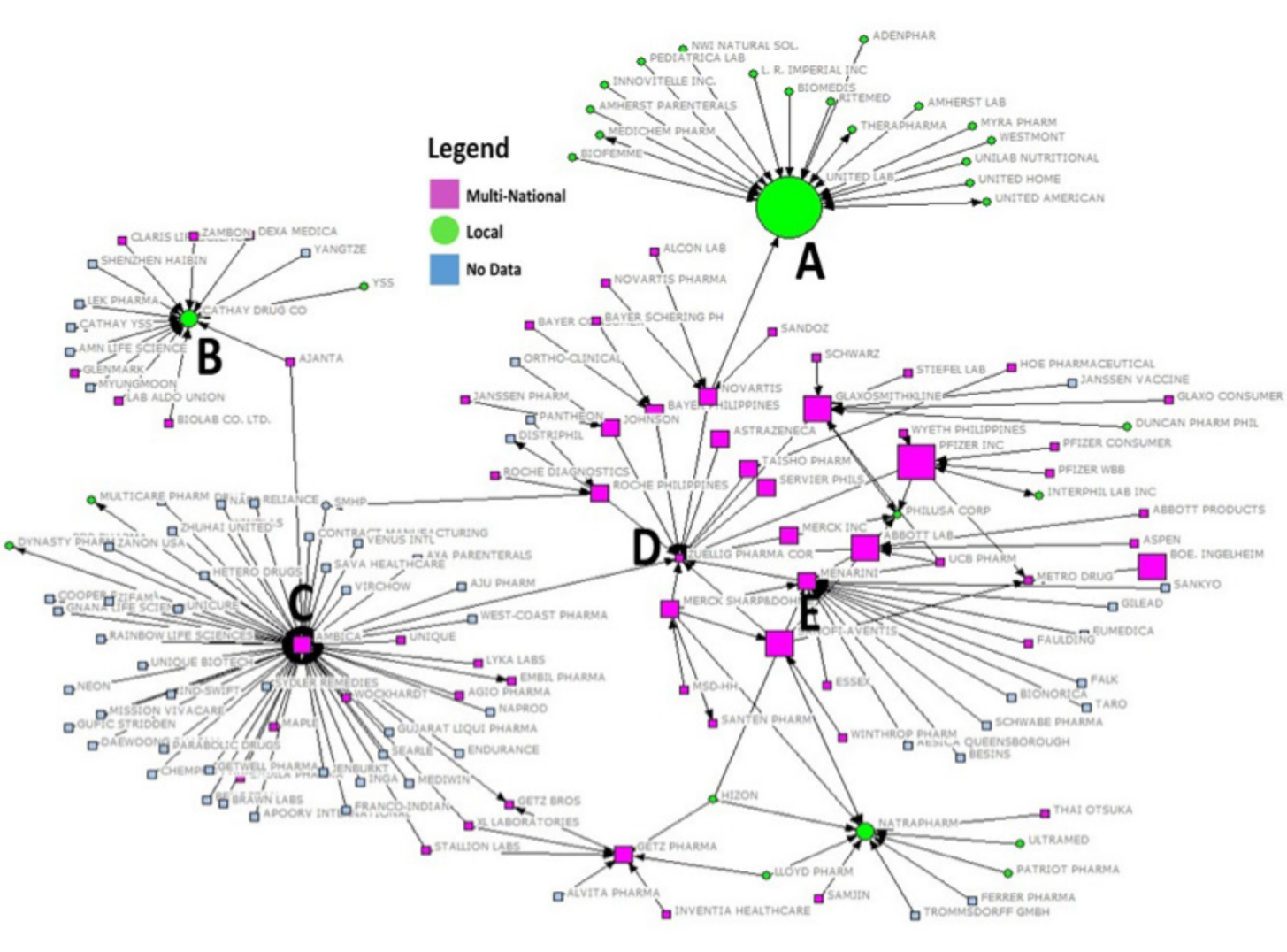
26 http://cathaydrug.ph/about-us/

Figure 18. Ego-centric networks of Top 20 pharmaceutical establishments in 2016 (node size is based on degree)



Sources of basic data: MIMS Philippines and IQVIA Philippine

Figure 19. Ego-centric networks of Top 20 pharmaceutical establishments in 2016 by ownership and market share



Sources of basic data: MIMS Philippines and IQVIA Philippine

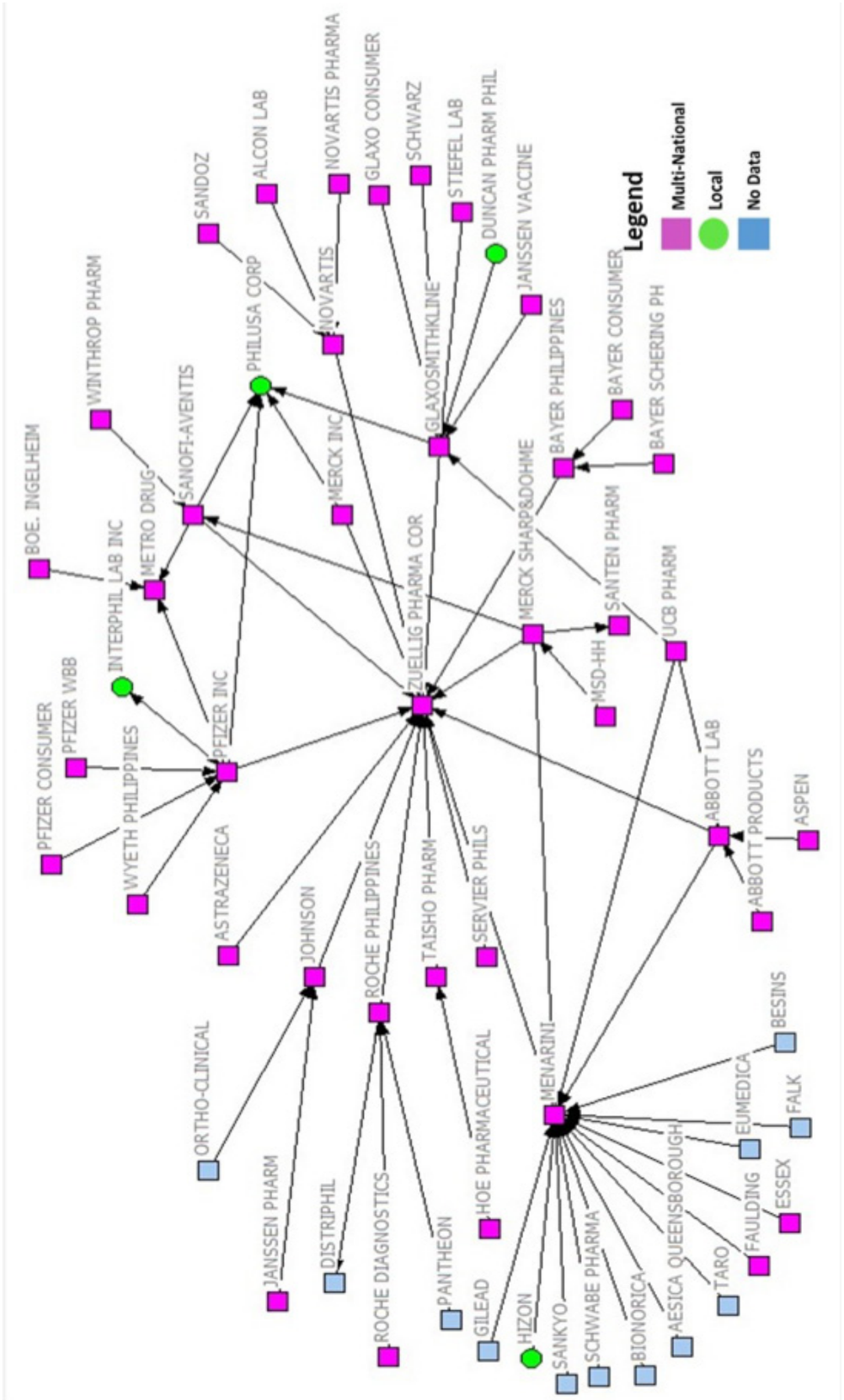


Figure 20. Ego-centric networks of Top 20 pharmaceutical establishments in 2016 by ownership and market share, subset of selected MNCs

Sources of basic data: MIMS Philippines and IQVIA Philippine

of originator drugs in the market. Such highly centralized structure appears to be an efficient way of supplying such drugs. It also clearly illustrates that Zuellig Pharma has a central position in the supply of originator drugs in the country.

Network graphs of bigger firms

Figure 21 represents the egocentric network of other big firms that are not in the top 20 but with sales valued at over PhP100 million in 2016. The graph shows that there are isolated firms operating on their own capacity, whether in terms of manufacturing and/or distribution (see column of nodes on the left side of the graph). Again, to obtain a more in-depth assessment of the structure of linkages, the analysis focused on the main component or biggest cluster (the red-colored nodes in Figure 21) and presented as Figure 22 below. Note that node size in Figure 22 are proportional to their betweenness, or a measure of centrality based on a firm's ability to broker or mediate other firms.

Among these big firms, those that dominate the structure of the market are: (1) Metro Drug and (2) Zuellig Pharma. These two firms are shown to have the largest nodes representing their high centrality score in terms of going between different firms. Note that Metro Drug is a subsidiary of Zuellig which has a dominant role in the supply of medicines in this group. Aside from Metro Drug and Zuellig Pharma, a firm that has relatively central position than the rest is (3) Macropharma, a locally-owned distributor and marketer.

Network graphs of medium-sized firms

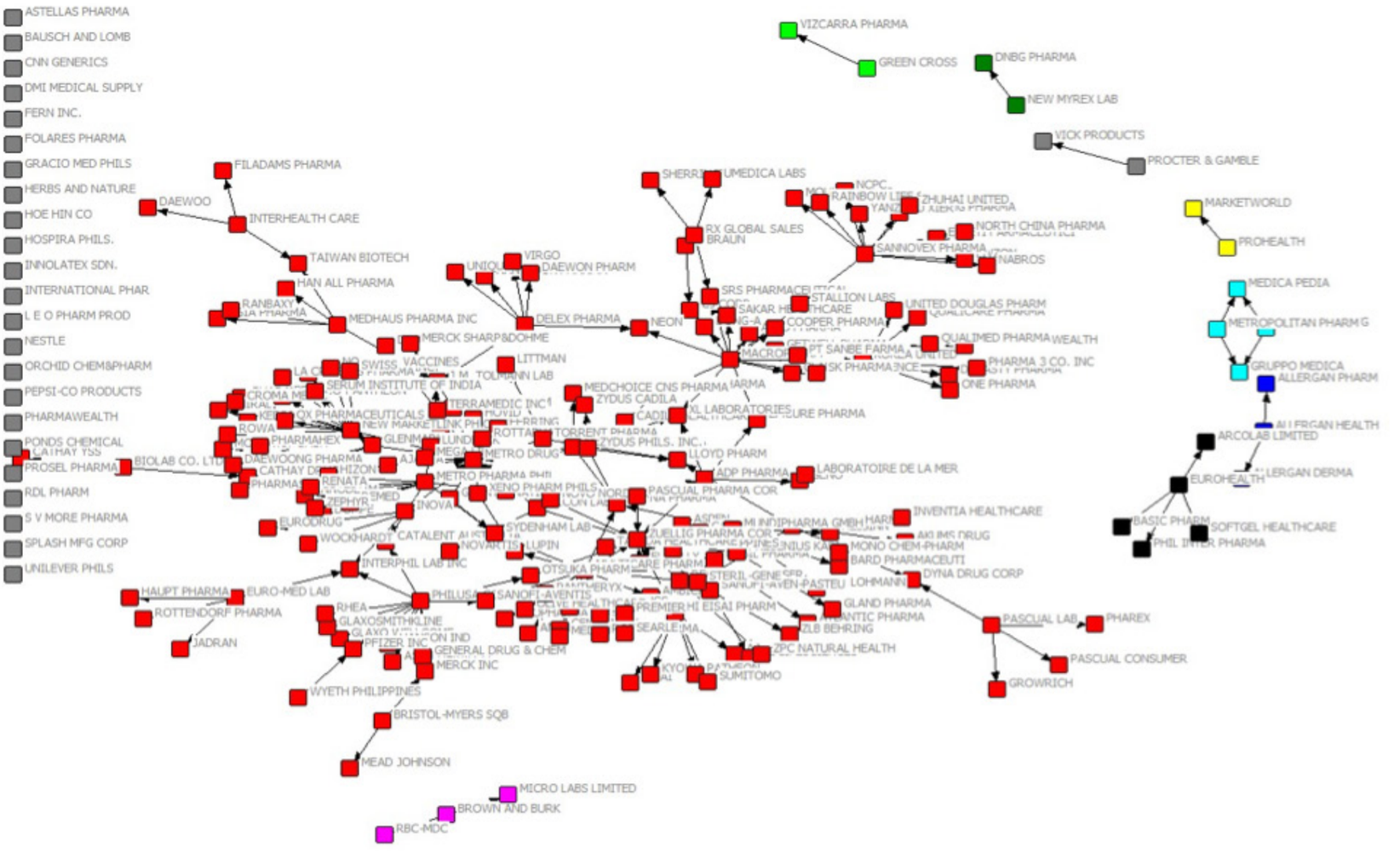
Figure 23 shows the ego-centric network graph of medium-sized firms. Apart from the main component (in blue-colored nodes), there are smaller groups comprising of pairs and triads. Looking at the main component, control over the market appears to be more diffused compared to the group of bigger firms. Locally-owned firms play more central roles than multi-national firms as shown by the larger nodes of local players (in circle nodes) suggesting that their betweenness scores are higher as shown in Figure 24. An interesting pattern suggests that these central firms also appear to consolidate the products of numerous manufacturers.

Network Graphs of Small Firms

Small-sized pharmaceutical firms are also relatively more diffused with many isolates shown in the left side of the graph. Based on the MIMS and IQVIA data, these firms conduct their own manufacturing and distribution. Apart from a massive main component (in blue nodes shown in Figure 25), there are many small clusters of firms surrounding the main component. The main component or largest cluster is expanded in Figure 26. It shows that although a multi-national firm XL Laboratories (marked as "X") seems to play a central role, many other players appear to have a bridging role as shown by relatively larger nodes surrounding the inner core marked with a "Y".

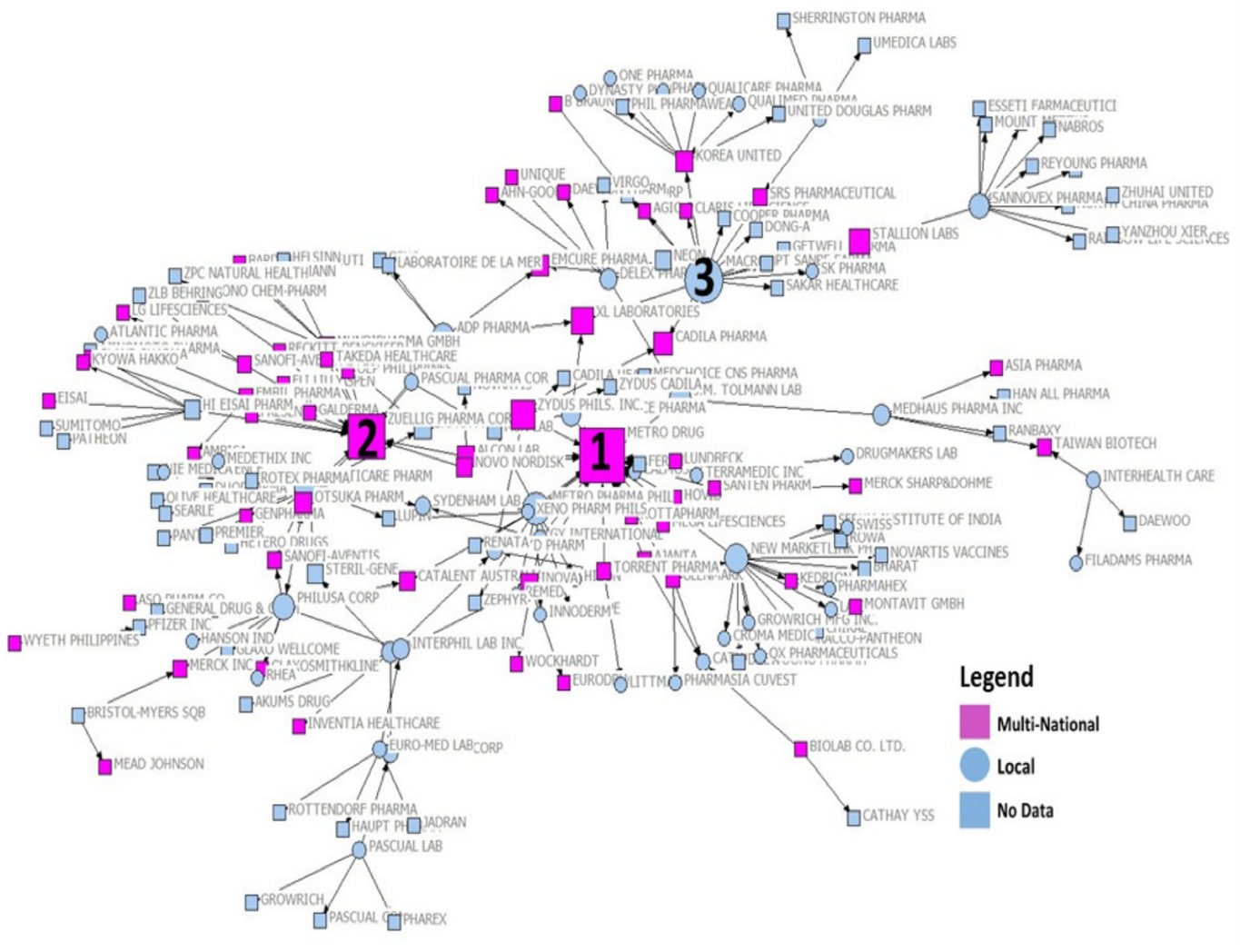
Mapping of the linkages among pharmaceutical establishments draws varied insights. First, distribution of products of the top MNCs is exclusively carried out by Zuellig Pharma and its subsidiary Metro Drug. There is a non-negligible number of small players doing their own manufacturing and distribution. Moreover, numerous smaller players in the industry use multiple but small distribution and manufacturing companies. There are also more connections among the smaller firms than among the bigger companies. Given these, the network is rather diffused and less centralized. Lastly, Unilab which utilizes its own divisions and subsidiaries is not integrated with the rest of the industry players.

Figure 21. Egocentric networks of other big firms (with 2016 sales of PhP100 million but not among the top 20)



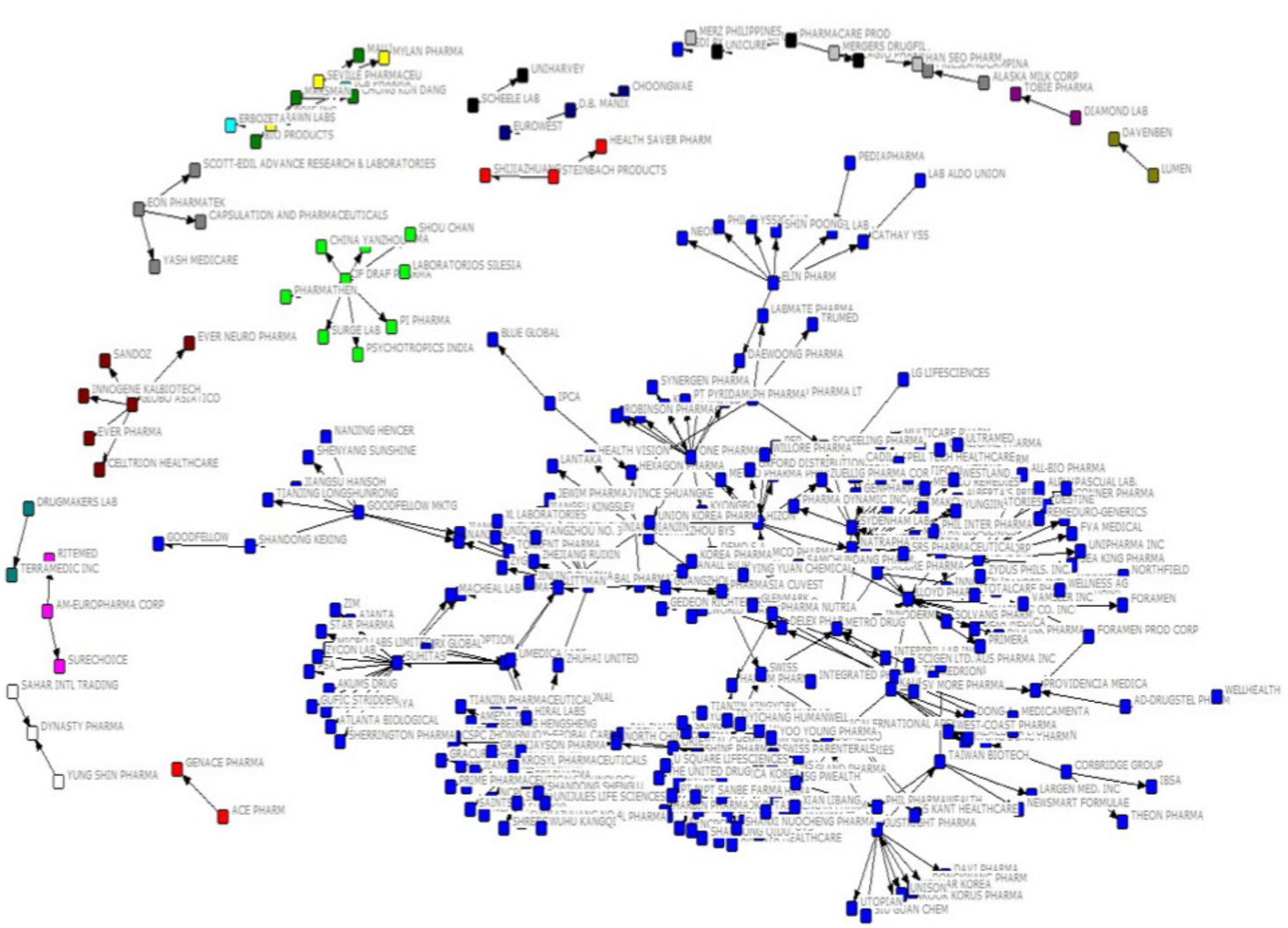
Sources of basic data: MIMS Philippines and IQVIA Philippine

