MARKET STUDY

PHARMACEUTICAL INDUSTRY IN MAURITIUS

MS/004

Report for Consultation

11th September 2020

competition commission

shaping markets, furthering progress

Table of Contents

List of Figures

List of Tables

Executive Summary

The role and significance of the pharmaceutical industry in Mauritius are immense in the efficient provision of healthcare services. It is an integral part of the health sector that contributes to the well-being of people. The health sector, which comprises both public and private healthcare institutions, is equally important for the economy. In 2017, for instance, some Rs 26 billion or around 5.7% of the Gross Domestic Product (GDP) were spent on healthcare.[1] Of this amount, around Rs 15 billion or 60% relates to private healthcare expenditure, which were met mainly from 'out-of-pocket' and to a lesser but increasing extent through private health insurance and corporate schemes. The remaining Rs 11 billion were spent by the government for healthcare services provided free of charge in all public healthcare institutions.

Mauritius is heavily dependent on importation of pharmaceutical products for supply to both public and private healthcare institutions. In 2019, the market value of pharmaceutical products imported and distributed in the country was estimated to be over Rs 5 billion or 20% of the total healthcare expenditure. Government expenditure on pharmaceutical products amounted to around Rs 1 billion whereas some Rs 4 billion or 80% of the total pharmaceutical expenditure were private, financed mainly from 'out-of-pocket'.

The bulk of pharmaceutical products available in both public and private channels of distribution are imported and supplied by registered wholesale pharmacies. As at July 2020, there were 40 registered wholesale pharmacies. Of these, 4 are found to be the major ones with a combined share of supply exceeding 60% and being representatives and/or appointed distributors of 14 top international pharmaceutical companies. While an assessment of the broader wholesale pharmaceutical market does not indicate such a high degree of concentration, a more in-depth analysis of the market would inevitably reveal several concentrated sub or relevant markets. This is because, unlike other commodities, substitution between pharmaceutical products is very limited, even for molecules with equivalent therapeutic value. Amongst other factors, this can be attributed to, for instance, doctors' prescription patterns and inertia to switch products on account of risks of provoking side effects or patient intolerance.

In public healthcare institutions, pharmaceutical products are distributed at various points of healthcare delivery. In the private channel of distribution, there are presently 354 retail pharmacies across the island. 43 of these retail pharmacies are owned by 8 wholesale pharmacies. In this regard, it has been submitted that vertical linkages between retail and wholesale pharmacies could provide strong incentives for those retail pharmacies to promote their own products to the detriment of other non-integrated wholesale pharmacies. This issue, however, does not appear to raise major concern in so far as prescription medicines are concerned. This is so because doctors are the ones who decide on the choice of medicines rather than users or pharmacies. Retail pharmacies cannot promote their own products unless doctors are incentivised to do so. It should, however, be noted that promotion of pharmaceutical products are not allowed by law.

The market for pharmaceutical products in Mauritius is a highly regulated one. The principal legislations and their various revisions provide for a formal process for the registration and commercialisation of pharmaceutical products; licensing of operators across the supply chain; and pricing of pharmaceutical products.

[1] See WHO Global Observatory Database. Available at: http://apps.who.int/gho/data/node.main.HEALTHFINANCING?lang=en

In relation to the registration of pharmaceutical products, concerns have been raised by several stakeholders about the lack of transparency and predictability of the process. The guidelines of the Pharmacy Board on the registration process are not publicly available. This situation could result in an information asymmetry and create uncertainties on applicable criteria for approval or non-approval to register products. This may somehow undermine the competition process.

Another issue raised by some stakeholders is a situation of perceived conflict of interest given that the Pharmacy Board and its Trade and Therapeutic Committee could comprise of private pharmacists that may be involved in the wholesale pharmacy business. As such, they may form part of the decision-making process which could involve their own products and that of competitors. Also, these private pharmacists could be privy to information such as names of applicants, product details and other commercial data that are submitted in the registration process. They may also have access to the list of registered products which is currently not in the public domain. Therefore, in line with international best practices, it has been suggested that the pharmaceutical products registration guidelines be made more transparent and that the composition of the Pharmacy Board and its sub-Committees does not include private pharmacies which are involved in the wholesale business.

Concerns were also expressed by stakeholders in relation to the quantum of the registration fees introduced in 2016. It was submitted that the registration fees were high, which would raise the costs of wholesale pharmacies and be at the detriment of smaller wholesalers with orphan/low selling drugs on the market. However, an assessment of the situation has revealed that the number of wholesale pharmacies and registered new products have both increased since 2016 when the new registration fees were introduced. As such, no such foreclosure effect has been noted.

Under the current regulatory framework, the pricing of pharmaceutical products is based on a mark-up system. Prices are fixed by applying the maximum applicable mark-up of 35% on the cost price of medicines, inclusive of insurance and freights; and providing for a special allowance of 2% on landed costs. The concern arising from the current pricing mechanism is that a fixed percentage mark-up is applied irrespective of the value of the products. As such, the higher the cost price of medicines the higher is the quantum of mark-up and consequently price of medicines to buyers.