Figure 22. Egocentric networks of big firms (with 2016 sales of at least P100 million, but excluding top 20), main component only and node size proportional to the betweenness score, pink ones are multi-nationals, and circle nodes refer to local firms



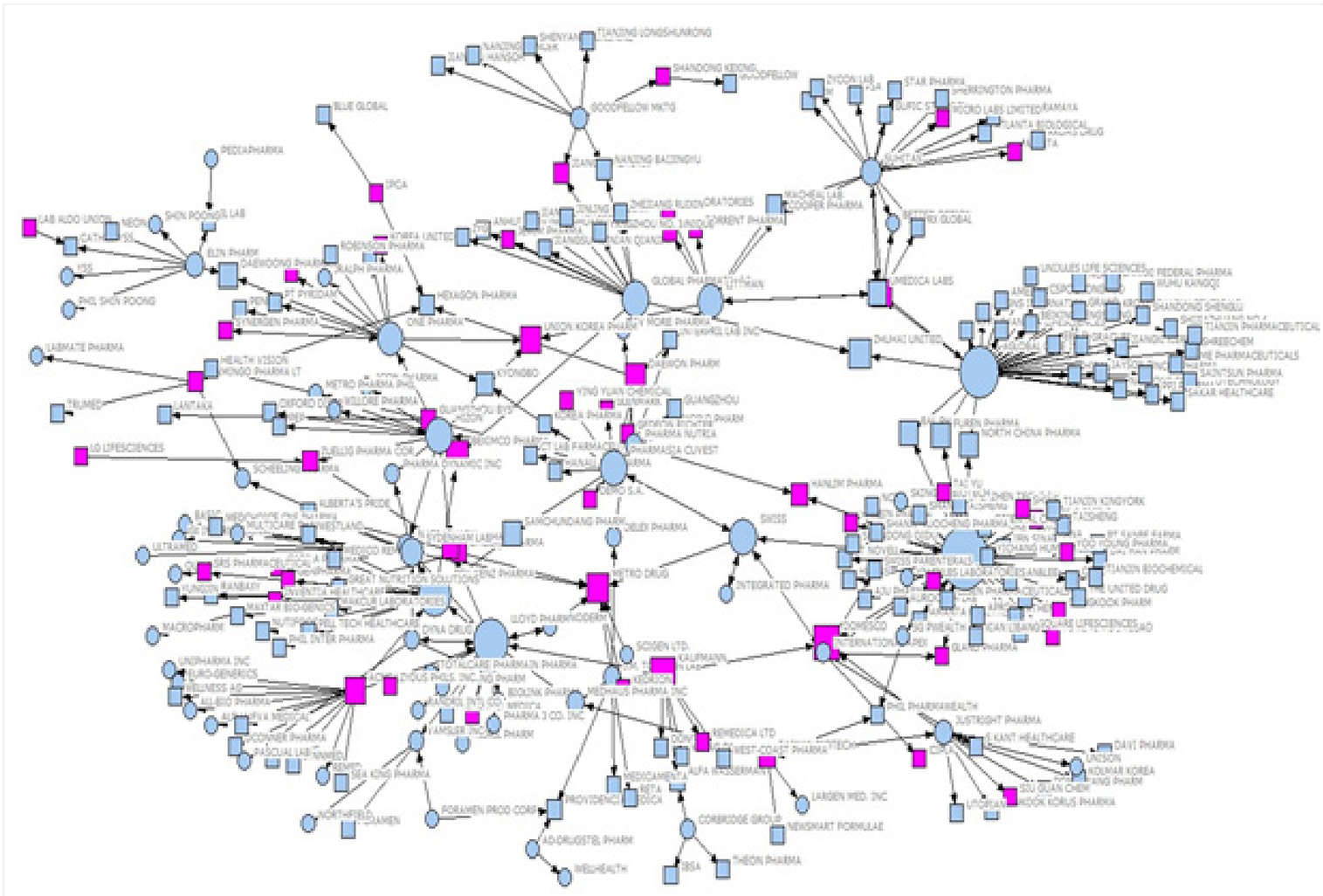
Sources of basic data: MIMS Philippines and IQVIA Philippine

Figure 23. Egocentric networks of medium-sized firms (with 2016 sales of over 20 million to less than 100 million) by component[28]



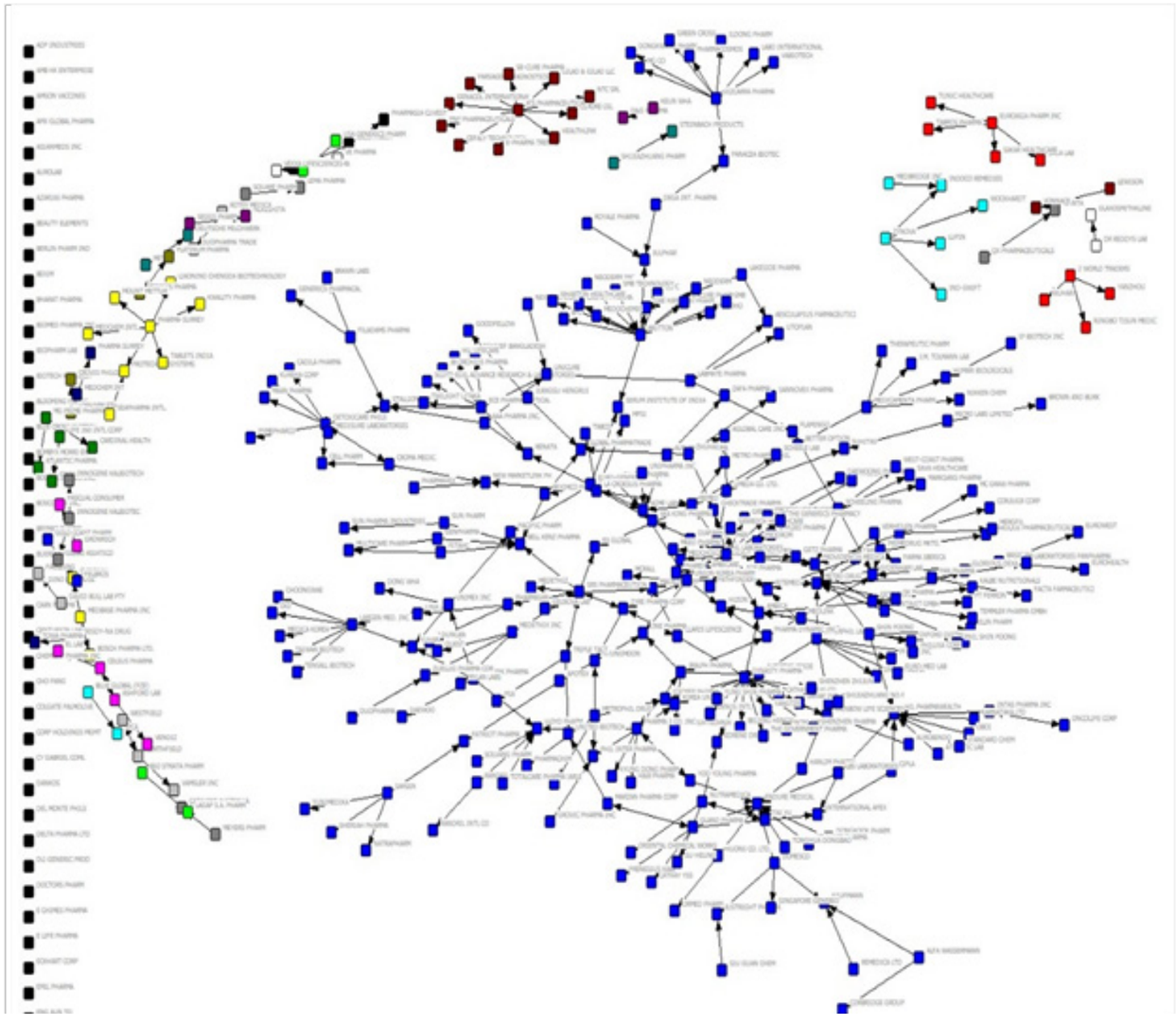
Sources of basic data: MIMS Philippines and IQVIA Philippine

Figure 24. Egocentric networks of medium-sized firms (with 2016 sales of over 20 million to less than 100 million), main component only and node size proportional to the betweenness score, pink ones are multi-nationals, and circle nodes refer to local firms



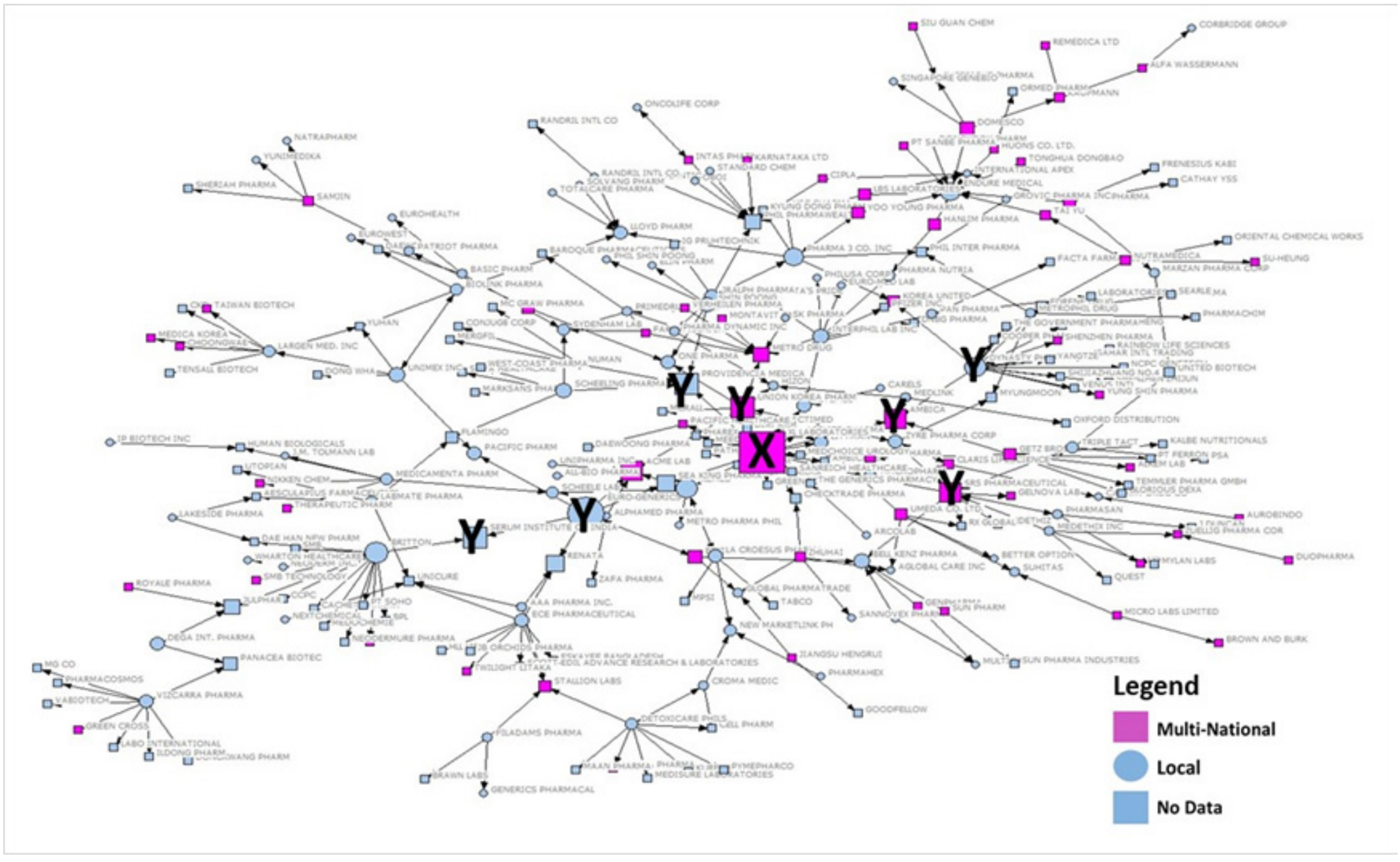
Sources of basic data: MIMS Philippines and IQVIA Philippine

Figure 25. Egocentric networks of smaller firms (with 2016 sales of P20 million or less)



Sources of basic data: MIMS Philippines and IQVIA Philippine

Figure 26. Egocentric networks of smaller firms (with 2016 sales of P20 million or less), main component only and node size proportional to the betweenness score, pink ones are multi-nationals, and circle nodes refer to local firms



Sources of basic data: MIMS Philippines and IQVIA Philippine

3.4. Dominant Players & Trends in Market Concentration

The top 20 pharmaceutical corporations captured a combined share of 73 percent of the market in 2016. Unilab had a market share of 25 percent, followed by Pfizer (6.4 percent), GlaxoSmithKline (4.8 percent), Boehringer Ingelheim (3.9 percent)percent), and Abbott Lab (3.7 percent)percent). Meanwhile, the top 20 multi-national corporations captured 44 percent of the pharmaceutical market while local companies controlled around 38.8 percent. Based on SEC data,[28] the top 20 corporations contributed at least P705 million in tax and license payments. Their combined net profit was PhP8.1 billion while the combined value of assets was around PhP136 billion.[29]

While the market is still dominated by MNCs, local companies' share is increasing. From 11.1 percent in 2007, the share of local companies excluding Unilab has inched up to 18.4 percent in 2016. For the biggest player Unilab, market share also increased from 21.3 to 25.1 percent. In contrast, the share of multi-nationals has decreased from 67.6 to 56.5 percent.

To examine the extent of market control by the industry's biggest corporations and to demonstrate in figures the degree in which an industry is oligopolistic, this study calculates the concentration ratios (top 4, top 5, and top 8 firms) in broad categories of the pharmaceutical sector. It also uses Herfindahl-Hirschman Index (HHI) or Herfindahl Index in addition to the concentration ratios. The formula for HHI is:

$$HHI = \sum_{i=1}^{n} s_i^2$$

Where S_i represents the market share of firm i in the market, and *N* denotes number of firms. A lower index represents a relatively more competitive industry with no dominant players and a higher index denotes a more concentrated market. Markets with index below 0.15 is deemed as unconcentrated, while those with index between 0.15 and 0.25 are considered moderately concentrated; markets with index above 0.25 are said to be highly concentrated.[30] Note that "If all firms have an equal share the reciprocal of the index shows the number of firms in the industry. When firms have unequal shares, the reciprocal of the index indicates the "equivalent" number of firms in the industry."[31]

Likewise, this paper looks into the market structure of several sub-sectors such as but not limited to the supply of drugs by license type (originator, branded generic, and unbranded generic). This is augmented by a closer look at the cardiovascular medicines which are used to treat the top causes of mortality in the country.

Looking at the aggregate industry, there seems to be no concern in terms of possible dominance of a few firms. The combined market shares of the top 4, 5 and 8 firms in the industry have slightly gone down in the last decade. To illustrate, the share of Top 4 went down from 0.45 in 2007 to 0.40 in 2016; that for Top 8 firms also declined from 0.5867 to 0.5242 during the same period (Table 9). Meanwhile, as shown in Table 10 the Herfindahl index of the entire industry in 2016 is 0.079710 which is slightly higher than in 2007 (0.076707) suggesting that the pharmaceutical market can be considered competitive as it is below 0.15. The reciprocal of the two indices are 13 and 12.5, respectively. This means that in 2016, the market structure is equivalent to having around 12 firms of the same size. In 2007, the market structure is equivalent to having 13 firms.

On the other hand, the disaggregated sectors of the industry provide a rather variable picture. The originator drugs market has an index of 0.0666 in 2016 while that of the generics market has a higher index of 0.1196, hence the originator drugs market is relatively less concentrated, although both appear as unconcentrated markets. The shares of the top firms also have diminished through the years as shown in Table 10.

Table 8. Top 20 pharmaceutical companies in 2016 by type

All			Local		Multi-nationals	
Corporation	Ownership	Share in 2016 total sales	Corporation	Share to total sales, 2016	Corporation	Share to total sales, 2016
UNITED LAB	Local	25.1	UNITED LAB	25.1	PFIZER INC	6.4
PFIZER INC	Multi National	6.4	CATHAY DRUG CO	2.7	GLAXOSMITHKLINE	4.8
GLAXOSMITHKLINE	Multi National	4.8	AMBICA	2.4	BOE. INGELHEIM	3.9
BOE. INGELHEIM	Multi National	3.9	NATRAPHARM	2.1	ABBOTT LAB	3.7
ABBOTT LAB	Multi National	3.7	PASCUAL LAB	1.1	SANOFI-AVENTIS	2.9
SANOFI-AVENTIS	Multi National	2.9	MULTICARE PHARM	1.1	NOVARTIS	2.8
NOVARTIS	Multi National	2.8	INTERMED MKTG	0.8	MERCK SHARP&DOHME	2.5
CATHAY DRUG CO	Local	2.7	ADP PHARMA	0.6	JOHNSON	2.4
MERCK SHARP&DOHME	Multi National	2.5	EURO-MED LAB	0.5	BAYER PHILIPPINES	2
JOHNSON	Multi National	2.4	GX INTERNATIONAL	0.4	ASTRAZENECA	2
AMBICA	Local	2.4	NEW MARKETLINK PH	0.3	SERVIER PHILS	1.4
NATRAPHARM	Local	2.1	PASCUAL PHARMA COR	0.3	ROCHE PHILIPPINES	1.3
BAYER PHILIPPINES	Multi National	2	INTERNATIONAL PHAR	0.2	TAISHO PHARM	1.3
ASTRAZENECA	Multi National	2	DELEX PHARMA	0.2	MERCK INC	1.2
SERVIER PHILS	Multi National	1.4	NEW MYREX LAB	0.2	GETZ PHARMA	1.2
ROCHE PHILIPPINES	Multi National	1.3	PHILUSA CORP	0.2	MENARINI	1.1
TAISHO PHARM	Multi National	1.3	TERRAMEDIC INC	0.2	NESTLE	1
MERCK INC	Multi National	1.2	MACROPHARM	0.2	TORRENT PHARMA	0.8
GETZ PHARMA	Multi National	1.2	METRO PHARMA PHIL	0.1	TAKEDA HEALTHCARE	0.8
MENARINI	Multi National	1.1	PROSEL PHARMA	0.1	HOSPIRA PHILS.	0.8

Source: IQVIA Philippines

Table 9. Concentration ratios by license type

	Industry			Originator			Generic			Branded generic			Unbranded generic		
Year	TOP 4	TOP 5	TOP 8	TOP 4	TOP 5	TOP 8	Top 4	Top 5	Top 8	Top 4	Top 5	Top 8	Top 4	Top 5	Top 8
2007	0.4534	0.4953	0.5867	0.4996	0.5536	0.7036	0.4873	0.5215	0.5948	0.4958	0.5320	0.6085	0.7437	0.7807	0.8581
2008	0.4418	0.4836	0.5764	0.5080	0.5617	0.7033	0.4758	0.5112	0.5847	0.4831	0.5206	0.5982	0.7362	0.7738	0.8498
2009	0.4345	0.4681	0.5620	0.4827	0.5382	0.6784	0.4675	0.5007	0.5800	0.4785	0.5137	0.5938	0.7425	0.7966	0.8730
2010	0.4173	0.4533	0.5482	0.4704	0.5252	0.6647	0.4501	0.4846	0.5727	0.4640	0.5007	0.5817	0.7250	0.7990	0.8863
2011	0.4237	0.4588	0.5549	0.4464	0.5042	0.6568	0.4648	0.4948	0.5713	0.4722	0.5038	0.5795	0.7615	0.8143	0.8810
2012	0.4158	0.4482	0.5394	0.4360	0.4986	0.6575	0.4531	0.4843	0.5608	0.4591	0.4889	0.5608	0.7701	0.8201	0.9081
2013	0.4231	0.4568	0.5494	0.4164	0.4893	0.6418	0.4637	0.4916	0.5609	0.4616	0.4900	0.5640	0.8221	0.8551	0.9180
2014	0.4132	0.4486	0.5371	0.4104	0.4825	0.6355	0.4535	0.4801	0.5511	0.4479	0.4765	0.5519	0.8426	0.8776	0.9294
2015	0.4014	0.4378	0.5250	0.4064	0.4770	0.6332	0.4376	0.4687	0.5497	0.4293	0.4619	0.5446	0.8170	0.8777	0.9230
2016	0.4019	0.4393	0.5242	0.4035	0.4707	0.6117	0.4382	0.4692	0.5493	0.4298	0.4622	0.5438	0.8037	0.8682	0.9115

Table 10. Herfindahl index by license type

Year	Industry	Originator	Generic	Branded generic	Unbranded generic
2007	0.0767	0.0880	0.1094	0.1099	0.1809
2008	0.0746	0.0885	0.1086	0.1085	0.1871
2009	0.0756	0.0857	0.1107	0.1126	0.1752
2010	0.0723	0.0800	0.1071	0.1102	0.1701
2011	0.0764	0.0755	0.1177	0.1176	0.1995
2012	0.0772	0.0745	0.1183	0.1166	0.2136
2013	0.0805	0.0706	0.1240	0.1176	0.2863
2014	0.0786	0.0689	0.1199	0.1115	0.3179
2015	0.0779	0.0684	0.1172	0.1077	0.3236
2016	0.0797	0.0666	0.1196	0.1104	0.3343

28 Reference years may differ for every corporation, but data were gathered from SEC between January and March 2018.
29 In this estimate, data for Bayer, Taisho Pharm and Menarini were not included due to unavailability.
30 https://www.justice.gov/atr/horizontal-merger-guidelines-08192010#2d
31 https://en.wikipedia.org/wiki/Herfindahl_index

Meanwhile, the structure of the generics market has relatively worsened; HHI inclined slightly to 0.1196 from 0.1094 in the last decade. Nevertheless, the shares of the top firms are now lower than in the past. Further, disaggregating generics market into branded and unbranded reveals a much greater differentiation. The Herfindahl index for branded generics in 2016 is 0.1104 which reflects an unconcentrated market.[32] As for the unbranded market, the situation is significantly different. The Herfindahl index has nearly doubled from 0.1809 in 2007 to 0.3343 in 2016. Note that HHI above 0.25 is considered a highly concentrated market. The reciprocal of the 2016 index is 2.99 which indicates that the market structure is equivalent to having only around 3 firms of the same size. With an index of 0.1809 in 2007, the reciprocal is 5.52. Therefore, the market for unbranded medicines has become more concentrated through the years.

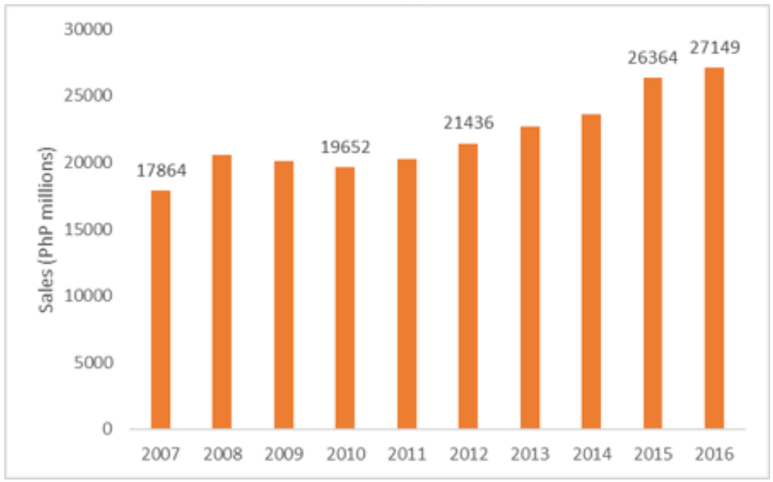
For a much closer look, the market for cardiovascular medicines was examined. In 2016, there were PhP27 billion sales from cardiovascular-related medicines, a 52-percent increment since 2007. The bulk (59 percent) of these medicines are branded generics, around 32 percent are originator drugs while only 9 percent are unbranded generics. The market trend shows an increasing role of generics vis-à-vis originator drugs.

The multi-nationals captured 55.5 percent of the total amount of 2016 sales for medicines against cardiovascular diseases, but the local giant, Unilab, held the biggest share (27.76 percent). The share of all local corporations has been consistently rising from only 29.9 percent in 2007 to 44.5 percent in 2016, with Unilab accounting for a large proportion of the increment. United Laboratories, Pfizer, Boe. Ingelheim, and Servier Phils jointly held the majority (53%) of the cardiovascular medicines market in 2016. The top 5 firms jointly control 57 percent while the top 8 corporations enjoy 68.6 percent. Looking at the 4-firm and 5-firm ratios, the market structure seems to have become relatively more oligopolistic but the 8-firm ratio shows a relatively less concentrated market (refer to Table 11). Meanwhile, the HHI for this drug category is at 0.1098 which indicates low concentration. In terms of players, there are now more corporations engaged in the production of cardiovascular medicines: from 114 firms in 2007 to 179 in 2016 (Table 12). These are the firms which have made positive sales value in this drug category.

3.5. Profile of industry entrants

As noted earlier, 2006 and 2012 CPBI data indicate downsizing among manufacturers of pharmaceutical products. In relation

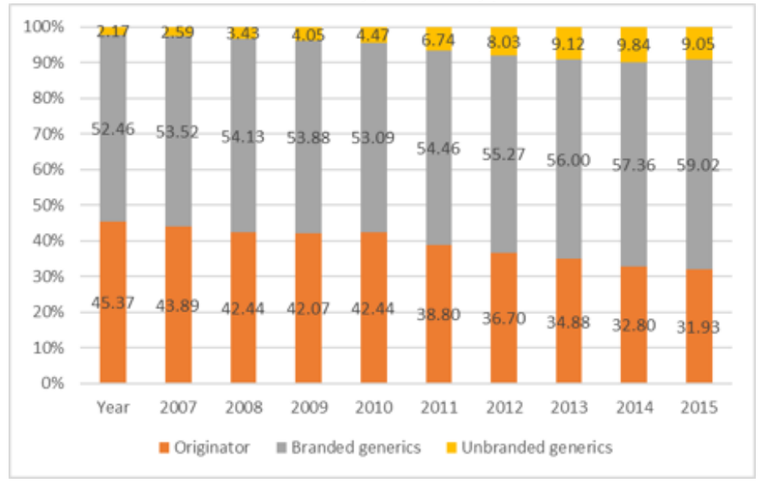
Figure 27. Sales from cardiovascular medicines by year



Source of basic data: IQVIA Philippines

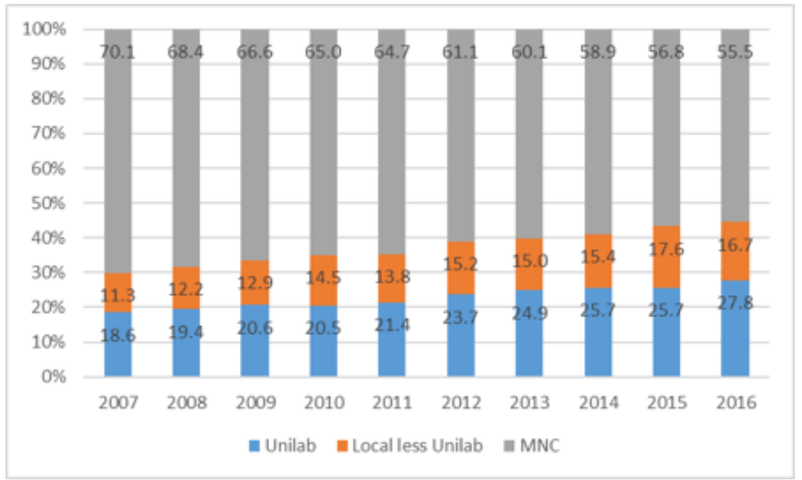
32 https://www.justice.gov/atr/horizontal-merger-guidelines-08192010#2d

Figure 28. Cardiovascular medicines market by license type



Source of basic data: IQVIA Philippines

Figure 29. Market share in cardiovascular medicines by type by year



Source of basic data: IQVIA Philippines

Table 11. Herfindahl index and concentration ratios, cardiovascular medicines

Year	Herfindahl index	TOP 4	TOP 5	Top 8
2007	0.0935	0.5101	0.5657	0.7127
2008	0.0962	0.5212	0.5777	0.7188
2009	0.0961	0.5125	0.5683	0.7070
2010	0.0897	0.4979	0.5537	0.6954
2011	0.0920	0.4935	0.5589	0.7063
2012	0.0965	0.5003	0.5597	0.7005
2013	0.0990	0.4997	0.5567	0.6938
2014	0.1012	0.5087	0.5598	0.6882
2015	0.1005	0.5079	0.5552	0.6796
2016	0.1098	0.5288	0.5726	0.6861

Source of basic data: IQVIA Philippines

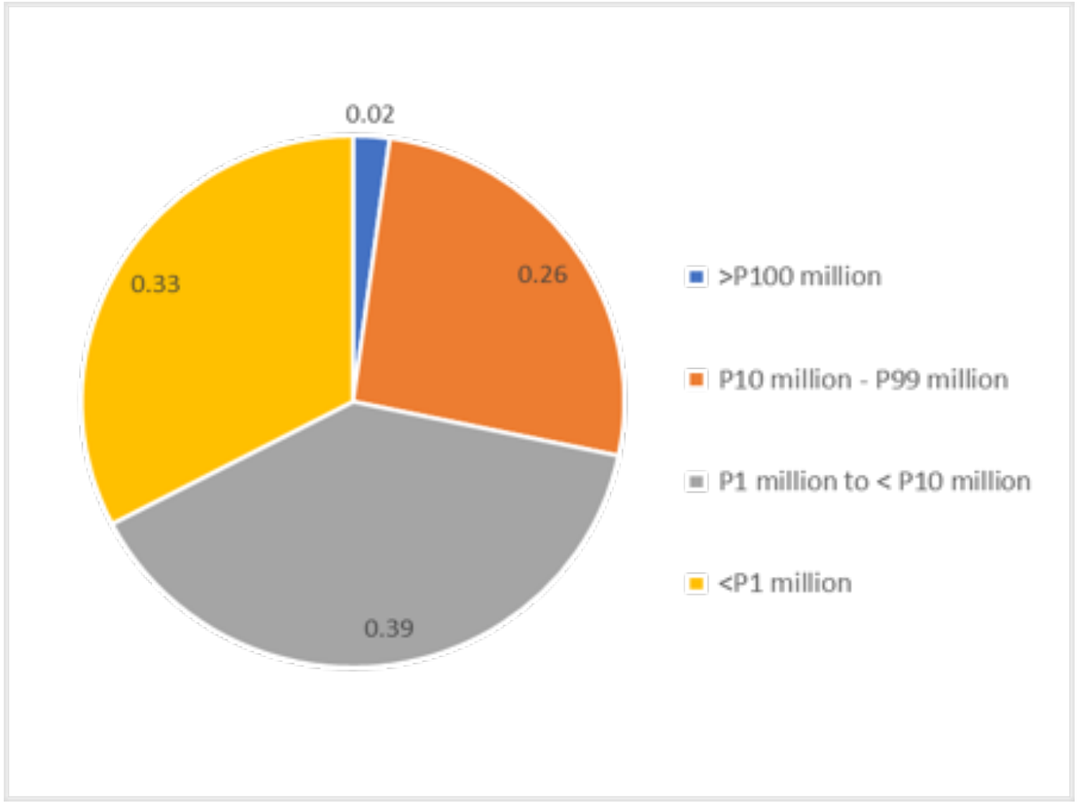
Table 12. No of corporations engaged in the cardiovascular medicines market

Year	Number of corporations[1/]
2007	114
2008	135
2009	146
2010	163
2011	168
2012	170
2013	171
2014	186
2015	186
2016	179

Source of basic data: IQVIA Philippines, 1/ Based on firms which have non-zero sales in the year indicated

to this, it is imperative to examine the profile of industry entrants to understand how their entry has made an impact. An 'entrant' is defined in this paper as a firm without sales in 2007 but had positive sales in 2016. The analysis shows that there are some 322 such companies composed of manufacturers, traders, importers (excluding distributors and retailers) that have entered the pharmaceutical production/importation sector between 2008 and 2016. Their combined share in the market, based on 2016 sales data, is only 2.4 percent (PhP4.2 billion). Seven out of ten of these companies have sales below PhP10 million, while only two out of 100 have sales above PhP100 million. The mere increase of industry players masks essential details and does not automatically depict improvement of competition.

Figure 30. Distribution of new pharma market entrants (n=322) by 2016 sales category



Source: IQVIA

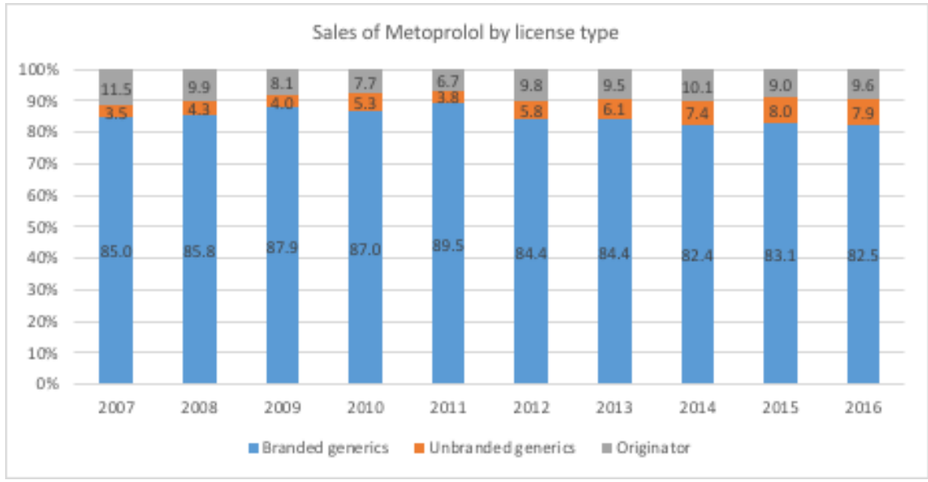
3.6. Trend in market share of originator medicines

Aside from profiling new entrants, it is also useful to examine how the market share of originators changes over time with the presence and dominance of the generics sector. The study used the cases of Metoprolol and Atenolol, beta blockers that are used to treat conditions such as hypertension, heart failure, and chest pain, and Captropril, another medicine used for treating hypertension and hearth ailments, to examine the market share of originators. Do originators, which are more expensive, retain their market share despite the presence of more affordable generic alternatives?

Time-series sales data on Metoprolol show that the market presence of originator has slightly gone down from 11.5 percent in 2007 to 9.6 percent in 2016. Its market share shrank to as low as 6.7 in 2010 but has bounced back close to 10 percent. Interestingly, the share of unbranded generic has doubled in the last ten years. On the other hand, the case of Atenolol is quite different in that the share of originator in the sales has been declining since 2011 (from 9.4 percent to only 6.2 percent in 2016). The unbranded generics captured the market, surpassed the share of the originators, and doubled market share within half a decade. Note that the only unbranded generic player in this medicine is the RiteMed of Unilab. Meanwhile, the market presence of branded generics is quite stable during the period.

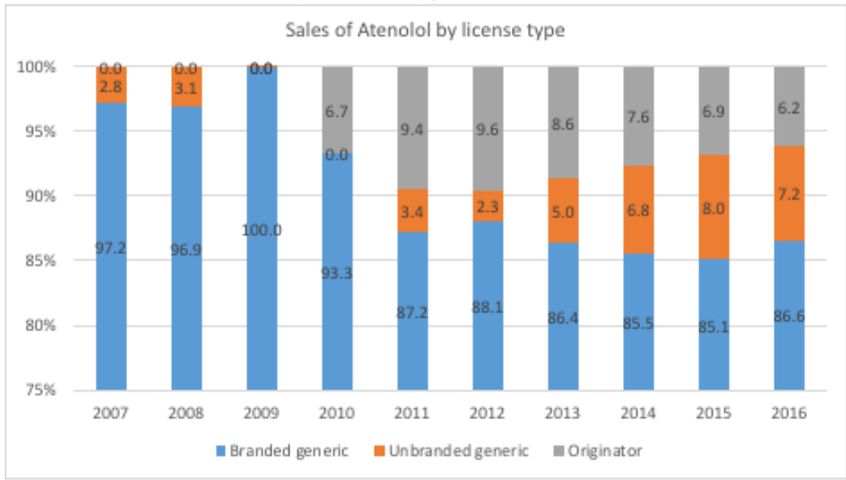
IQVIA data cites Captropil as an example of a medicine where the originator (i.e.,

Figure 31. Market share in Metoprolol by license type



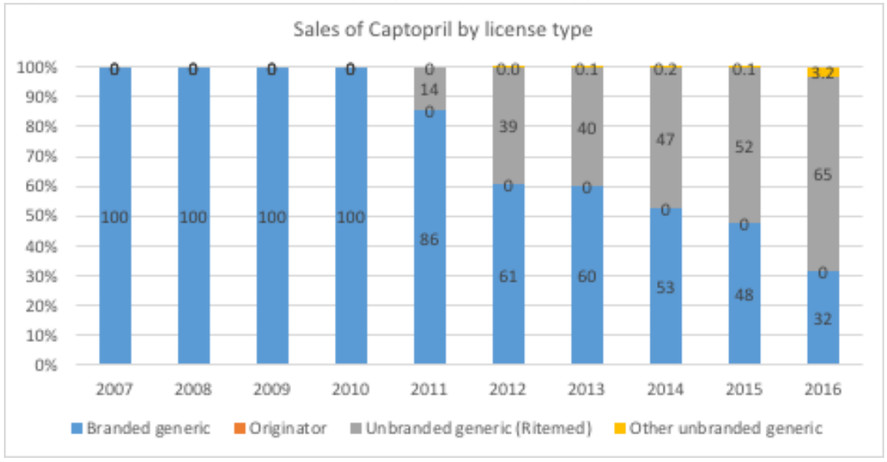
Source of basic data: IQVIA Philippines

Figure 32. Market share in Atenolol by license type



Source of basic data: IQVIA Philippines

Figure 33. Market share in Captopril by license type



Source of basic data: IQVIA Philippines

Capoten) no longer has presence in the Philippine market. Figure 33 shows that several years prior to 2011, all the Captopril in the market was supplied as branded generic. In 2011, unbranded generics were released capturing 14 percent of the market and in only a matter of five years, unbranded generics have surpassed branded generics with 65 percent market share. This limited account of the trends in originator's market share indicates that the continued dominance of generics can be expected and if the trend described above continues, unbranded generics' position will further expand.

3.7. Extent of Consolidation

It is challenging to assess the magnitude of industry players to understand the extent competition within the industry. The mere number of establishments that are subsidiaries of bigger pharmaceutical companies makes it hard to capture the real situation. For instance, information obtained from the Securities and Exchange Commission (SEC) shows that some 31 establishments are actually owned by only 5 entities or groups. This, however, is not an exhaustive list as the authors did not go through all pharmaceutical companies registered in the country. It is possible that there are more establishments under each group or that there may be more clusters that are not included in the list due to data gathering limitations. This finding came from an analysis of SEC raw data where links between companies were examined based on the presence of similarity in the officials/ stockholders of the companies. For instance, if company Y and company Z share the same set of officers and stockholders, these two are considered mere parts of a 'cluster' (for lack of better term). This clustering of establishments is consistent with key informants' approximation that the industry has been reduced to just about ten actors particularly in the manufacturing sector. Although there are still way more than ten establishments, either the big ones just expanded and created more subsidiaries, or they have bought the smaller competitors. Also, the establishments within a cluster play several roles in the value-chain, cater to different markets, or produce different products.

4. Trends in Prices of Medicines

The Philippine government aims to bring down drug prices through the Generics Law and the Maximum Drug Retail Price policy, and ensure that drugs entering the Philippine market are of decent quality and have met standards and regulatory requirements for the protection of Filipino consumers. Despite the prominence of generic medicines in the market, the proportion of out-of-pocket payments is still huge. Philippine prices remain high

Table 13. Example of Clusters of Pharmaceutical Companies

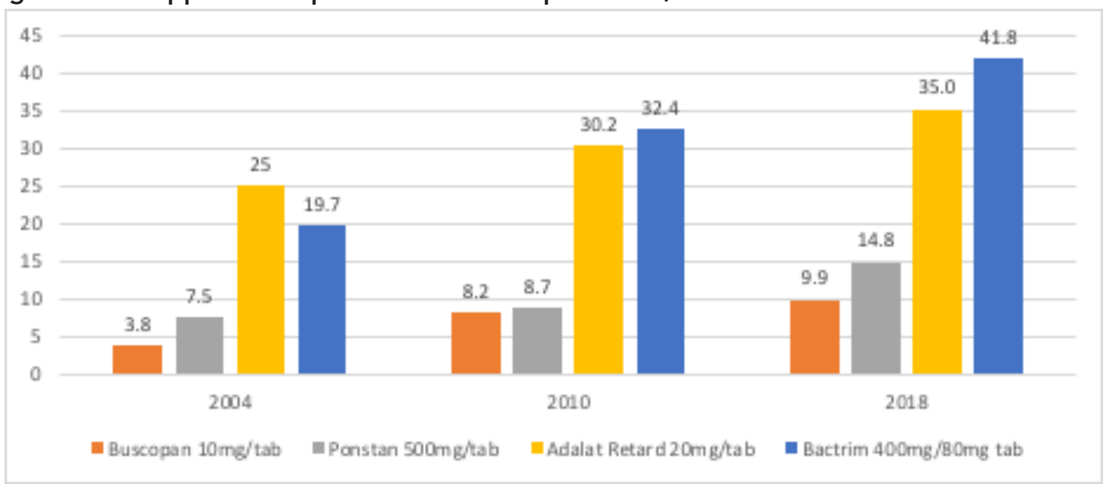
United Laboratories RiteMed AM Europharma Westmont Pharmaceuticals Pediatrica Asian Antibiotics Amherst Laboratories United American Pharmaceuticals Therapharma Biofemme Innovitelle Bio-oncology Biomedis Pharex Healthcorp Myra Pharmaceuticals	Lloyd Laboratories Foramen Products Northfield Laboratories Innogen Pharmaceuticals Vamsler Philippines Vitalink Health Metz Pharmaceuticals Westfield Pharmaceuticals Medhaus Pharma JM Tolmann
Natrapharm Patriot Pharmaceuticals	Hizon Laboratories JRalph Pharmaceuticals
El Laboratories Elin Pharmaceuticals	Sydenham
Zuellig Pharma Corp Interphil Laboratories Metro Drug Inc.	Mercury Philusa Corporation Rhea Generics
Ayala Healthcare Actimed Inc. Generika	The Generics Pharmacy South Star Drugs

Source of basic data: SEC

Note: Links are established based on the presence of similarity in the officials/stockholders of the companies, for instance, Hizon and Jralph share the same set of officers and stockholders.

compared to major sources of medicines such as India. Figure 34 shows the Philippine-India price ratio – for example in 2004 the price of Bactrim (400mg/80 mg tablet) in Philippines was 19.7 times that in India and worsened to 41.8 times in 2018. India produces medicines at a very low cost. Indonesia is a better comparator. Using the Ponstan case, the current prices (in Philippine Pesos) of Ponstan in the three countries are compared side by side. The price of Ponstan in the Philippines is 14 times that in India, and 4 times that in Indonesia.[33] As of mid-July 2018, the unit price of a 500-mg tablet of Ponstan was PhP32.26; its equivalent in India is merely

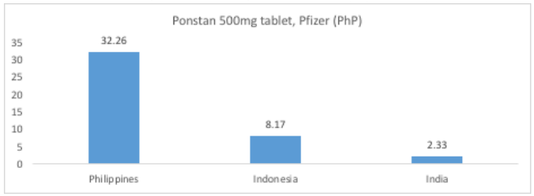
Figure 34. Philippine retail price to India retail price ratio, selected medicines



Sources: 2004 & 2010 data from Lavado (2011); 2018 basic data from CIMS India and Muramed PH

33 As of July 2018

Figure 35. Retail price of Ponstan (500mg) by country, in Philippine pesos



Sources: https://www.mims.com/philippines/drug/info/ponstan-ponstan%20sf; https://www.mims.com/indonesia/drug/info/ponstan; http://www.mims.com/india/drug/info/ponstan

PhP2.33 while in Indonesia, PhP8.17.[34] The wide gaps in the prices of these originator medicines between the Philippines and other countries may be partly attributed to taxes imposed in the country but this study did not examine this in detail.