The pricing issue arising from the application of the fixed percentage mark-up to arrive at the final retail price of medicines is compounded by the depreciating trend observed in the Mauritian rupee vis-à-vis the principal trading currencies such as the US Dollar and Euro. In consequence, the cost base for the application of the fixed percentage mark-up has been rising which has merely amplified the burden of final consumers in terms of higher retail prices. Moreover, the current pricing model may also incentivise wholesalers and retailers to stock higher-priced drugs, eventually favouring more expensive options over cheaper alternatives with equivalent therapeutic value, to the detriment of users of pharmaceutical products.

Another issue related to prices of pharmaceutical products in Mauritius is the extent to which these are competitive. The price comparison analysis on a selected sample of pharmaceutical products compared to their international reference prices tends to indicate that local medicine prices are high. However, the result of price comparison based on international reference prices as benchmark should be interpreted with caution. There are various factors such as the small size of the Mauritian market, the significant add-on costs like: insurance and freights, local charges and distribution costs; and the mark-up system that need to be factored in. These factors could potentially account for the higher retail price of pharmaceutical products in Mauritius. To address the pricing issues, a regressive mark-up system, as recommended by the World Health

Organisation, can be considered. At the same time, generic medicines could be promoted through a mix of policies and strategies.

Given the intellectual property (IP) exhaustion regime adopted in Mauritius, it is at the discretion of owners of registered trademarks to withhold their consent for parallel import of registered pharmaceutical products. Restriction on parallel imports may in itself limit competition and could lead to dual pricing to the detriment of customers. In other words, restriction on parallel imports reduces intra-brand competition and forecloses potential competitors from the market. Thus, another potential reason for higher prices of pharmaceutical in Mauritius compared to their international reference prices could be attributed to our IP exhaustion regime which somehow confers market power to the IP holders. In this regard, the law can be amended to allow for parallel importation of pharmaceutical products.

1. Introduction

1.1. Pursuant to Section 30(h) of the Competition Act 2007 ('the Act'), the Executive Director of the Competition Commission ('the Executive Director') undertook this general study to assess the effectiveness of competition in the pharmaceutical sector in Mauritius ('the Study').

1.2. The objective of the Study is to understand and publicise the conditions of competition in the pharmaceutical sector; the reasons for any lack of competition and if necessary, to come up with recommendations to make the market more competitive. Our focus is therefore solely on competition. The Competition Commission has no authority or expertise to address issues and make recommendations on matters other than competition in the market.

1.3. The recommendations, if any, arising from this market study can form the basis for advice by the Commission. The latter, pursuant to Section 19 of the Act, may advise Government on any action of the State or a public body, which can harm market competition. Government, however, may take any wider public interest concern into account when considering any recommendation that the Commission might make.

A. Motivation and Scope of the Study

1.4. The Study was launched by the Executive Director following complaints by two wholesale pharmacies and issues raised by consumer organisations, in relation to the registration process and pricing of pharmaceutical products.

1.5. It aims at undertaking an assessment of the conditions of competition in the supply of pharmaceutical products[2] in Mauritius. In this regard, it provides for the market background and regulatory framework characterising the pharmaceutical sector. The competitive assessment of the pharmaceutical market is then undertaken to identify any potential competition concern that may be arising therefrom. More specifically, the Study aims at:

- understanding the pharmaceutical market structure and supply chain in Mauritius;
- understanding the regulatory framework governing the sector in particular the framework governing the licensing of economic operators, product entry and pricing of pharmaceutical products; and
- assessing the conditions of competition in the supply of pharmaceutical products.

1.6. It is to be highlighted that the Study neither seeks to identify any wrongdoing by individual companies nor reaches any conclusion as to whether certain practices infringe the Act. It may, however, provide the Competition Commission with a factual basis for deciding whether any enforcement action is needed.

B. Purpose of the Report for Consultation

1.7. By way of this Report, the Competition Commission is soliciting the views and comments of interested stakeholders on the findings of the Study and proposed recommendations.

1.8. All stakeholders are invited to submit their views and comments, in writing, not later than **12th October 2020** to the **Executive Director** of the Competition Commission, 10th Floor, Hennessy Court, Corner Suffren Road and Pope Hennessy Street, Port Louis.

[2] Throughout this Study, we will use the term 'pharmaceutical products' to include medicines and drugs as well.

C. Structure of the Report

1.9. The rest of the Report is structured as follows:

- Section 2 provides an overview of the healthcare sector and the pharmaceutical supply chain.
- Section 3 describes the regulatory framework governing the trade and sale of pharmaceutical products. It includes the licensing, product registration and pricing framework.
- Section 4 provides an assessment of the conditions of competition in the supply of pharmaceutical products and an identification of potential competition issues.
- Section 5 concludes and provides recommendations to address any potential competition issues identified.

2. Overview of healthcare sector and pharmaceutical industry in Mauritius

2.1. Beside competent healthcare professionals and medical equipment, pharmaceutical products are essential in the provision of healthcare services. Pharmaceutical products are paramount in the diagnosis, treatment or prevention of diseases and hence contribute to the well-being of people and the general prosperity of the economy. The pharmaceutical industry is therefore an important part of the health sector and as such to better appreciate its contribution, this section provides a brief overview of the sector. Thereafter, the pharmaceutical supply chain and market background are covered.