In terms of prices of medicines within the Philippine market, this study investigated medicines listed as essential drugs in the Philippine National Drug Formulary (PNDF). The PNDF lists essential medicines that are "selected with due regard to public health relevance, evidence of efficacy and safety and comparative cost-effectiveness" (PNFP, 2008). The study focused on medicines that treat the top causes of mortality – cardiovascular diseases such as Atorvastatin, Simvastatin, Losartan, and Amlodipine, including fast-moving drug like Amoxicillin. The analysis is limited to those that have price data from websites such as the MIMS, Rose Pharmacy, and muramed.com. The paper also used self-reported retail price data from the Department of Health's Drug Price Watch (DOH Electronic Drug Price Monitoring System).

Atorvastatin (20mg), a lipid regulating agent used for prevention of cardiovascular disease costs as low as PhP5.00 (Atorbet) to PhP39.00 (Lipitor brand). The prices of unbranded generic alternatives have less variation as shown by a much narrower bar in Figure 36; prices range from PhP17.75 to PhP23.00 per tablet. The cheapest brands among those in Table 13 are Atorbet and Atorsaph, both Indian-made. Lipitor, the originator costs around 8 times the cheapest branded generic and twice the price of the cheapest unbranded generic made by Rhea (made by the same maker of Lipitor – Pfizer) and RiteMed.

Figure 36. Retail price of Atorvastatin, 20mg, by license type

Simvastatin, a substitute for Atorvastatin, is also available in different brands and prices. A 20-milligram tablet costs as low as 16 cents to as high as PhP35.50. The prices of unbranded generic alternatives have less variation as shown by a much narrower bar in Figure 37, where prices range from PhP8 to PhP14.90 per tablet. The cheapest brand among those in Table 14 is Zostatin which is made in China. Zocor, the originator, costs 200 times the cheapest branded generic and 7 times the price of the second cheapest branded generics, Lipidrex and Philstat. Lipidrex is a Philippine brand made by New Myrex while Phistat is a China-made product. The unbranded Simvastatin is 23 to 42 percent the price of the originator. Note that there is a branded generic (Vidastat) that is even more expensive than the originator. This product is German-made and is imported by Sandoz and distributed by United Laboratories.

The study also took the example of Losartan Potassium, an antihypertensive medicine. The branded generic 50-milligram tablet costs as low as PhP6.50 to as high as PhP26.75. The originator's price (Cozaar at PhP21.00) is relatively lower than the most expensive brand (United Laboratories' Lifezar at PhP26.75). The unbranded generic alternatives cost from PhP10.50 to PhP13.55. The cheapest brands among those in Table 15 (i.e., Natrasol and Angel 50) are both made in India. The most expensive brand is four times the price of the cheapest alternative. Meanwhile, the unbranded Losartan is priced 50 to 64 percent of the price of the originator.

34 As of August 27, 2018, the price of Ponstan 500 at Rose Pharmacy online was P37.25.

Table 14. Retail price of Atorvastatin (20 mg) by brand and origin

Atorvastatin, 20 mg	Brand	Price per tablet (PhP)	Origin
Originator	Lipitor	39.00	Ireland
Branded generics	Atorwin	31.75	Czech Republic
	Avamax	31.00	Malaysia
	Xentor	24.00	India
	Zydusatorva	20.00	India
	Lolip	19.46	-
	Bestatin	18.00	India
	Atorcad	14.50	-
	Saatin	12.50	-
	Atorsaph	9.00	India
	Atorbet	5.00	India
Unbranded generics	Natrapharm Atorvastatin	23.00	Canada
	Pharex Atorvastatin	18.00	-
	RiteMed Atorvastatin	17.75	Malaysia
	Rhea Atorvastatin	17.75	Philippines

Sources: MIMS Philippines, Rose Pharmacy, Muramed.com

Figure 37. Retail price of Simvastatin, 20mg, by license type

Table 15. Retail price of Simvastatin (20 mg) by brand and origin

Simvastatin, 20 mg	Brand	Price per tablet (PhP)	Origin
Originator	ZOCOR	35.00	United Kingdom
Branded generics	VIDASTAT	35.50	Germany
	SAFESTAT	29.90	Philippines
	CHOLESTAD	22.00	Thailand
	CHOLESTROL	20.00	-
	XIMVAST	20.00	-
	CARDIOSIM	15.30	-
	STAVID	15.00	-
	ZIMVAST	7.50	India
	PHILSTAT	4.75	China
	LIPIDREX	4.75	Philippines
	ZOSTATIN	0.16	China
Unbranded Generics	PHAREX	14.90	-
	RITEMED	10.25	Philippines
	ROSEMED	8.00	-

Sources: MIMS Philippines, Rose Pharmacy, Muramed.com

Figure 38. Retail price of Losartan Potassium, 50mg, by license type

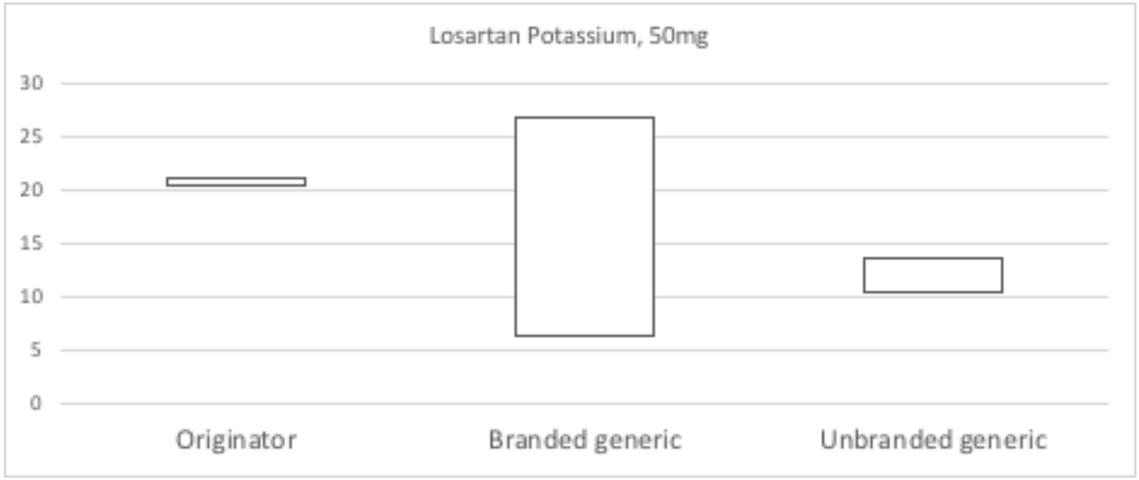


Table 16. Retail price of Losartan Potassium (50mg) by brand and origin

Losartan Potassium (50mg)	Brand	Price per tablet (PhP)	Origin
Originator	Cozaar	21.00	United Kingdom
Branded generics	Lifezar	26.75	Philippines
	Anzar	19.95	Pakistan
	Arbloc	19.00	Philippines
	Kardiostan	16.25	Philippines
	Xartan	14.90	Poland
	Losargard	12.95	Philippines
	Vivasartan	11.50	Sandoz
	Neosartan	9.25	Philippines
	Natrasol	6.50	India
	Angel 50	6.50	India
Unbranded generics	Pharex Losartan	13.55	-
	RiteMED Losartan	11.75	Philippines
	RoseMed Losartan	10.50	-

Sources: MIMS Philippines, Rose Pharmacy, Muramed.com

Figure 39. Retail price of Amlodipine besylate, 10mg, by license type

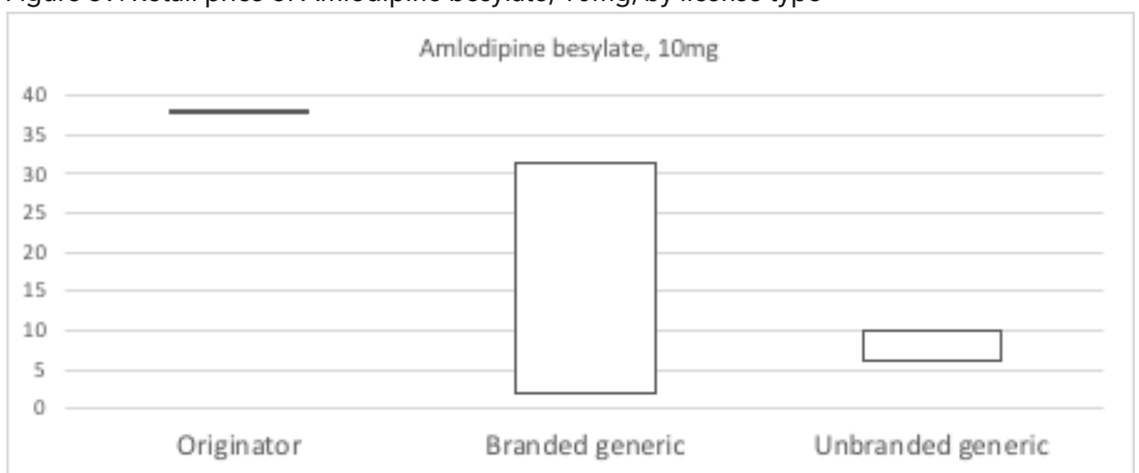


Figure 39. Retail price of Amlodipine besylate, 10mg, by license type

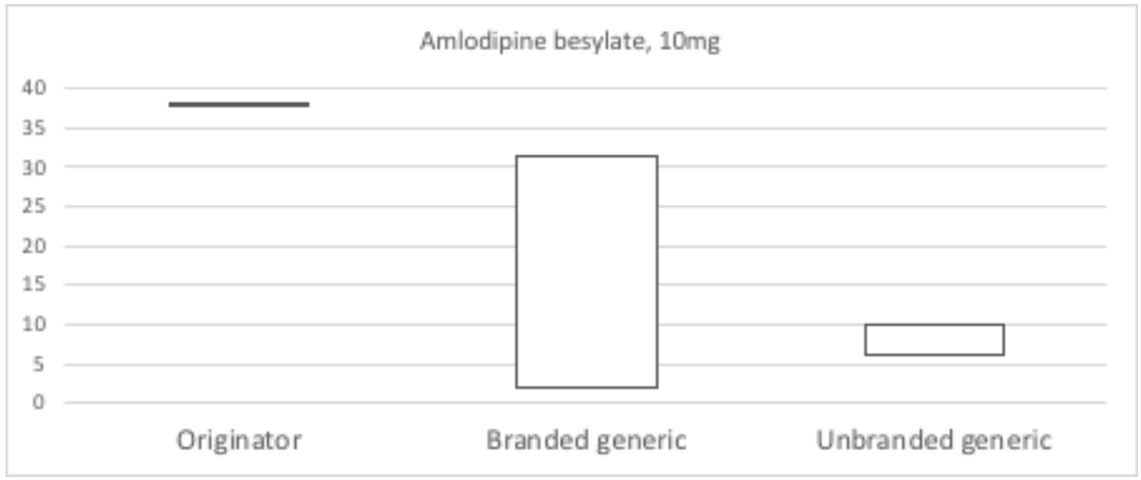


Table 17. Retail price of Amlodipine besylate (10mg) by brand and origin

Amlodipine besylate 10mg	Brand	Price per tablet (PhP)	Origin
Originator	Norvasc	38.00	Australia
Branded generics	Amvasc-BE	31.50	Philippines
	Vasalat	23.00	Canada
	Amlokard	21.00	Philippines
	Ambesyl	14.75	Turkey
	Cardivasc	12.75	-
	Aforbes	7.50	Indonesia
	Lodipex	3.00	Philippines
	Amlorex	2.00	Philippines
	Diadipine	2.00	Philippines
Unbranded generics	GX	10.00	-
	RiteMed	9.65	Philippines
	RoseMed	6.25	-

Sources: MIMS Philippines, Rose Pharmacy, Muramed.com; Note: Prices are as of August 27, 2018

Table 18. Retail price of Amoxicillin (500 mg) by brand

Amoxicillin (500mg capsule)	Brand	Manufacturer	Distributor/Trader	Origin	Price per tablet (PhP)	Price based on DOH Drug Price Watch	
						Min	Max
Originator	Amoxil , GSK			France	15.00	14.25	31.00
Branded generics	Acumox (cap)	Lloyd Laboratories	Basic Pharmaceutical	Philippines	-	-	-
	Supramox (cap)	Lloyd Laboratories	Biolink Pharma	Philippines	-	-	-
	Maelenoxyl (cap)	Lloyd Laboratories	Foramen Products	Philippines	17.70	-	-
	Himox	Asian Antobiotics	Westmont Pharmaceutical	Philippines	15.00	-	-
	Megamox	-	-	Philippines	13.25	-	-
	Bactigent	-	-	-	10.90	-	-
	Medvox	-	-	-	10.20	10.20	11.60
	Promox (cap)	Lloyd Laboratories	Heltker A.G. Corp.	Philippines	8.70	-	-
	Vaxman	-	-	-	8.50	-	-
	Medvox	-	-	-	8.00	-	-
	Trexil	-	-	-	7.75	-	-
	Medimoxil	-	-	-	6.50	-	-
	Littmox	Syn Penn Research, Inc.	Littman Drug Corporation	Philippines	6.50	9.56	9.56
	Nuevamoxil	-	-	-	6.00	6.00	16.00
	Globapen	-	-	-	5.60	5.60	13.24
	Vhellox	-	-	India	5.05	5.00	10.00
	Benedex	-	-	-	3.50	2.50	3.50
	Ambimox	CSPC Zhongnuo Pharma		China	2.50	2.50	10.00
	Amorex	-	-	-	2.50	2.50	3.00
	Harbimox	-	-	-	1.36	1.36	5.00
Unbranded	RiteMed	Asian Antobiotics	RiteMed	Philippines	7.50	7.50	8.00

Sources: Rose Pharmacy at https://www.rosepharmacy.com/, www.muramed.com, MIMS Philippines, and DOH Drug Price Watch, Retrieved August 26, 2018

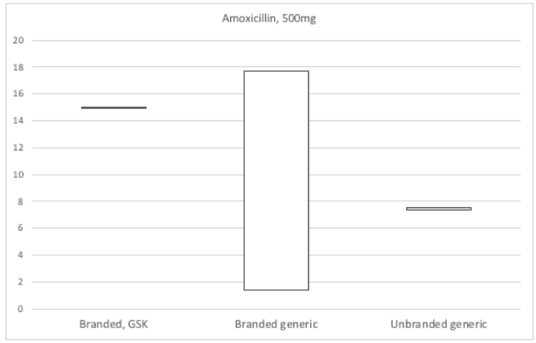
The prices of another important prescription medicine – Amlodipine, which is used to treat high blood pressure, coronary artery disease and angina or chest pain were examined. The branded generic 10-milligram tablet costs as low as PhP2.00 to as high as PhP38.00. The originator's price (Norvasc at PhP38.00) is 19 times the cheapest brands (e.g. Amlorex and Diadipine, sold at PhP2.00 per tablet). The price of the unbranded generics ranges from PhP6.25 to PhP10.00. Unlike the above-discussed medicines, the cheapest brands of Amlodipine available in the market are locally made. Unbranded generics are also relatively affordable as they are about 16 to 26 percent the price of the originator.

Another example is Amoxicillin, an antibiotic (Table 18). The price of one capsule of Amoxicillin (500mg) is as low as PhP1.36 and as high as PhP17.70 based on price data from Rose Pharmacy website, muramed.com, and MIMS Philippines. This wide range applies to branded generics. The unbranded generic costs only half of the price of originator. The medicines at the lower end of the range comprise of China-made Ambimox, Indian products Vhellox, Amorex, and Harbimox while those at the higher end are medicines made in the Philippines – Himox and Maelenoxyl. The only unbranded medicine in Table 18 is RiteMed. The GSK-made Amoxil is made in France. It is interesting to see two brands (Himox and RiteMed) having the same manufacturer but whose prices vary such that the high-priced brand (Himox at PhP15.00) costs twice the lower-priced brand (RiteMed at PhP7.50). Such is also the case of Maelenoxyl and Promox manufactured by Lloyd Laboratories but marketed by different companies.
The abovementioned prices are based on online sources but data from the DOH database, Drug Price Watch, show that prices vary depending on the retail store or hospital. Although the originator, Amoxil, costs PhP15.00 based on online sources, the actual price ranges from PhP14.25 to as high as PhP31.00 per unit. One of the cheapest brands, Ambimox, is priced as low as PhP2.50 and as high as PhP10.00. It should be noted, however, that the DOH data do not contain complete list of all prices because not all retail stores submit data to the price monitoring system. The drugstores that provide data to the system are The Generics Pharmacy, South Star, Chavez Pharmacy, Generika, and Manson Drug. There is also a good number of hospitals submitting data into the system.

This paper also looked into the retail prices of another antibiotic – Co-Amoxiclav, used for the treatment of a number of bacterial infections. In Table 18, the price for each 500mg/125mg tablet/capsule ranges from PhP25.00 (TGP, Arvoclav, and Comxicla) to PhP50.50 (Natravox). The price of the originator, Augmentin, also approximates the highest priced brand at PhP49.00 per piece (Figure 41). Again, the pattern is quite similar to the previously discussed medicines, India is the origin of the more affordable brands; locally-made medicines are significantly more expensive (i.e., twice the price of the cheapest brands). Unbranded generics cost 51 to 74 percent of the originator's price. Again, the price of medicines made by the same manufacturer varies depending on the traders, an indication that the two brands target different markets. RiteMed's Co-amoxiclav costs 75 percent of the price of Amoclav. Both of these are made by Bilim Pharma in Turkey. Prices of medicines manufactured locally by Lloyd Laboratories also have varying prices, from PhP45.25 to PhP50.50. It is quite disturbing to see that based on DOH drug price watch, the originator's price can go as high as PhP95.00, which is twice as expensive (Table 18) and depends on the channel of distribution (retail store or hospital). This is also the case of branded generics Amoclav and Bactiv.

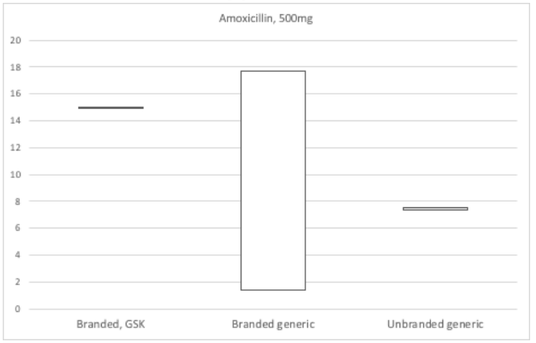
Mefenamic Acid, a fast-moving drug, was also analyzed. Its price starts at PhP1.75 to PhP37.00, depending on the brand. Unbranded generics are offered as low as 12 percent of the originator's price. This time, Philippine-made brands are the cheapest among the available options but still, the most expensive ones (originator Ponstan, and branded generics Revalan and

Figure 40. Retail price range of Amoxicillin Trihydrate (500 mg capsule) by license type



Sources: Rose Pharmacy at https://www.rosepharmacy.com/ and www.muramed.com, Retrieved August 26, 2018

Figure 41. Retail Price range of Co-Amoxiclav (500 mg/125 mg) by license type



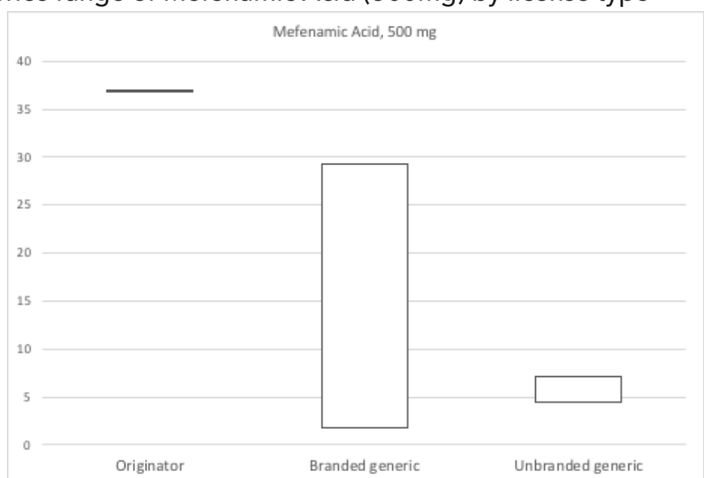
Sources: Rose Pharmacy at https://www.rosepharmacy.com/, www.muramed.com, MIMS Philippines, and DOH Drug Price Watch, Retrieved August 26, 2018

Table 19. Retail Price of Amoxicillin Co-Amoxiclav (500 mg/125 mg) by brand

Co-Amoxiclav (500mg/125 mg tablet)	Brand	Manufacturer	Distributor/Trader	Origin	Price per tablet (PhP)	Drug Price Watch	
						Min	Max
Originator	Augmentin	Smithkline Beecham	GSK Philippines	United Kingdom	49.00	48.90	95.00
Branded generics	Natravox	Lloyd Laboratories	Natrapharm	Philippines	50.50	48.90	97.00
	Amoclav	Bilim Pharma	United Laboratories	Turkey	48.40	48.90	105.00
	Clovimax	Lloyd Laboratories	Vamsler Phils.	Philippines	45.75	83.15	83.15
	Sullivan	Lloyd Laboratories	Medhaus Pharma	Philippines	45.25	-	-
	Bactoclav	Micro Labs	OEP Philippines	India	43.75	38.00	38.00
	Bactiv	Aurobindo	The Cathay Drug	India	39.60	39.60	64.00
	Auget	-	Getz Pharma	-	38.50	38.50	38.50
	Descari	-	-	-	35.00	35.00	35.00
	Aumox	-	The Generics Pharmacy	-	33.00	33.00	33.00
	Comxicla	Indchemie Health	Suhitas Pharma	India	25.00	19.60	30.00
	Arvoclav	M.s. M/K Pharma	ArvinCare	India	25.00	-	-
Unbranded generics	RiteMed	Bilim Pharma	United Laboratories	Turkey	36.25	-	-
	TGP	-	-	-	25.00	25.00	25.00

Sources: Rose Pharmacy at https://www.rosepharmacy.com/, www.muramed.com, MIMS Philippines, and DOH Drug Price Watch, Retrieved August 26, 2018

Figure 42. Retail price range of Mefenamic Acid (500mg) by license type



Sources: Rose Pharmacy at https://www.rosepharmacy.com/, www.muramed.com, MIMS Philippines, and DOH Drug Price Watch, Retrieved August 26, 2018

Table 20. Retail Price of Mefenamic Acid (500mg) by brand

Mefenamic Acid (500 mg)	Brand	Manufacturer	Distributor/Trader	Origin	Price per tablet (PhP)	Drug Price Watch	
						Min	Max
Originator	Ponstan	Interphil	Pfizer	Philippines	37.00	36.25	57.00
Branded generics	Revalan	Amherst Laboratories	BioFemme	Philippines	29.25	27.50	44.79
	Dolfenal	Amherst Laboratories	Westmont Pharma	Philippines	26.25	26.25	45.00
	Gardan	Sanofi-Synthelabo	Sanofi-aventis Philippines	Vietnam	26.25	26.25	26.25
	Istan	-	-	-	10.30	10.30	23.58
	Mefenax	Hizon Laboratories	One Pharma	Philippines	10.13	10.13	14.00
	Selmac	Lloyd Laboratories	Prosel Pharma	Philippines	8.50		
	Ponser	Lloyd Laboratories	Medhaus Pharma		6.44	6.44	9.24
	Stangesic	Hizon Laboratories	GX International	Philippines	5.10		
	Dolsten	-	-	-	4.75	3.75	3.75
	Megyxan	Sapphire Lifesciences	Nelpa Lifesciences	India	4.50		
	Analmin 500	Flamingo Pharma	Pasteur Pharma	India	2.50	3.00	7.00
	Biomef	Drugmakers	Biotech Research	Philippines	2.00		
	Flamic	-	TGP	-	2.00	2.00	
	Megalin	New Myrex	TGP	Philippines	1.75	1.75	2.50
	Myrefen	New Myrex	-	Philippines	1.75	1.75	1.75
Unbranded generics	RiteMed	Amherst Laboratories	RiteMed	Philippines	4.45	4.50	4.50
	Pharex	-	-	-	7.10	7.10	7.10

Sources: Rose Pharmacy at https://www.rosepharmacy.com/, www.muramed.com, MIMS Philippines, and DOH Drug Price Watch, Retrieved August 26, 2018

Dolfenal) are also locally-made. Again, there are varying prices for products of the same manufacturer. RiteMed sells its Mefenamic Acid at PhP4.45 a piece, equivalent to only 17 percent of the price of Dolfenal, a brand with the same maker, Amherst Laboratories. Variation in the pricing of the same brand can also be observed depending on who sells it (i.e., retail store or hospital). Ponstan is priced at PhP36.25 to PhP57.00; Dolfenal is sometimes sold at PhP26.25 but its price goes up to as much as PhP45.00 in others (Table 19). Such price differentiation is also observed for Atorvastatin and Amlodipine (Table 6 in the Appendix).

There seems to be a trend in the average prices of medicines based on the profile of its maker. For Atorvastatin, the mean prices of medicines from smaller and medium-sized firms (i.e. PhP12.50 to PhP15.50) are relatively lower than those in the bigger companies (ranging from PhP18.56 to PhP27.38). This is somewhat similar with Simvastatin where smaller and medium companies offer the 20-milligram tablet ranging from PhP9.56 to PhP22.00 while the bigger/top companies sell a similar tablet from PhP13.25 to PhP25.15 (Table 18). Industry actors distinguish the two groups as "traded" drugs and "promoted" drugs, respectively. Traded medicines pertain to those that go directly to traders, without being promoted while promoted drugs are those that are marketed and promoted, hence, generally more expensive.

With regards to price movements based on license type, the study found a relatively stable price for the originator of Amlodipine, Norvasc. Its price barely moved from PhP38.50 to PhP38.00 during the period

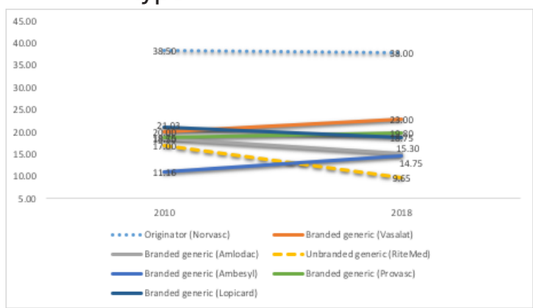
Table 21. Retail price of lipid regulating agents by type of company

Company type	Atorvastatin, 20 mg	Simvastatin, 20 mg
Originator	39.00	35.00
Top 20 (mean)	27.38 [1/]	25.15 [6/]
Bigger (mean)	18.56 [2/]	13.25 [7/]
Medium (mean)	12.50 [3/]	22.00 [8/]
Smaller (mean)	15.49 [4/]	9.56 [9/]
Unilab (mean)	24.38 [5/]	22.88 [10/]

1/ Mean (Atorwin, Natrapharm Atorvastatin); 2/ Mean (Xentor, Zydusatorva, Saatin, Rhea); 3/ Mean (Bestatin, Atorcad, Atorbet); 4/ Mean (Lolip, Pharex, Atorsaph); 5/ Mean (Avamax, Ritemed); 6/ Mean of Cardiosim, Zocor; 7/ Mean of Lipidrex, Stavid, and Ximvast; 8/Cholestad; 9/ Mean of RoseMed, Philstat, Zostatin, Pharex, Cholestrol; 10/ Mean of Vidastat and RiteMed; Sources: MIMS Philippines, Rose Pharmacy, Muramed.com

2010 to 2018 (Figure 41). In contrast, the more affordable unbranded generic (RiteMed) has become even more affordable through time; its price was slashed by about half – from PhP17.00 to PhP9.65 during the same period. The price changes for branded generics vary depending on the brand. Vasalat, a Canadian-made product has become more expensive; this is also the case of Ambesyl (which is made in Turkey). The brands that have reduced their prices through the years are Lopicard and Amlodac[35].

Figure 43. Retail price movements of Amlodipine Besylate by license type



Sources: MIMS Philippines, Rose Pharmacy online, muramed.com

The foregoing discussion provides several insights about medicine prices in the Philippine market. First, the prices of selected medicines in the Philippines remain high compared to other sources of medicines like India and Indonesia. It was also found out that there is a substantial variation in the prices of the medicines that were examined. In particular, branded generics have a wide variety of prices. Those at the lower end of the price range usually consist of imported medicines from India and China, although there are some affordable ones that are locally-made. The average price of unbranded generics is usually half the originator's price. It was also noted that the prices of unbranded generics vary less. Whether this is related to the sub-sector of unbranded generics becoming more concentrated through the years is something that requires a deeper analysis. But the price of unbranded generics, such as RiteMed, has gone down significantly through the years while that of branded generics either went up or down depending on the brand. The presence of such alternatives is important amidst the originator's constantly high price. Lastly, there seems to be a pattern in the pricing such that smaller firms or those that have very small share in the market impose relatively lower average price, while the relatively bigger ones impose relatively higher prices. This is perhaps attributed to the distinction between 'promoted' versus 'traded' drug products.

The discussion on different prices of brands with the same maker illustrates that different prices do not always reflect different quality. Several brands made by the same company have the same quality as these went through the same facility and processes. It does not make sense to assume these were produced differently because of the importance of economies of scale in the production of medicines. The price differences can be attributed to: (1) varying capacity for distribution by the trader or marketing authorization holder (MAH); (2) varying capacity for marketing; or (3) different market or target population. The

35 Unfortunately, the authors could not find data about the origins of these brands.

actual reasons behind the price differences is an important area that requires in-depth research.

A significant finding of this price data analysis is that the price of a brand of medicine can have extensive variations. Using DOH's Drug Price Watch, it can be observed that the price of certain brand varies depending on who is selling them (retail store or hospital). Further research must be done to determine whether this is attributable to location or simply the tendency to generate more profits. Another surprising pattern in the pricing particularly of some hospitals is the imposition of the same price for both originator and generic brands. For instance, Lipitor, Atorvast, and Avamax are sold at PhP39.13 each 20mg tablet but Avamax costs less than PhP33.00 in retail stores, while Atorvast is sold at PhP23.00. The 5-mg Amlodac, Vasalat, are priced similarly to Norvasc, at PhP22.85. Vasalat costs only PhP14.25 in retail stores. The 500-mg tablet Azithromycin as Dihydrate Azimin, Azithro Natrapharm, Zenith, and Zithromax are priced at PhP151.43. Zenith costs PhP137.00 in retail stores, while Azimin costs PhP56.50 in other hospitals. Hence, consumers do not enjoy the benefit of the cheaper generic brand because these are priced as the originator.

5. Regulation of the Pharmaceutical Industry

5.1. Licensing and drug registration

In the Philippines, the regulatory authority that issues licenses to operate (LTO) and registers drugs is the Food and Drug Administration (FDA). The FDA ensures the pharmaceutical establishments comply with quality standards, have good manufacturing practices (GMP), as well as good storage and distribution practices. Prior to importation, distribution, marketing, advertising or manufacturing of pharmaceutical products in the Philippines, an establishment must first obtain a license to operate (LTO) as importer/distributor/wholesaler for imported products or as manufacturer, for locally manufactured products. Application for a Certificate of Product Registration (CPR) is possible only after the issuance of LTO to a company. The process starts with filing of application, followed by an interview with the Food and Drug Registration Office (FDRO). The Licensing Department reviews the application requirements, and issues order for payment to the applicant. The applicant requests for schedule of physical inspection of office and facility by the FDRO. Approval by the department director and release of LTO documents come after physical inspection.[36] This processing of LTO for distributors, importers and retailers takes 30 calendar days to complete. However, an informant revealed that getting the license to operate at the retail level may take up to 6 months.

Further, the inspection process for drug manufacturers entails 60 days. After the inspection, manufacturers go to FDA for processing and evaluation. The license is released upon compliance.

The whole licensing process, which is done electronically (i.e., e-LTO) since September 2016, takes approximately 90 calendar days. A Risk Management Plan (RMP) is required for the granting of LTO, on top of other requirements, as mentioned.

Prior to manufacturing of drugs for consumption, producers register their products with the FDA. The validity of new registration is 5 years while 2 years for renewal. Drug registration process takes 254 calendar days for initial drug registration. For automatic renewal (no variation to original registration), the process takes 31 calendar days, while the processing for regular renewal depends on the variation of the drugs being registered. Variation pertains to change in ownership, labeling, etc. While these are FDA's policy pronouncements, the processing time varies depending on the case. Some key informants reported that processing of new drug registration actually takes two years. Table 22 below shows the actual timeline

36 http://www.tripleiconsulting.com/fda-license/

Table 22. Examples of actual drug registration timelines

Product	Submission Date	Status to date (February 2018)	Remarks
Metoprolol Tablet	1/26/2013	No feedback since 9/26/2016 (no approval)	5 years (2 NODs were is-sued in 2014 and 2016. Company complied.)
Chlorphenamine + Phe-nylphrine	07/09/2013	No feedback since 1/24/2014 (no approval)	4 years (NOD issued in 2014. Company complied)
Paracetamol + phe-nylephrine hcl + chlor-pheniramine maleate 500mg/10mg/ 2mg tablet	7/16/2013	No feedback since 7/16/2013 (no approval)	4 ½ years
Ambroxol Hydrochloride 15mg/5ml	9/2/2013	No feedback since 12/9/2014 (no approval)	5 years (2 NODs were issued in 2014. Company complied.)
Co-amoxiclav 500mg/125mg Film Coated Tablet	12/06/2017	Released 12/22/17	16 days processing only

Source: PCPI Secretariat

and status of some drug registered with the FDA based on PCPI records. The timeline ranges from 16 days to 5 years.

There are a number of requirements for drug registration and renewal of old products. One of the key requirements for the registration of generics is the bioequivalence (BE) test. The BE test is done to ensure that the drug for registration is at least 90 percent similar to the originator or comparator drug. To quote the WHO on the definition of bioequivalent – "Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives, and their bioavailabilities, in terms of rate…and extent of absorption…, after administration of the same molar dose under the same conditions, are similar to such a degree that their effects can be expected to be essentially the same."[37]

On the other hand, some generic products that are highly soluble/permeable are not required to undergo and pass the BE test. A biowaiver test is conducted to determine the need for BE test. The process is costly in terms of use of facility and personnel. In the Philippines, however, not all molecules that are required to pass the BE test can use the biowaiver to be duly-registered with FDA. The process of the BE includes the clinical test, bioanalytical test, which is the most expensive component, and the writing of the BE document. A key informant noted that the bioequivalence study costs at least PhP1 million pesos depending on the number of testing subjects involved. For medicines that require 18 human subjects in the clinical trial, the cost is around PhP2-3 million.[38] For those that require 48 human subjects, like Simvastatin, the cost is around PhP6 million. The length of BE process could vary depending on the testing center that an establishment uses. Some informants report that it takes at least 6 months to one year for one BE testing process (including documentation).

Some industry informants claim that requiring all oral preparations (per WHO recommendation) to undergo and pass the BE test was unprecedented; without adequate time to prepare, establishments were badly hit. But the concept of the BE/BA for drug registration is not new. It started in 1989 through Administrative Order 67 (AO 1989-67). BFAD then released a set of drugs under List B-Prime (B') as those that require bio-availability studies for registration. However, there were no bioavailability testing units in the country when the A.O. 67 s. 1989 became effective. Hence, the Bureau did not strictly enforce the said requirement. On January 21, 1997, the agency enforced AO 1989-67 and required all drug manufacturers, traders and distributors and importers to have bioavailability testing for 104 products that make up the List B-Prime. However, again due to lack of bioavailability/bioequivalence

37 http://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex7-TRS992.pdf
38 Based on KII

data, selective moratorium was imposed in 1999 (via Bureau Circular 1999-13A), with Rifampicin-containing oral preparations as the only drug that requires BE/BA test. The Circular also provided that such requirement would be imposed when bioanalytical methods are available for other products in List B-Prime. Then in 2006, through Bureau Circular 2006-008A, the FDA lifted the moratorium and included 11 drugs to the existing Rifampicin to be subjected to BE; the FDA likewise provided a list of reference drugs for the additional 11 molecules. This brings the number of drugs requiring BE/BA to 12.

In 2013, the FDA promulgated FDA Circular 2013-014, which requires to expand the coverage of the BE/BA requirement, effective 1 July 2013, to all Biopharmatics Classification System (BCS)[39] class IV APIs as determined by the WHO. These are molecules that have low solubility and low permeability properties. The same directive likewise requires that effective 1 January 2014, the BE/BA requirement is further extended to include not just the BCS class IV drugs, but also the following: (1) the BCS class II (low solubility, high permeability) drugs which are not eligible for biowaiver; (2) generics products marketed after patent expiration of innovator; and (3) all modified-release oral preparations.

Aside from the high cost of a BE test, especially for an establishment that has a limited manufacturing capacity and market presence, some key informants noted that there are inadequate BE testing centers in the country. Aside from CEDRES stationed in Alabang, the other testing centers mentioned were Pharmalytics and De La Salle University Hospital in Dasmariñas, Cavite. Setting up a testing laboratory requires heavy investment which explains why there is only a handful of testing centers in the country.

Despite this, the KIIs revealed that there are only few companies bringing their products for bioequivalence test. This is according to representatives of the CEDRES, the only testing center in the country which conducts the complete process of BE test. CEDRES conducts only around 30 BE tests annually and that the center is not in full capacity. The available facility determines the timeline for doing the BE test. CEDRES noted that under regular circumstances, the whole process takes around 100 days with its facility manned by 30 persons; 26 of which are all technical personnel.

CEDRES revealed that there is no queue for BE testing at CEDRES and that only a small number of companies producing generic products utilize its service. Its usual clients are local pharma manufacturers. This is inconsistent with the contention of some stakeholders that the queue at BE delays the process. In response, some industry informants claimed that the absence of a queue at CEDRES is because the test is costly for smaller local pharmaceutical establishments. Indeed, the cost of the BE is a significant barrier: some companies pay the testing fee on installment basis according to CEDRES.

5.2. Comparative qualitative analysis

The interviews with key informants in the industry left an impression that pharmaceutical regulation in the Philippines is more stringent than in other comparable countries. Hence, pharmaceutical regulatory environment in the Philippines was also examined in comparison with other countries in Asia. The examination focused on countries that have similar systems as the Philippines. Both Indonesia and Vietnam are suitable comparators because these have out-of-pocket health payment systems like the Philippines. It would be difficult and inappropriate to compare the Philippines with those that have different systems like Malaysia and Thailand which implement reimbursable health systems. It could be interesting to understand the policies behind the globally competitive Indian pharmaceutical industry as it is known as “pharmacy of the world”. Hence, India is a good benchmark. In addition, like the Philippines, India, Indonesia, and Vietnam are all rapidly growing economies. This section aims to provide an overview of the salient differences between these countries’ pharmaceutical industry regulatory contexts to draw general understanding, and does not intend to provide in-depth comparative assessment.

The pharmaceutical markets of the Philippines, Vietnam and Indonesia are relatively at par with each other. Indonesia's market is valued at US$6.2 billion in 2016 while the estimate for Vietnam for 2017 is US$ 5.2 billion, although both higher than the 2016 estimate for the Philippines (US$3.5 billion). The Indian's pharmaceutical market (US$27.6 billion) is nowhere near. Both markets of Indonesia and Vietnam have been growing double digits at 10 percent and at least 17 percent, respectively; India’s growth is slower at 5.6 percent.

The Philippine market on the other hand has been growing at 8 percent annually. The CPBI data shows that there are only 71 drug manufacturers in the Philippines. In Vietnam, there are 170 while Indonesia has 206. In contrast, India has over 10,000 manufacturing units. In terms of exports of pharmaceutical products, the Philippines lags behind Indonesia, Vietnam and India. In 2015, the value of Philippine exports was only US$50.6 million vis-à-vis Vietnam's US$113 million, and Indonesia's US$586 million. But all of these are dwarfed by India’s exports amounting to US$16.89 billion.

In the Philippines, foreign entities own up to 99 percent of the paid-up capital in pharma establishments that manufacture, import, and distribute medicines. The country's largest distributor of pharmaceuticals is a 99.99 percent foreign-owned company – Zuellig Pharma Corporation. In India, pharma companies can be 100% FDI because of the Indian government's thrust of attracting multi-nationals to further enhance the country's competitive advantage in the global market. In contrast, foreign entities are allowed to import and manufacture but not to distribute in Vietnam; such is allowed only for domestic companies. In contrast, Indonesia only allows up to 85 percent foreign investment in manufacturing but none in distribution and importation. In other words, foreign or multi-national entities are excluded from the important drug distribution and importation business. In manufacturing pharmaceuticals, they are also required to manufacture drugs locally or partner with locals prior to registration of their products. Indeed, among the four markets, the role of multi-nationals/foreign players is largest in the Philippines with 57 percent share of its domestic market. In Indonesia, this is equivalent to only 20 to 25 percent; while in Vietnam, the share is only 20 percent (domestic production). Market control of MNCs in India is also comparatively lower at 30 percent.

The growth of India’s pharmaceutical industry can be attributed to the role played by small and medium enterprises (SMEs) since the country allows third-party manufacturing or what is termed as loan licensing. Manufacturers offering loan licenses only need to seek approval from regulatory agencies for quality adherence. The Indian Drug Manufacturing Association (IDMA) estimates that more than 40 percent of drug production in India is generated through loan licensing.[40] For multinational companies, the percentage of drugs manufactured through third parties ranges from 50 to 90 percent. It is reported that SMEs are still in the process of adopting GMPs.[41] Recently, it was proposed that loan licensing be scrapped for reasons concerning quality. The proposal is to phase out this practice over the next three years or be allowed for only a maximum of 10 percent of the company’s total production. This proposal, however, has received strong disapproval from industry players. In terms of regulation, it is reported that pharmaceutical companies in India do not go through complex certification

39 The Biopharmaceutics Classification System (BCS) was proposed in 1995 by Amidon et al.1 It is a scientific framework which divides active pharmaceutical ingredients (APIs) into four groups, according to their solubility and permeability properties.

40 http://www.livemint.com/Industry/q8sAJkHB6v3tfdi0akImHO/Govt-proposal-to-scrap-loan-licensing-in-draft-pharma-policy.html; http://www.livemint.com/Industry/5N30F4unfm7gJew2m1rJwl/Industry-wary-over-governments-new-pharma-policy.html; https://www.biosimilar-development.com/doc/india-s-draft-pharmaceutical-policy-a-game-changer-0001 Retrieved January 31 2018

41 https://www.slideshare.net/InstantGMP/what-is-gmp-in-india

procedures; FDA of India only conducts facility inspection for products going to the US market.

In the Philippines, there is no such thing as loan licensing. Only duly-registered manufacturers are allowed to manufacture pharmaceutical products; requirement for product registration is a GMP clearance; there is also pre-opening and post-licensing inspection; post-licensing may also be required prior to any major variation (change of ownership, additional production line, transfer of location, change of activity). Foreign-sourced Certificate of Product Registration (CPR) is valid upon compliance to documentary requirements of the FDA.

The Philippine pharmaceutical industry faces competition from countries that incentivize local production in their own pharmaceutical industries. For instance, in Indonesia, multi-national companies wanting to enter the local market must satisfy several requirements. Within 5 years of initial registration, a foreign pharmaceutical company has to manufacture drugs locally; transfer technology; and form partnership with a local manufacturer for it to register its medicines (Decree 1010, 2008). There are some exceptions, and these include patented products and those that due to restrictions on manufacturing capacity cannot be produced locally.[42] Moreover, importation of products locally available is not allowed. Based on 2014 data, 90 percent of registered drugs in Indonesia are locally manufactured. Meanwhile, Vietnam has enacted a new Law on Pharmacy, promulgated in 2016, which prioritizes the purchase of locally produced products such as locally manufactured generics and biosimilar, herbal and traditional medicines manufactured in domestic facilities satisfying good manufacturing practice standards. Vietnam also grants some selected pharmaceutical molecules exclusively to Vietnamese manufacturers. To cite one report: "…the new law reflects a preferential treatment for domestically produced drugs over imported drugs …. That is, when domestically produced drugs are available that satisfy the Ministry of Health's requirements on medical treatment, price, and supply, the dossier for a drug tender must stipulate that tenderers are not allowed to offer imported drugs. As a result of those regulations, there are more foreign pharmaceutical companies considering the option of going 'local'."[43] Moreover, the Vietnam government plans to invest around US$1.5 billion to boost the domestic pharmaceutical sector and reduce imports. While it is a policy of the Philippine government to promote local production of essential medicines as stipulated in the Philippine National Drug Formulary, there seems to be no clear directive or policy that specifically incentivizes local production.

There are also differences in terms of the bioequivalence test as a requirement for drug registration. The Philippines' FDA requires all generic oral preparations to undergo bioequivalence test. But Indonesia requires BE for only 88 molecules while Vietnam requires the test for 12 molecules. India, itself, does not require its producers to conduct BE tests on drugs for local consumption. Its international clients, however, require Indian manufacturers to have their products tested.[44]

42 https://www.pacificbridgemedical.com/publication/2013-indonesia-pharmaceutical-market-update/

43 https://www.tilleke.com/sites/default/files/IC_2016_Aug_New_Pharma_Law_in_Vietnam_1.pdf

44 Some Indian pharmaceutical companies have had some challenges involving the BE test. In 2009, India's biggest drug manufacturer and one of the largest generics supplier in the world – Ranbaxy Laboratories – has been penalized by the US FDA after the latter caught the company falsifying data from one of its Indian manufacturing plants. In 2013, a whistle-blower also accused the same company of faking bioequivalence test results. For this, the company paid US$500 million as settlement, the largest-ever amount paid by a generic manufacturer over drug safety. In 2014, the German regulator BfArM reported that it suspended the marketing authorizations for all products whose approval was based on bioequivalence data produced by GVK Biosciences, a contract testing facility in Hyderabad, India. Prior to this, the French regulator ANSM has also raised serious concerns about GVK's conduct of the clinical part of the bioequivalence trials in that same facility. BE tests are required of Indian producers supplying to the US and Europe, and other developed countries but within India, the BE test is not a requirement. Such requirement has been proposed in 2013 but was later rejected by India's Drug Consultative Committee on the basis of commercial feasibility. The body noted that since 'the infrastructure for conduct of such studies is not uniformly available in the country it cannot be implemented as a rule." India implemented this requirement to 'some' medicines only in 2017. In contrast, the Philippines' FDA requires all generic oral preparations identified by the WHO and which did not pass the biowaiver test to undergo the BE test starting 2013-2014.

6. Issues or areas requiring improvement

The foregoing discussion indicates that the regulatory environment in the Philippines seems to be more stringent than those in other countries reviewed. However, despite the sophistication of Philippine regulations, the host of issues and challenges are difficult to ignore and requires urgent understanding and proper action.

6.1. Lengthy drug registration process

The slow drug registration process constrains the ease of entry in production based on interviews with key informants from both small and big pharmaceutical companies. This lengthy drug registration process is a hurdle that gets in the way of timely product launches for companies to recover their investments. Pharmaceutical manufacturing has become more capital-intensive than ever before. It no longer is a business for the small and medium enterprises (SMEs) because of the heavy investments needed for physical infrastructure to adhere to strict quality standards, on the R&D of formulations, and on carrying out expensive bioequivalence tests.

While all industry players, big and small, manufacturers and importers, face the same predicament, the extent of effects varies depending on the nature of the activities undertaken by pharmaceutical companies. Big pharmaceutical manufacturers can spread the costs of such investments, while smaller ones have lower capacity to recover from business losses. Between importing and producing the goods locally, the findings suggest that there is greater incentive in importation since a company does not have to: (1) invest heavily on infrastructure, and (2) conduct expensive R&D and bioequivalence tests. The implication of such is that, in the future, there may be less and less domestic manufacturers, or the smaller ones may tend to consolidate. It is also possible that the bigger ones acquire the smaller ones which are unable to compete with those with high investments and high marketing capacity.

When asked about the problem of slow registration process, the FDA mentioned some issues concerning personnel, infrastructure, the recent increase in the number of requirements, and lack of coordination between holders of 'mother and baby' certificate of product registration (CPR). The drug registration unit at FDA has only 62 plantilla personnel but not all of these are filled in. The total number of personnel at FDA, including those at the regional offices, is around 900. However, there are only about 60 evaluators handling human drugs. There are only two (2) evaluators for drug registration via the CLIDP (Certificate of Listing of Identical Drug Product) channel. For a better perspective on how these numbers weigh against the annual load of drug registration, there are 29,000 units of drugs that are registered or in need of registration as of November 2018.[45]

With regards to infrastructure, FDA has an online system of submission of application requirements but because of the numerous and complex requirements, the electronic files are big, and such could not get through FDA's electronic system. Applicants are therefore required to manually bring their data storage units to FDAC to submit the application materials. Such bottleneck is worsened by a recent increase in the number of requirements. Prior to 2013, the FDA imposed on manufacturers/traders to have BE test of only 12 generics (oral preparations) but the inclusion of all oral preparations (per WHO directive) in 2013-2014 to undergo the BE has added to the mounting backlogs of the FDA.

There are also some aspects beyond the control of FDA which contribute to the length of the registration process such as the lack of coordination between holders of the "mother and baby" CPR (in the CLIDP registration system) in the renewal application. The CLIDP system was created to address concerns of unnecessary

45 Per FDA informant

duplication of technical dossier evaluation in relation to the registration of identical drug products, defined as having identical drug formulation and manufacturer/source of finished product with that of the principal product. Companies who want to market the same product that was already registered by another company must register under the CLIDP system which normally takes a shorter turnaround time. The holders of the principal registration and the 'baby' registration must coordinate during application for renewal to avoid delays. The FDA noted that such coordination failure may cause further setbacks in the process.

6.2. Lack of dialogue between industry and regulator

Some industry players lament the lack of dialogue between them and the regulator. The KIIs show that the FDA lacks openness in its policy-making process where industry hardly participates in the process and that there is a very small window for interaction. Currently, FDA's system of formal communication and coordination is through the FDAC (Food and Drug Action Center), 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; the same facility where FDA also provides the outcome of the application process. The facility strictly follows a queueing system therefore those with inquiries or requests (including the data requests made by the authors of this report) to the FDA course their concerns through the FDAC. The entire application cycle may take time because concerns are not immediately conveyed and therefore answers are delayed. In response, the FDA acknowledged such need and noted that it has commenced its regular session of dialogue between the industry and the regulator, called "Kapihan" where industry issues are discussed.

6.3. Reliance on imports

While the Philippine pharmaceutical market grows quite robustly, the trend is towards greater reliance on imported medicines, at least based on the number of registered drugs at FDA. In the minds of some local industry informants, the increased reliance on imports especially from countries that do not have the same strict standards as that of the Philippines' FDA raises questions on quality and integrity. For instance, in countries that implement a policy allowing licensed pharmaceutical manufacturing companies to loan out their license to third-party producers, the manufacturer identified in the product's packaging may not necessarily be the facility that actually manufactures the product. And because one cannot trace who the maker is, this tends to stir doubt with respect to the quality, efficacy and safety of the product.

6.4. The problem with counterfeit drugs

The FDA notes that counterfeit drugs exist in the market and the real magnitude is unknown. In recent reports, Paracetamol is said to have been targeted by counterfeit drug producers. In January 2018, some US$3 million-worth of counterfeit medicines were seized in Manila.[46] The Philippine President has since ordered the crack-down on all facilities that are involved in the production of counterfeit drugs.

The percentage of counterfeit medicines are larger 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. In the US, counterfeiting and piracy cost their economy more than US$200 billion each year and account for the more than 750,000 job losses. Estimates made by the World Health Organizations (WHO) show that counterfeit medicines account for 10 percent of the US$300 billion industry in low and middle-income countries.[47]

Researchers cautioned the public that the internet has been channeling counterfeit medicines that are difficult to trace (Blackstone, et al 2014). In November 2017, the FDA warns the public against fake drugs circulating through the internet. FDA Mindanao head, Annette Tan revealed that at least 90 percent of the products including drugs, food supplements and cosmetics being sold online are not FDA-registered.

6.5. Smaller local players' difficulty in competing with bigger firms

Local manufacturers/traders note their difficulty in competing with bigger ones. Only few products manufactured locally have economies of scale; hence local production is costlier. Based on PPMA's report, the cost of 10 kilograms of active pharmaceutical ingredient (API) Amlodipine is PhP14,153 per kilogram while that for a bulk purchase of 1,000 kilograms, cost is only PhP7,215.00 per kilogram or roughly half the price for 10 kilograms.[48] The inability of local manufacturers to compete is perhaps due to the fact that all raw materials are imported from abroad; a depreciation of the Philippine peso therefore adversely affects these imports. The problem also lies with high labor costs and power costs. Small companies have also difficulty paying for bioequivalence tests –sometimes paid on installment. Smaller companies also lack marketing capacity, constraining their ability to supply medicines to hospitals and drugstores.

6.6. Manufacturing sector becoming more concentrated

There are fewer local manufacturing facilities now and the Philippine government does not require foreign firms to establish manufacturing plants in the country for them to operate. Industry actors raised concern that the pharmaceutical manufacturing sector is shrinking in terms of number of manufacturers. As shown in the above discussion, the number of manufacturers went down by more than half, based on the data of pharmaceutical manufacturers in FDA's drug registration data for 2009-2010 and 2018. While the authors' estimate of the number of manufacturers is around 100 as of January 2018, industry informants noted that the real number is way below that – there may be less than ten manufacturers. The estimates could be imprecise since many establishments are actually subsidiaries of big pharmaceutical companies.

Medalla et al. (2018)[49] corroborated that the pharmaceutical manufacturing sector is one with a high concentration index. Producers have emphasized the importance of having a vibrant local production industry as this is necessary for the country to have the adequate human resources to evaluate pharmaceutical products that enter the market. Without a vibrant local industry, there would be less demand for experts.

6.7. Inability to get qualified people

Industry informants, the FDA, a testing center and a chain drugstore, all 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; its rate of turn-over is quite high. FDA also noted that it is very difficult to get people with technical skills who can work in the evaluation of drug registration applications, and it would take up to 6 months to train a chemist in the production of medicine. Retailers have difficulty in hiring pharmacists as well. Many establishments find it difficult to follow FDA's regulation which requires one pharmacist for each drugstore. Although there may be many sources of pharmacy graduates, pharmacists have different fields of expertise (e.g. retail, industrial, research pharmacist, among others) and therefore, not all of them are

46 https://www.worldfinance.com/markets/stopping-counterfeit-drugs-in-their-tracks-in-the-philippines

47 http://www.pna.gov.ph/articles/1017274

48 Report made by The Philippine Pharmaceutical Manufacturers' Association (PPMA) presented by Higinio Porte Jr. on June 1, 2017 at the House of Representatives

49 Public Seminar at Philippine Competition Commission (PCC), June 2018

Table 23. Examples of generic products of selected drugstores

Drugstore	Example of medicine (own label)
The Generics Pharmacy	
Watsons Generics	
Mercury Drug Philusa's Rhea Generics (Philusa is a subsidiary of Mercury Group of Companies)	

skilled enough to man drugstores. A large pharmaceutical retail company emphasized this challenge as a significant blunder.

6.8. Trend of integration and consolidation

There is some evidence of consolidation. To compete more effectively in the retail market, firms may see the need to consolidate. For instance, TGP's majority shares have been bought by Robinsons Retail Holdings which also owns South Star Drug. It is known that Robinsons Retail has acquired 100 percent stake in Batangas-based drugstore chain, Chavez Pharmacy in 2014. Prior to that, South Star Drug also acquired 53 drugstores from Manson Drug in Central Luzon in 2001. Earlier, it was noted that many pharmaceutical manufacturing establishments are also owned by only very few groups or entities. If establishments that have similar owners are pooled, some 31 pharmaceutical establishments would consolidate into only 5 companies. There is also an emerging pattern of integration by producers – doing end-to-end services from manufacturing to distribution to marketing, to testing for bioequivalence of generic medicines and then to hospital service. Meanwhile, retail companies are coming up with their own label. For instance, Watsons has Watsons Generics, TGP has its own line of generic medicines, and Mercury Drug has Rhea Generics (Table 20). Although the study cannot substantiate problems or issues that emanate from such trends, these are aspects that require further analysis in the future.

6.9. Wide variation in prices by brand and by retailer/hospital

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. Based on DOH's Drug Price Watch, there is evidence that the price of the same brand depends on the seller, retail store or hospital. Further research must be done to determine whether this is attributable to location or simply the tendency to generate more profits. Also, some medicines made by a manufacturer

can be marketed and priced differently depending on the trader or marketing authorization holder. A surprising pattern in the pricing of some medicines particularly of some hospitals also emerged in this paper and that is the imposition of the same price for both originator and generic brands. Generic brands Atorvast, and Avamax are sold at the same price as Lipitor; Amlodac and Vasalat are also priced similarly to Norvasc; and Azimin, Azithro Natrapharm, Zenith, and Zithromax have also the same price. In these situations, consumers do not enjoy the benefit of the cheaper generic brand because these are priced as that of the originator. The actual reasons behind the price differences and the implications of such are important areas that require more in-depth research.

7. Policy insights/recommendations

7.1. Industry roadmap

Ensuring a reliable supply of good quality, safe and effective medicines is a salient policy domain because it is about the promotion of healthcare of the population. This is achieved through improvement of the local pharmaceutical industry's capacity for production and distribution, in promoting capability for exportation. This study sees the need for a roadmap for the local pharmaceutical industry to identify industry-level objectives and methods to attain these objectives, and to delineate the roles of various stakeholders in achieving such objectives. While the shaping of such roadmap requires a much deeper analysis of the industry and the issues and challenges, this study has identified some areas for immediate improvement.

7.2 Provision of adequate resources

Successful imposition of high standards requires adequate human resource and infrastructure. This is in addition to the basic elements of FDA's mandate such as registration and licensing, monitoring and surveillance against different kinds of violations, and prevention of smuggling and proliferation of counterfeit drugs.

FDA's ability to carry out its mandate of ensuring the quality, safety, and efficacy of medicines both locally-produced and imported is hampered by its lack of qualified personnel and poor infrastructure. The infrastructure problem also affects the facilitation of applications for registration. These constraints have led to a long backlog in processing drug registration which penalizes the industry by poor return of investments. The smaller players may even cease to operate if their key products are not registered on time. Such delays also deny the Filipino consumers timely launching of potentially important medicines for the treatment of illnesses. Efforts, therefore, must be prioritized to resolve FDA's human resource and infrastructural predicaments. On the other hand, delays may be reduced if the FDA considers extending the validity of registration. The validity of renewal may be extended into 5 instead of the current 2 years validity. Such move can be beneficial to both regulator and the industry because it lessens the administrative burden of having to process renewal frequently.

7.3. Open dialogue with the stakeholders

In addition, policy directives must also be properly coordinated and communicated with the industry and other stakeholders. In a stringent regulatory environment, dialogue and clarity of directives are very crucial so that misunderstanding and confusion are avoided.

7.4. Improved monitoring system

FDA's regulatory capacity also requires improvement in terms of monitoring the industry. In particular, the regulator should come up with readily available and accessible database that provides numbers of industry actors distinguishable by type/operation such as manufacturers, packers/re-packers, purely importers, purely traders, distributors and retailers. 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.
At its current state, analysis of the drug registration data is a very tedious and challenging task because the names of establishments, countries of origins, among others are not unique. 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 FDA. Also, an unprecedented increase, for instance, in the number of imported products calls for more resources towards the evaluation of imported products and deployment of more foreign auditors.

Likewise, the Department of Health's EDPMS is an important tool for monitoring prices of medicines and its coverage must be enhanced to include all drugstores and hospitals in the country. The study discovered that at least some key drugs store chains still do not report to the system.

6.5. Policy review

Ensuring that standard metrics are used for both imported medicines and locally-produced medicines is crucial. The government must review its policies to ensure that the country imports from producers that are compliant to high quality standards. Also, it is important for people to know whether a pharmaceutical company adheres to safety and quality standards. It may require all generic drug producers to disclose the names of companies that they use for bioequivalence test through FDA or their websites so that people can become aware of such and incorporate this information into the decision-making process.

7.6. Intensive information campaign

The government must carry out effective efforts to eradicate counterfeit medicines in the market, and to ensure that all medicines being sold in the market are duly registered by the FDA. Likewise, it is crucial to improve people's access to the wide variety of generic medicines especially those in rural, underserved areas. Authorities must also enhance its information and education campaign so that consumers make more informed choices.

The large proportion of healthcare expenses in medicines is an indication that people continue to buy the more expensive brands perhaps because they lack knowledge about the equivalence in the quality of generic medicines and originators. It is also possible that there are not that many options available in more visible retail stores, although there are actually many alternative brands. Likewise, if hospitals offer only 2 to 3 generic brands, then hospital patients do not have much choice. What is even more constraining is when originator medicines and generics, although these two are bioequivalent, are offered on the same price, such as in the case of some hospitals – when generics are supposed to be more affordable. The reason for this is that manufacturers of generics only need to recover the cost of production and marketing. Although they conduct some formulation R&D, they were not the ones who invested in expensive R&D for the development of the molecule, but the originator company. Again, these issues must be further examined for policy-making purposes.
Lastly, the study found that the industry is vast, complex, and opaque; it could not possibly examine every aspect and every issue or problem that requires attention. However, this study brings to the table insights on possible areas for improvement as well as some recommendations that can be done immediately to improve the current condition of the pharmaceutical industry.

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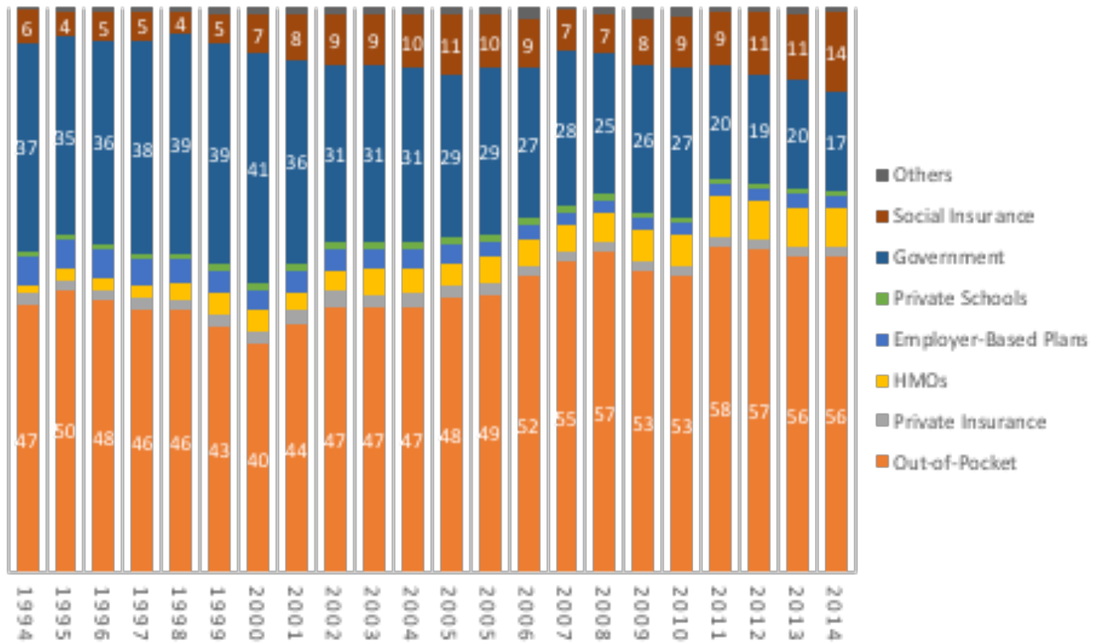
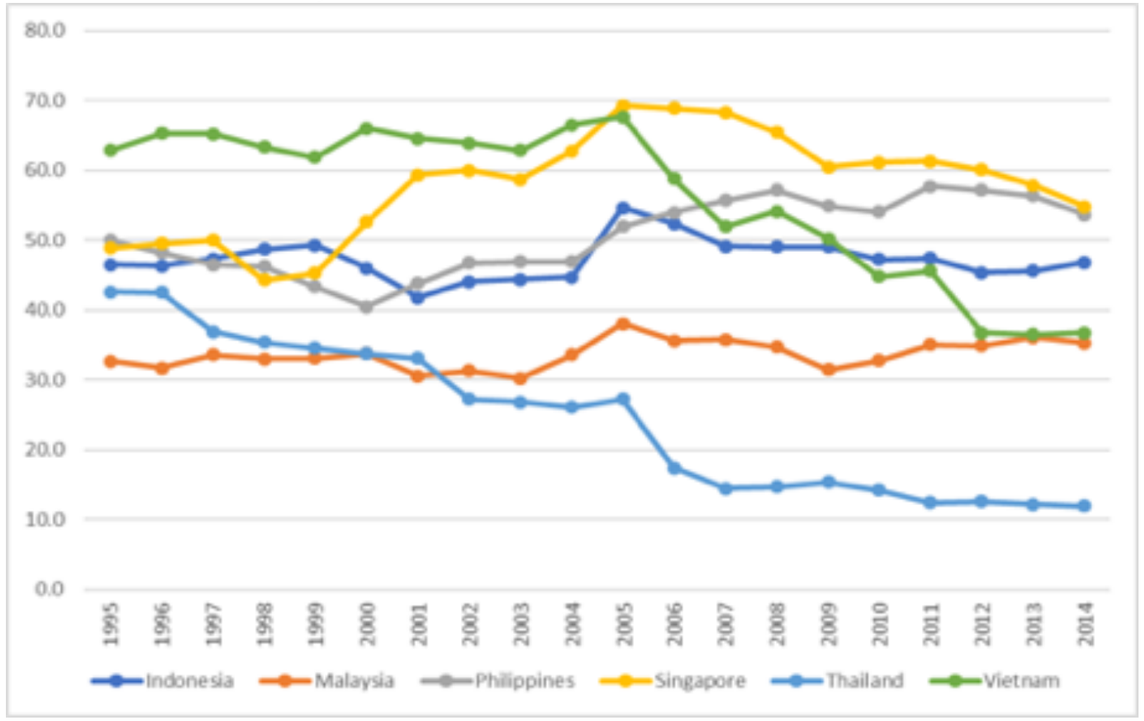
Appendix Tables and Figures

Appendix Figure 1. Sources of health expenditure, Philippines



Source of basic data: Philippine National Health Accounts

Appendix Figure 2. Out-of-pocket health expenditure (% of total expenditure on health) by country



Source of basic data: Philippine National Health Accounts

Appendix Table 1. Distribution of household medical care expenditure by category

Type of medical expenditure	Average per capita expenditure (in PhP)		Share (in percent)	
	2012	2015	2012	2012
Pharmaceutical Products	933	1,078	49.5	48.3
Hospital Services	626	777	33.2	34.8
Medical services	243	283	12.9	12.7
Therapeutic Aids	19	33	1.0	1.5
Paramedical Services	25	29	1.3	1.3
Dental Services	26	24	1.4	1.1
Other Medical Products	12	9	0.6	0.4
Medical care expenditure	1,884	2,232	100.0	100.0

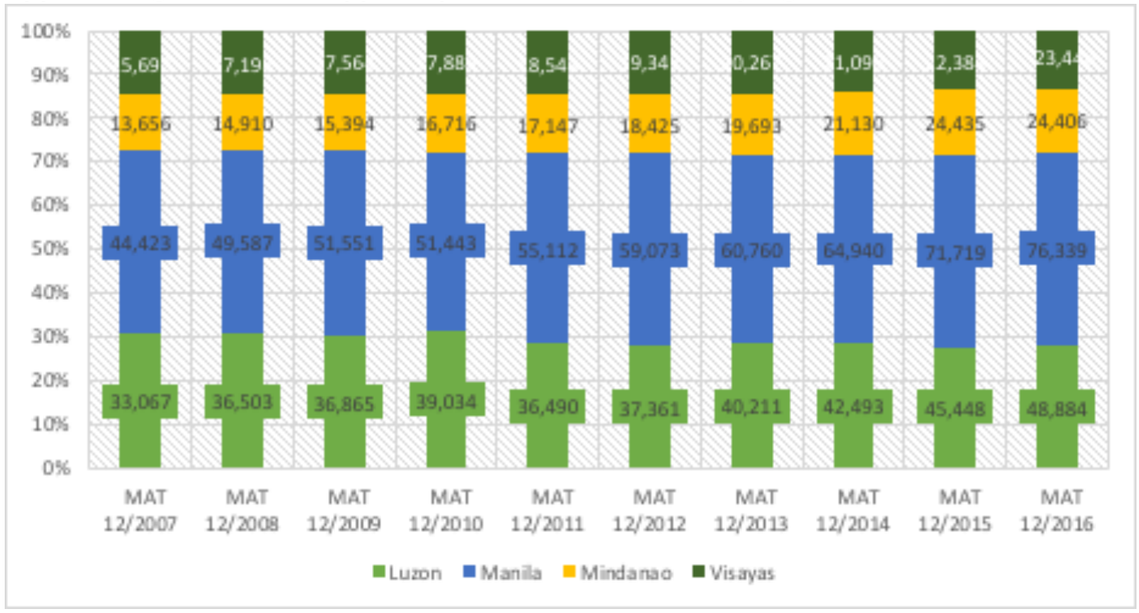
Source of basic data: FIES, PSA

Appendix Table 2. Household medical care expenditure by income class

Decile	Pharmaceutical Products		Total Medical Care		Share to total medical care	
	2012	2015	2012	2015	2012	2015
First	80	93	164	208	48.7	44.6
Second	139	180	271	369	51.3	48.7
Thrid	198	236	411	450	48.0	52.4
Fourth	264	292	504	602	52.3	48.4
Fifth	351	388	699	847	50.2	45.8
Sixth	466	593	864	1,131	54.0	52.4
Seventh	655	784	1,317	1,524	49.8	51.4
Eighth	1,038	1,230	2,138	2,332	48.6	52.7
Ninth	1,628	1,757	3,069	3,431	53.4	51.2
Tenth	3,745	4,287	7,850	9,468	47.7	45.3
Philippines	933	1,078	1,884	2,232	49.5	48.3

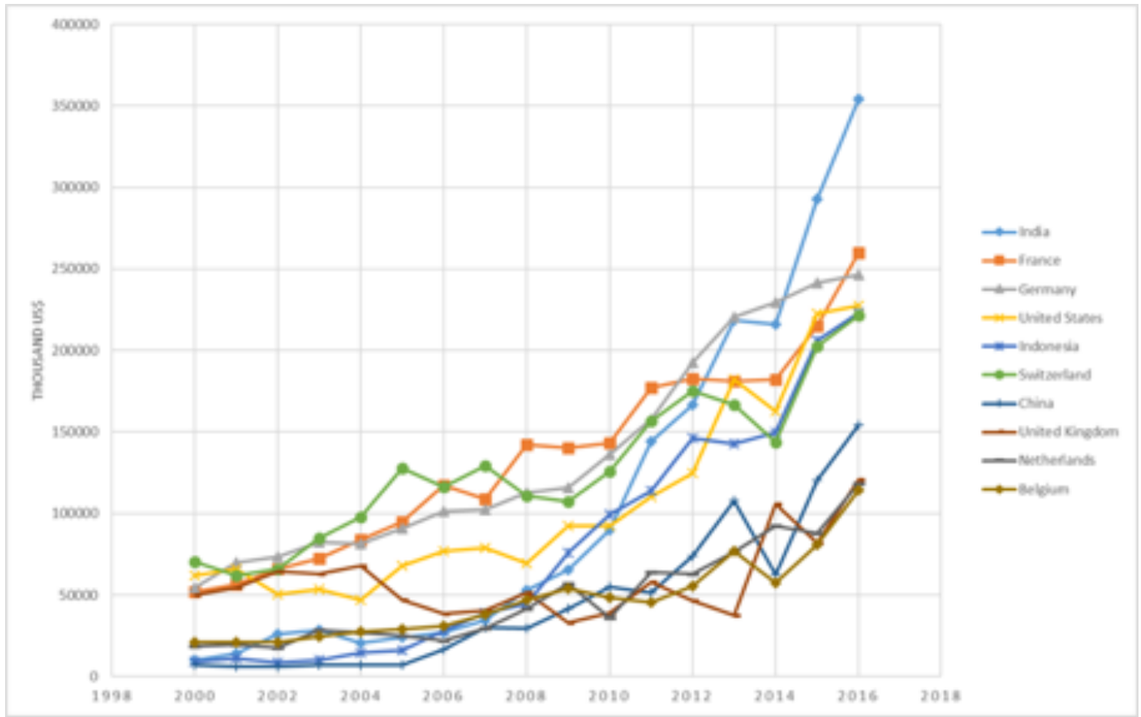
Source: Authors' estimates using Family Income and Expenditure Survey (FIES), Philippine Statistic Authority (PSA)

Appendix Figure 3. The Philippines' pharmaceutical market by region



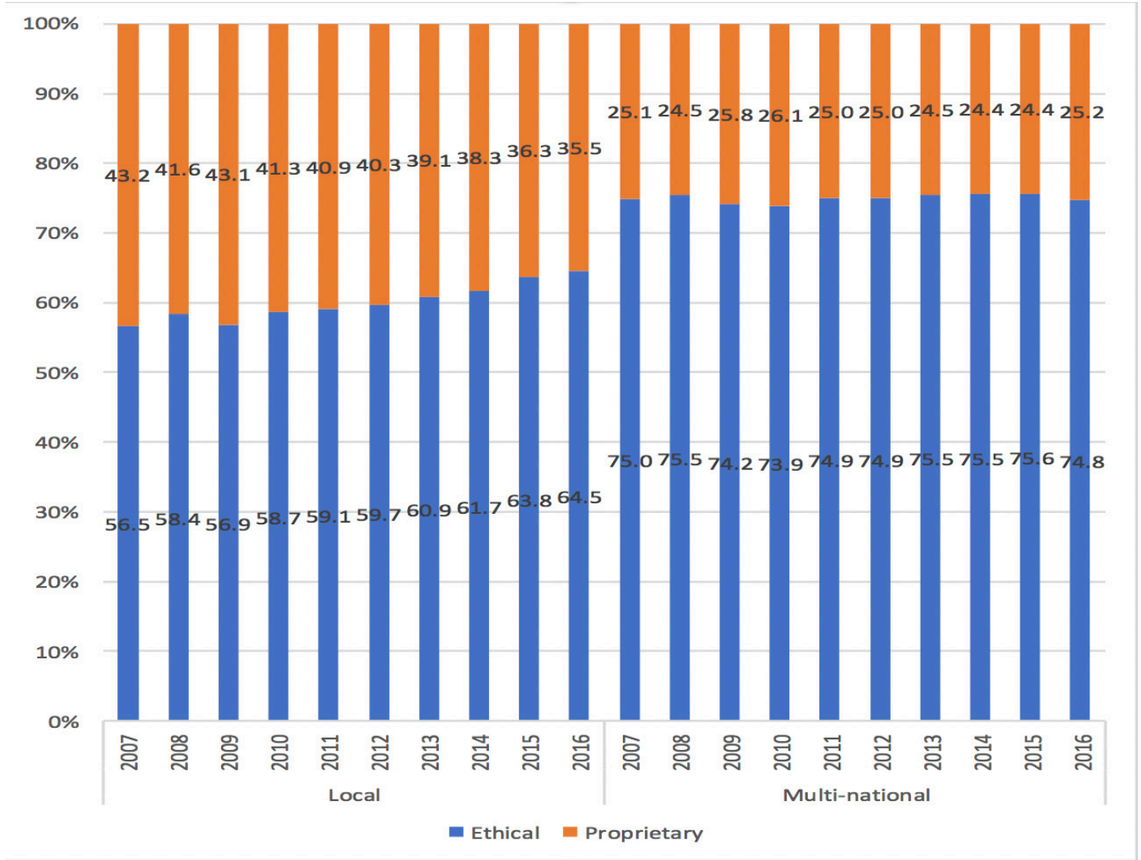
Source: IQVIA

Appendix Figure 4. Trend in gross imports of pharmaceutical products in the Philippines, top 10 sources in 2016



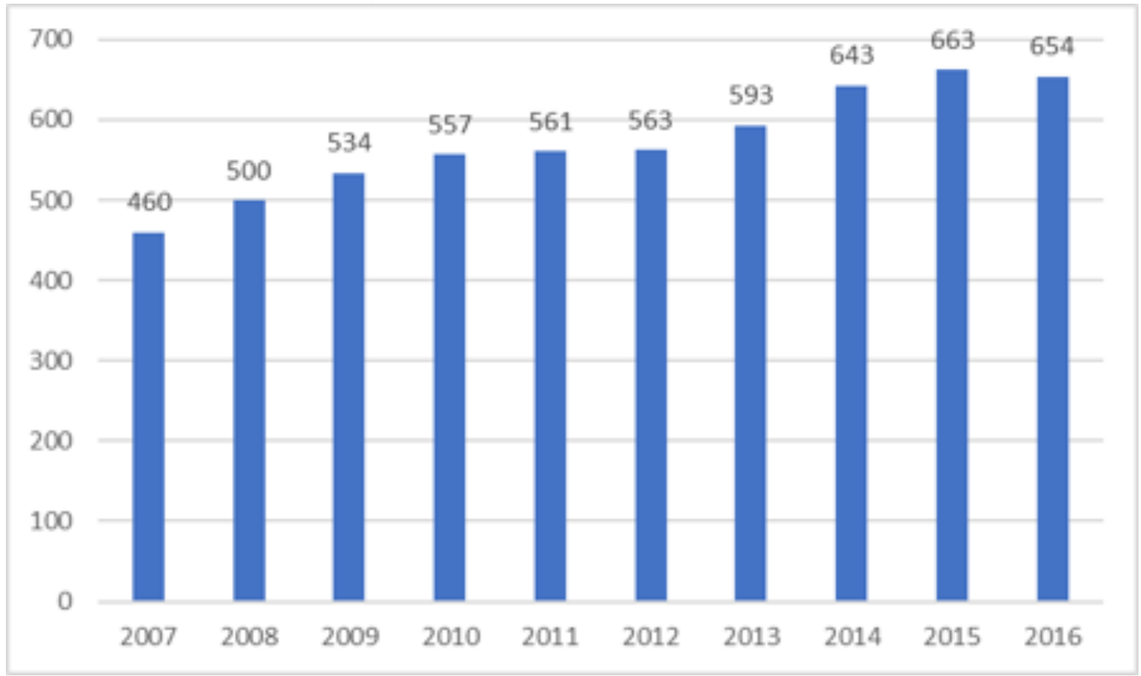
Source: COMTRADE

Appendix Figure 5. Sales in pharmaceutical products by type of corporation and ethical status, 2007 to 2016



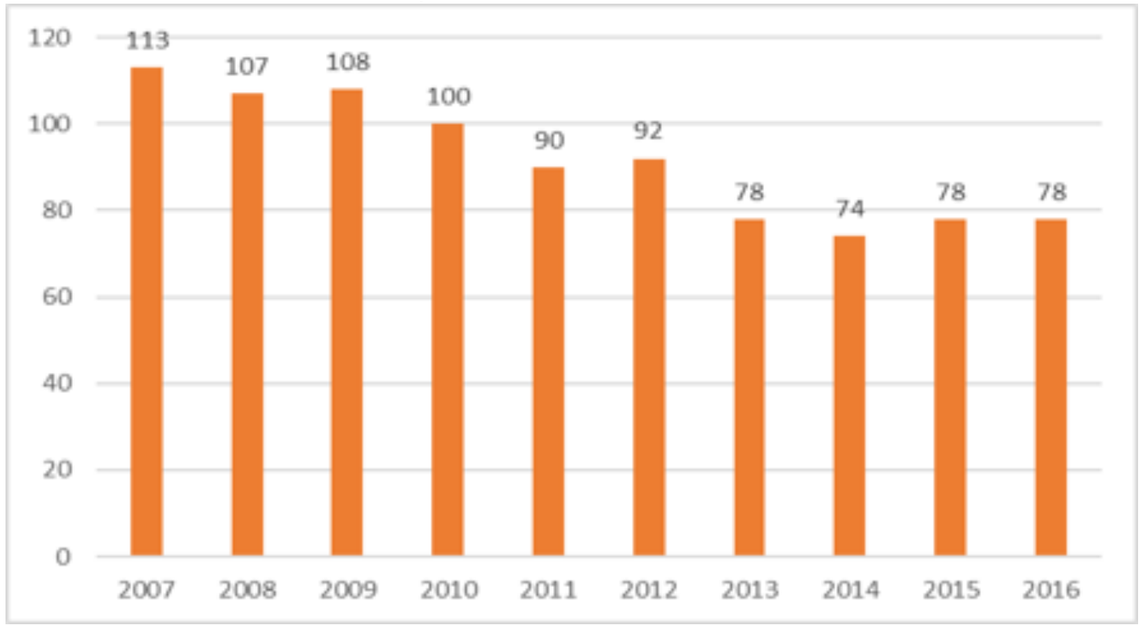
Source of basic data: IQVIA

Appendix Figure 6. Number of pharmaceutical corporations supplying branded generics (i.e. those with positive sales value), 2007 to 2016



Source of basic data: IQVIA

Appendix Figure 7. Number of pharmaceutical corporations supplying unbranded generics (i.e. those with positive sales value), 2007 to 2016



Source of basic data: IQVIA

Appendix Table 3. Top 20 corporations in branded generics market

Top 20	Corporation	Type	Share to 2007 total sales	Corporation	Type	Share to 2016 total sales
1	UNITED LAB	Local	29.8	UNITED LAB	Local	31.4
2	GLAXOSMITHKLINE	Multi-national	7.8	GLAXOSMITHKLINE	Multi-national	4.0
3	PFIZER INC	Multi-national	7.3	PFIZER INC	Multi-national	3.9
4	ABBOTT LAB	Multi-national	4.7	ABBOTT LAB	Multi-national	3.7
5	WYETH PHILIPPINES	Multi-national	3.6	CATHAY DRUG CO	Multi-national	3.2
6	BRISTOL-MYERS SQB	Multi-national	2.7	NATRAPHARM	Local	2.9
7	MERCK SHARP&DOHME	Multi-national	2.5	AMBICA	Local	2.8
8	BOE. INGELHEIM	Multi-national	2.5	BOE. INGELHEIM	Multi-national	2.4
9	NOVARTIS	Multi-national	2.3	NOVARTIS	Multi-national	2.2
10	NATRAPHARM	Local	2.3	MERCK SHARP&DOHME	Multi-national	2.0
11	JOHNSON	Multi-national	2.2	JOHNSON	Multi-national	1.9
12	TAISHO PHARM	Multi-national	2.1	TAISHO PHARM	Multi-national	1.8
13	SANOFI-AVENTIS	Multi-national	2.0	GETZ PHARMA	Multi-national	1.7
14	GX INTERNATIONAL	Local	1.6	MULTICARE PHARM	Local	1.5
15	ASTRAZENECA	Multi-national	1.5	SANOFI-AVENTIS	Multi-national	1.4
16	ROCHE PHILIPPINES	Multi-national	1.5	NESTLE	Multi-national	1.4
17	BAYER PHILIPPINES	Multi-national	1.5	BAYER PHILIPPINES	Multi-national	1.3
18	MERCK INC	Multi-national	1.2	MERCK INC	Multi-national	1.2
19	INTERMED MKTG	Local	1.2	TORRENT PHARMA	Multi-national	1.2
20	PASCUAL LAB	Local	1.0	INTERMED MKTG	Local	1.1

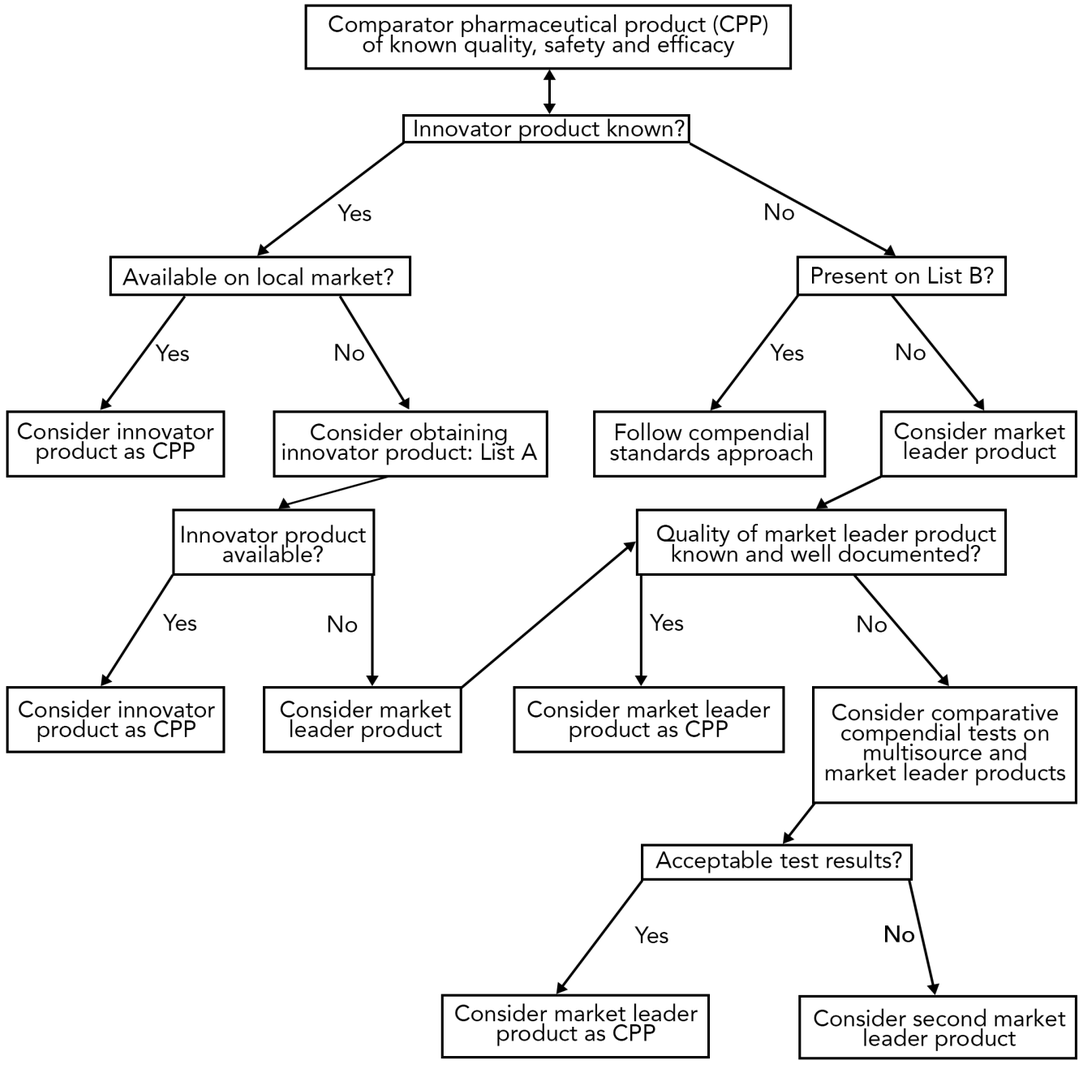
Source of basic data: IQVIA

Appendix Table 4. Top 20 corporations in unbranded generics market, 2007 & 2016, Philippines

Top	Corporation	Type	%Share to total sales, 2007	Corporation	Type	%Share to total sales, 2016
1	UNITED LAB	Local	33.0	UNITED LAB	Local	55.5
2	PASCUAL LAB	Local	21.3	PASCUAL LAB	Local	9.3
3	EURO-MED LAB	Local	13.2	HOSPIRA PHILS.	Multi National	8.8
4	HOSPIRA PHILS.	Multi National	6.9	AMBICA	Local	6.8
5	DLI GENERIC PROD	Local	3.7	EURO-MED LAB	Local	6.5
6	PHILUSA CORP	Local	3.2	PHILUSA CORP	Local	2.0
7	PHARMAWEALTH	Local	2.6	NOVARTIS	Multi National	1.2
8	J B ORCHIDS PHARM	Local	1.9	SANOFI-AVENTIS	Multi National	1.1
9	BAXTER	Multi National	1.5	ACE PHARM	Local	0.9
10	BRISTOL-MYERS SQB	Multi National	1.3	L E O PHARM PROD	Multi National	0.6
11	ASPEN	Multi National	1.3	B BRAUN	Multi National	0.5
12	B BRAUN	Multi National	0.8	PHARMAWEALTH	Local	0.5
13	L E O PHARM PROD	Multi National	0.8	INTERNATIONAL PHAR	Local	0.5
14	BOIE INC	Local	0.7	NEW MYREX LAB	Local	0.5
15	LUMAR	Local	0.6	GLAXOSMITHKLINE	Multi National	0.4
16	GLAXOSMITHKLINE	Multi National	0.6	LLOYD PHARM	Local	0.4
17	AM-EUROPHARMA COR	Local	0.5	IPCA	Local	0.4
18	ELIN PHARM	Local	0.5	BAXTER	Multi National	0.4
19	BAYER PHILIPPINES	Multi National	0.5	J.M. TOLMANN LAB	Local	0.3
20	J.M. TOLMANN LAB	Local	0.4	SCHEELE LAB	Local	0.3

Source: IQVIA Philippines

Appendix Figure 8. WHO guideline for selecting the comparator drug of Active Pharmaceutical Ingredients



Source: Figure 1 of WHO Technical Report Series, 2002, Annex 11. Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generics) products at http://apps.who.int/medicinedocs/documents/s19641en/s19641en.pdf

Appendix Table 5. Share of foreign investments in pharmaceutical multi-national companies

Company Name	Total paid-up capital	Share of foreign ownership in paid-up capital
PFIZER INC.	1,834,915,200.00	100.00
GLAXOSMITHKLINE PHILIPPINES INC.	1,330,167,010.00	100.00
ELI LILLY (PHILS.) INC.	723,896,750.00	100.00
WYETH PHILS. INC	610,418,100.00	100.00
SANOFI-AVENTIS PHILIPPINES INC.	591,157,500.00	100.00
ZUELLIG PHARMA CORP.	500,000,000.00	100.00
ROCHE (PHILS.) INC.	300,000,000.00	100.00
NOVARTIS HEALTH CARE PHILS. INC.	298,794,000.00	100.00
GLAXOSMITHKLINE CONSUMER HEALTHCARE PHILIPPINES INC.	271,437,904.03	100.00
ABBOTT LABORATORIES	254,963,000.00	100.00
BAXTER HEALTHCARE PHILIPPINES, INC.	253,335,000.00	100.00
BOEHRINGER INGELHEIM (PHILS.) INC.	240,000,000.00	100.00
ABBOTT PRODUCTS (PHILIPPINES), INC.	236,723,000.00	100.00
ASTRAZENECA PHARMACEUTICALS (PHILS.) INC.	209,523,300.00	100.00
SERVIER PHILIPPINES, INC.	200,000,000.00	100.00
MULTICARE PHARMACEUTICALS PHILIPPINES INC.	149,026,500.00	51.00
HOSPIRA PHILIPPINES, INC.	141,717,000.00	100.00
ASTELLAS PHARMA PHILIPPINES, INC.	135,000,000.00	100.00
SANOFI PASTEUR, INC.	134,000,000.00	100.00
OTSUKA (PHILS.) PHARMACEUTICAL INC.	115,434,000.00	100.00
TAKEDA PHARMACEUTICALS (PHILIPPINES), INC.	98,429,000.00	100.00
MERCK INC.	91,513,000.00	100.00
RECKITT BENCKISER (PHILS.) INC.	87,668,700.00	100.00
FRESENIUS KABI PHILIPPINES INC.	78,000,000.00	100.00
HI EISAI PHARMACEUTICAL INC.	68,250,000.00	50.00
AMBICA INTERNATIONAL CORPORATION	63,500,000.00	40.00
CROMA MEDIC INC.	57,494,000.00	100.00
OEP PHILIPPINES INC.	55,250,000.00	100.00
NOVO NORDISK PHARMACEUTICALS (PHIL.) INC	50,000,000.00	100.00
SCHERING PLOUGH CORP.	50,000,000.00	100.00
JOHNSON & JOHNSON (PHILS.) INC.	44,525,000.00	99.12
TORRENT PHARMA PHILIPPINES, INC.	38,548,400.00	100.00
MACROPHARMA CORP.	13,687,500.00	36.26
TRANSFARMA PHILIPPINES INC.	12,999,000.00	99.98
GALDERMA PHILS. INC.	12,500,000.00	100.00
UCB PHILIPPINES INC.	12,500,000.00	0.00
GETZ PHARMA (PHILS.), INC.	10,000,000.00	100.00
KOREA UNITED PHARMA, INC.	250,000.00	80.00
A. JOHNSON PHARMA INTL. CORP.	190,000.00	39.37

Source of basic data: Securities and Exchange Commission

Appendix Table 7. Sales of pharmaceutical products by therapeutic class, license and corporation type, Philippines (Part 1 of 6)

Year	Sales (Value) PhP Million	Year-on-year growth (%)	Share to total					Year-on-year growth (%)				
			Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator	Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator
Alimentary T. & Metabolism												
2007	21,485		43.48	56.52	79.75	18.05	2.20					
2008	23,259	8.25	44.30	55.70	78.76	18.92	2.32	10.28	6.70	6.91	13.49	14.12
2009	24,846	6.82	45.71	54.29	79.26	18.08	2.66	10.23	4.11	7.51	2.07	22.43
2010	26,186	5.39	45.75	54.25	78.75	18.63	2.63	5.48	5.32	4.71	8.59	4.10
2011	26,368	0.69	46.07	53.93	77.11	20.10	2.79	1.41	0.09	-1.39	8.66	6.80
2012	28,554	8.29	48.05	51.95	77.20	19.46	3.34	12.93	4.33	8.42	4.83	29.75
2013	30,248	5.93	47.72	52.28	76.89	20.06	3.05	5.22	6.59	5.50	9.24	-3.43
2014	32,259	6.65	47.07	52.93	77.06	20.10	2.83	5.20	7.97	6.89	6.87	-0.83
2015	35,246	9.26	47.42	52.58	77.09	20.16	2.75	10.05	8.56	9.30	9.57	5.94
2016	38,217	8.43	47.31	52.69	77.19	20.37	2.44	8.18	8.65	8.56	9.57	-3.59
Blood & B. Forming Organs												
2007	3,825		24.42	75.58	44.25	52.16	3.59					
2008	4,313	12.77	25.66	74.34	42.87	53.16	3.97	18.51	10.92	9.26	14.93	24.67
2009	4,256	-1.32	30.71	69.29	49.90	43.33	6.76	18.10	-8.03	14.86	-19.55	68.04
2010	4,418	3.79	33.44	66.56	52.16	43.02	4.82	13.01	-0.29	8.48	3.05	-26.04
2011	4,748	7.47	33.88	66.12	49.76	45.02	5.22	8.91	6.75	2.53	12.47	16.36
2012	5,266	10.91	36.46	63.54	49.49	44.40	6.11	19.34	6.59	10.30	9.37	29.91
2013	5,899	12.02	39.60	60.40	50.88	41.85	7.27	21.67	6.48	15.16	5.58	33.33
2014	6,528	10.67	40.59	59.41	49.97	41.98	8.05	13.45	8.85	8.69	11.02	22.55
2015	7,427	13.77	43.45	56.55	51.48	39.35	9.17	21.80	8.29	17.22	6.63	29.61
2016	7,640	2.86	46.02	53.98	55.31	36.22	8.47	8.92	-1.81	10.51	-5.32	-5.01
Cardiovascular System												
2007	17,864		29.90	70.10	52.46	45.37	2.17					
2008	20,581	15.20	31.58	68.42	53.52	43.89	2.59	21.68	12.44	17.54	11.43	37.61
2009	20,089	-2.39	33.43	66.57	54.13	42.44	3.43	3.33	-5.02	-1.27	-5.61	29.13
2010	19,652	-2.18	34.98	65.02	53.88	42.07	4.05	2.37	-4.46	-2.64	-3.01	15.44
2011	20,296	3.28	35.27	64.73	53.09	42.44	4.47	4.11	2.83	1.78	4.17	13.97
2012	21,436	5.62	38.88	61.12	54.46	38.80	6.74	16.43	-0.27	8.34	-3.44	59.36
2013	22,672	5.77	39.90	60.10	55.27	36.70	8.03	8.55	3.99	7.34	0.06	25.87
2014	23,637	4.26	41.08	58.92	56.00	34.88	9.12	7.33	2.21	5.64	-0.93	18.46
2015	26,364	11.54	43.22	56.78	57.36	32.80	9.84	17.36	7.48	14.24	4.91	20.32
2016	27,149	2.98	44.49	55.51	59.02	31.93	9.05	5.99	0.68	5.96	0.23	-5.29

Appendix Table 7. Sales of pharmaceutical products by therapeutic class, license and corporation type, Philippines (Part 2 of 6)

Year	Sales (Value) PhP Million	Year-on-year growth (%)	Share to total					Year-on-year growth (%)				
			Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator	Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator
Dermatologicals												
2007	3,682		15.27	84.73	73.23	25.08	1.69					
2008	3,972	7.88	16.62	83.38	73.03	25.36	1.61	17.37	6.18	7.59	9.09	2.88
2009	4,312	8.55	17.08	82.92	73.77	24.46	1.77	11.61	7.95	9.66	4.68	19.45
2010	4,794	11.17	19.15	80.85	74.04	23.98	1.98	24.60	8.40	11.58	8.99	24.11
2011	4,849	1.16	19.73	80.27	74.53	23.64	1.83	4.24	0.43	1.82	-0.26	-6.40
2012	5,410	11.56	22.77	77.23	75.99	21.87	2.14	28.73	7.33	13.74	3.21	30.33
2013	5,739	6.08	22.95	77.05	76.17	22.05	1.78	6.91	5.84	6.33	6.94	-11.67
2014	6,353	10.71	26.88	73.12	78.48	19.95	1.58	29.68	5.06	14.06	0.15	-2.14
2015	6,818	7.31	29.74	70.26	79.29	18.51	2.21	18.74	3.11	8.42	-0.43	50.28
2016	7,292	6.96	29.87	70.13	82.13	15.64	2.23	7.41	6.77	10.80	-9.61	8.00
G.U. System & Sex Hormones												
2007	3,482		15.08	84.92	51.01	48.07	0.92					
2008	3,727	7.05	17.02	82.98	50.69	48.48	0.83	20.80	4.60	6.37	7.96	-2.98
2009	3,817	2.41	20.11	79.89	53.86	45.28	0.86	21.02	-1.41	8.82	-4.35	6.17
2010	4,461	16.88	20.27	79.73	58.30	41.34	0.37	17.80	16.64	26.51	6.70	-50.12
2011	4,413	-1.09	22.65	77.35	57.83	41.73	0.44	10.53	-4.04	-1.87	-0.15	18.12
2012	4,888	10.77	23.51	76.49	66.38	32.93	0.68	14.95	9.54	27.14	-12.57	72.31
2013	5,271	7.84	23.90	76.10	68.51	30.79	0.70	9.62	7.29	11.28	0.82	10.80
2014	5,399	2.43	24.20	75.80	69.57	29.60	0.83	3.74	2.02	4.02	-1.52	20.95
2015	5,834	8.06	26.23	73.77	67.76	31.32	0.92	17.10	5.18	5.26	14.34	19.57
2016	5,503	-5.68	32.48	67.52	68.64	30.28	1.08	16.81	-13.68	-4.45	-8.82	10.82
Systemic Hormones												
2007	1,513		21.48	78.52	80.83	13.82	5.35					
2008	1,634	7.95	23.64	76.36	81.80	12.95	5.25	18.80	4.98	9.25	1.19	5.76
2009	1,737	6.31	23.26	76.74	86.25	9.46	4.29	4.61	6.84	12.09	-22.33	-13.06
2010	1,841	5.99	25.48	74.52	85.85	10.48	3.67	16.09	2.93	5.50	17.36	-9.19
2011	1,933	5.02	24.79	75.21	86.64	10.01	3.35	2.18	5.99	6.00	0.33	-4.41
2012	2,023	4.66	24.39	75.61	87.15	10.10	2.76	2.98	5.22	5.28	5.54	-13.79
2013	2,071	2.38	25.79	74.21	87.59	10.15	2.26	8.27	0.48	2.90	2.90	-16.05
2014	2,207	6.53	28.69	71.31	87.85	10.35	1.80	18.51	2.37	6.84	8.64	-15.04
2015	2,417	9.53	29.89	70.11	88.08	9.98	1.95	14.09	7.70	9.82	5.59	18.24
2016	2,526	4.52	28.62	71.38	87.16	10.96	1.87	0.09	6.40	3.43	14.88	0.73

Appendix Table 7. Sales of pharmaceutical products by therapeutic class, license and corporation type, Philippines (Part 3 of 6)

Year	Sales (Value) PhP Million	Year-on-year growth (%)	Share to total					Year-on-year growth (%)				
			Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator	Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator
Systemic Anti-infectives												
2007	16,675		45.72	54.28	69.46	21.07	9.47					
2008	18,055	8.28	47.38	52.62	67.73	22.70	9.57	12.21	4.96	5.58	16.66	9.38
2009	18,099	0.24	47.73	52.27	68.79	22.76	8.45	0.98	-0.42	1.81	0.50	-11.47
2010	18,460	2.00	53.05	46.95	67.79	21.86	10.35	13.37	-8.39	0.52	-2.04	24.93
2011	18,837	2.04	53.59	46.41	69.32	21.78	8.90	3.06	0.89	4.35	1.67	-12.30
2012	19,640	4.26	56.65	43.35	69.18	19.98	10.83	10.23	-2.63	4.05	-4.33	26.96
2013	19,910	1.38	57.96	42.04	72.11	19.16	8.73	3.71	-1.67	5.67	-2.78	-18.35
2014	20,502	2.97	61.07	38.93	72.68	17.25	10.07	8.50	-4.64	3.79	-7.30	18.78
2015	22,823	11.32	66.26	33.74	76.06	14.49	9.45	20.79	-3.54	16.49	-6.48	4.52
2016	23,570	3.27	65.72	34.28	77.24	14.39	8.37	2.43	4.92	4.87	2.52	-8.49
Hospital Solutions												
2007	1223.25		62.99	37.01	40.91	0	59.09					
2008	1290.52	5.50	56.22	43.78	40.77	0	59.23	-5.84	24.80	5.13	-	5.75
2009	1371.90	6.31	62.02	37.98	37.78	0	62.22	17.26	-7.76	-1.50	-	11.68
2010	1456.11	6.14	62.78	37.22	38.96	0	61.04	7.44	4.02	9.46	-	4.12
2011	1299.28	-10.77	65.56	34.44	35.67	0	64.33	-6.82	-17.43	-18.30	-	-5.97
2012	1313.13	1.07	65.04	34.96	39.91	0	60.09	0.27	2.57	13.06	-	-5.59
2013	1286.50	-2.03	66.39	33.61	40.77	0	59.23	0.00	-5.80	0.08	-	-3.43
2014	1282.54	-0.31	65.19	34.81	49.59	0	50.41	-2.10	3.24	21.26	-	-15.15
2015	1295.37	1.00	67.15	32.85	49.42	0	50.58	4.03	-4.67	0.66	-	1.34
2016	1211.00	-6.51	68.43	31.57	48.77	0	51.23	-4.73	-10.15	-7.74	-	-5.32
Antineoplast + Immunomodul												
2007	2960.32		3.36	96.64	27.72	68.68	3.60					
2008	3422.30	15.61	4.47	95.53	25.77	69.85	4.37	53.63	14.28	7.47	17.58	40.62
2009	3421.38	-0.03	5.73	94.27	22.18	72.37	5.45	28.28	-1.35	-13.95	3.58	24.48
2010	3512.73	2.67	6.45	93.55	18.79	75.71	5.50	15.56	1.89	-13.03	7.41	3.58
2011	3631.30	3.38	7.03	92.97	17.47	77.18	5.35	12.76	2.73	-3.88	5.37	0.68
2012	3821.49	5.24	10.99	89.01	16.13	76.37	7.49	64.38	0.76	-2.82	4.14	47.31
2013	3969.43	3.87	12.92	87.08	21.13	74.60	4.28	22.18	1.61	36.02	1.46	-40.72
2014	4570.21	15.14	10.95	89.05	19.91	75.36	4.73	-2.48	17.75	8.49	16.32	27.38
2015	5179.80	13.34	13.77	86.23	23.30	70.30	6.40	42.52	9.75	32.67	5.72	53.37
2016	6025.68	16.33	15.24	84.76	23.56	69.93	6.50	28.74	14.35	17.63	15.73	18.21

Appendix Table 7. Sales of pharmaceutical products by therapeutic class, license and corporation type, Philippines (Part 5 of 6)

Year	Sales (Value) PhP Million	Year-on-year growth (%)	Share to total					Year-on-year growth (%)				
			Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator	Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator
Respiratory system												
2007	11,550		38.24	61.76	77.15	22.15	0.70					
2008	13,048	12.97	40.21	59.79	77.54	21.62	0.84	18.78	9.37	13.53	10.29	35.63
2009	13,567	3.98	42.50	57.50	78.87	20.59	0.54	9.91	-0.01	5.76	-1.00	-32.54
2010	13,735	1.24	42.63	57.37	78.95	20.49	0.56	1.55	1.01	1.34	0.77	4.15
2011	14,991	9.15	42.76	57.24	78.39	20.86	0.75	9.48	8.90	8.38	11.08	47.01
2012	14,992	0.00	46.61	53.39	78.52	20.72	0.76	8.99	-6.72	0.17	-0.67	0.75
2013	15,746	5.03	46.37	53.63	78.55	20.42	1.03	4.51	5.49	5.06	3.54	42.44
2014	16,686	5.97	48.65	51.35	79.65	19.14	1.22	11.16	1.48	7.45	-0.72	25.41
2015	18,042	8.13	50.02	49.98	79.52	18.83	1.65	11.17	5.25	7.96	6.38	46.52
2016	19,802	9.75	51.12	48.88	79.24	18.86	1.90	12.17	7.33	9.37	9.94	26.15
Sensory Organs												
2007	1,245		5.94	94.06	79.38	20.47	0.14					
2008	1,230	-1.22	5.87	94.13	78.88	20.96	0.15	-2.46	-1.14	-1.84	1.14	5.69
2009	1,375	11.76	7.93	92.07	77.90	21.86	0.24	50.98	9.32	10.37	16.55	75.59
2010	1,794	30.49	8.73	91.27	79.07	20.51	0.42	43.61	29.36	32.45	22.42	125.78
2011	1,584	-11.71	8.19	91.81	75.68	23.93	0.40	-17.10	-11.19	-15.50	3.01	-16.54
2012	1,755	10.82	7.32	92.68	78.68	20.82	0.51	-0.97	11.88	15.22	-3.59	41.96
2013	1,808	3.02	7.24	92.76	78.47	20.79	0.73	1.90	3.11	2.75	2.92	48.53
2014	1,974	9.17	7.48	92.52	76.09	22.99	0.92	12.72	8.89	5.86	20.68	37.37
2015	2,387	20.90	7.98	92.02	76.22	23.01	0.77	29.05	20.24	21.10	21.03	1.11
2016	2,389	0.11	9.92	90.08	76.12	22.78	1.10	24.42	-2.00	-0.02	-0.89	42.96
Diagnostic Agents												
2007	249.21		33.42	66.58	22.12	77.88	0					
2008	353.77	41.96	23.09	76.91	34.09	65.91	0	-1.94	64.00	118.72	20.15	-
2009	391.35	10.62	27.05	72.95	31.89	68.11	0	29.63	4.92	3.49	14.31	-
2010	409.59	4.66	34.36	65.64	16.15	83.85	0	32.92	-5.82	-46.99	28.85	-
2011	473.22	15.54	36.32	63.68	15.72	84.28	0	22.12	12.09	12.45	16.13	-
2012	470.03	-0.68	33.67	66.33	14.62	85.38	0	-7.91	3.45	-7.62	0.62	-
2013	373.04	-20.64	11.00	89.00	19.23	80.77	0	-74.08	6.49	4.36	-24.92	-
2014	398.04	6.70	8.41	91.59	19.25	80.75	0	-18.36	9.80	6.82	6.68	-
2015	415.48	4.38	6.79	93.21	17.48	82.52	0	-15.81	6.24	-5.18	6.66	-
2016	511.46	23.10	7.57	92.43	16.09	83.91	0	37.30	22.07	13.30	25.18	-

Appendix Table 7. Sales of pharmaceutical products by therapeutic class, license and corporation type, Philippines (Part 6 of 6)

Year	Sales (Value) PhP Million	Year-on-year growth (%)	Share to total					Year-on-year growth (%)				
			Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator	Local	Multi National	Branded Non-Originator	Originator	Unbranded Non-Originator
Various												
2007	7,091		6.12	93.88	99.72	0.17	0.12					
2008	8,098	14.21	6.56	93.44	99.76	0.09	0.16	22.37	13.68	14.25	-40.47	54.16
2009	8,347	3.07	6.96	93.04	99.73	0.14	0.13	9.32	2.64	3.05	64.76	-12.87
2010	8,099	-2.97	7.75	92.25	99.73	0.19	0.08	8.10	-3.80	-2.98	34.96	-39.59
2011	7,082	-12.56	8.03	91.97	99.67	0.27	0.06	-9.38	-12.83	-12.61	22.19	-32.01
2012	7,302	3.11	9.49	90.51	99.43	0.27	0.31	21.89	1.47	2.86	3.43	393.87
2013	7,003	-4.10	10.22	89.78	99.46	0.29	0.25	3.28	-4.87	-4.07	2.71	-20.67
2014	7,629	8.94	9.92	90.08	99.43	0.36	0.22	5.74	9.30	8.90	35.06	-6.61
2015	8,235	7.95	10.99	89.01	99.39	0.36	0.25	19.57	6.67	7.91	8.42	23.81
2016	8,300	0.79	12.74	87.26	99.37	0.36	0.27	16.84	-1.20	0.76	1.83	8.66

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