A. Healthcare sector

2.2. In Mauritius, like in many countries, healthcare services are provided by both public and private healthcare institutions. The Ministry of Health & Wellness ('Ministry of Health' thereafter), being the responsible ministry, has the purview on the services provided by both public and private healthcare institutions. According to the latest National Health Accounts (NHA) Report[3], around 73% of the healthcare needs (include health education, disease prevention, diagnosis, treatment, rehabilitation, and terminal care) of the population are catered by public healthcare institutions while the remaining 27% are delivered by their private counterparts.

2.3. The public healthcare network, administered by the Ministry of Health, consists of 23 area health centres, 130 community health centres, 5 mediclinics, 5 regional hospitals, 4 specialised hospitals and 2 cardiac centres. According to latest available figures, the total bed capacity of public hospitals stands at 3,691[4].

2.4. The island-wide public healthcare network provides a comprehensive range of healthcare services free of charge at all public healthcare institutions. With respect to those specialised medical treatments which are unavailable locally, the government operates the means-tested Overseas Treatment Scheme. Under the scheme, the government provides financial assistance of up to Rs 1 million to cover all medical expenses for a patient travelling overseas for medical treatment, including cost of airfare and other services[5].

2.5. The contribution of private healthcare institutions is equally significant in the delivery of healthcare services in Mauritius. They provide healthcare services on a user fee basis, financed mainly through 'out-of-pocket' expenditure and to a lesser but increasing extent through private health insurance schemes. As at end of 2018, there were 19 registered private healthcare institutions with a total bed capacity of 724[6].

2.6. Table 1 below provides an overview of the number of health professionals and infrastructure in both public and private healthcare institutions.

[3] See National Health Accounts 2017 at http://health.govmu.org/English/Documents/2018/NHA%20Report%202017%2024%20September%202018.PDF

[4] See Health Statistics Report 2018. Available at: http://health.govmu.org/English/Statistics/Health/Mauritius/Documents/HEALTH%20STATS%20REPORT%202018.pdf

[5] Cabinet decision of 13 March, 2020 available at http://pmo.govmu.org/English/Documents/Cabinet%20Decisions%202020/%E2%80%8BCabinet_Decisions_taken_on_%E2%80%8B13_MARCH_2020.pdf

[6] Supra note 5.

Table 1: Healthcare Expenditure, 2008 – 2017 (Rs billion)

Resources	2011			2018		
	Public	Private	Total	Public	Private	Total
Doctors	970	571	1,561	1,525	1,685	3,210
Dentists	66	202	268	66	345	411
Pharmacists	23	385	408	66	470	536
Qualified Nurses and Midwives	3,089	581	3,670	3,907	493	4,400
Bed capacity	3,415	*706*	4,121	3,691	724	4,415

Source: Compiled from Health Statistics Report, 2018, Statistics Mauritius

2.7. As illustrated above, in 2018, there were 3,210 doctors, 411 dentists, 536 pharmacists and 4,400 qualified nurses and midwives. Except for the latter, the majority of health professionals are employed by private healthcare institutions.

2.8. Health expenditure has been rising significantly over time in both public and private sectors. For instance, for the period 2008-2017, total healthcare expenditure has more than doubled, rising from around Rs 11.3 billion in 2008 to reach about Rs 26.2 billion in 2017 (see Table 2).

Table 2: Healthcare Expenditure, 2008 – 2017 (Rs billion)

Year	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Government	4.0	4.7	6.2	5.9	6.7	7.3	9.7	9.8	11.0	11.2
Private	7.2	7.4	7.6	7.9	8.1	9.9	11.7	13.1	14.0	14.7
Out of pocket	*7.0*	*7.2*	*7.4*	*7.6*	*7.8*	*9.3*	*10.8*	*11.6*	*12.0*	*12.8*
Others	*0.2*	*0.2*	*0.2*	*0.3*	*0.3*	*0.6*	*0.9*	*1.4*	*1.9*	*1.9*
External financing	0.1	0.2	0.3	0.6	0.3	0.2	0.1	0.6	0.1	0.2
Total	**11.4**	**12.4**	**14.1**	**14.3**	**15.0**	**17.5**	**21.6**	**23.4**	**24.8**	**26.2**

Source: Compiled from WHO Global Observatory Database

2.9. Over the whole period 2008-2017, private healthcare expenditure has outsized expenditure in public healthcare institutions. In 2017, for instance, private healthcare expenditure amounted to about Rs 14.7 billion compared to only Rs 11.2 billion spent on public (government) healthcare expenditure. A general observation is that private healthcare expenditure is mainly met from 'out-of-pocket' payments. For 2017, 'out-of-payment' expenditure amounted to around Rs 12.7 billion, representing 87% of the total private healthcare expenditure.

2.10. It can thus be observed that the health sector in Mauritius has been continuously expanding both in terms of infrastructure and expenditure. Public and private healthcare institutions are both major contributors to the health sector.

B. The pharmaceutical sector

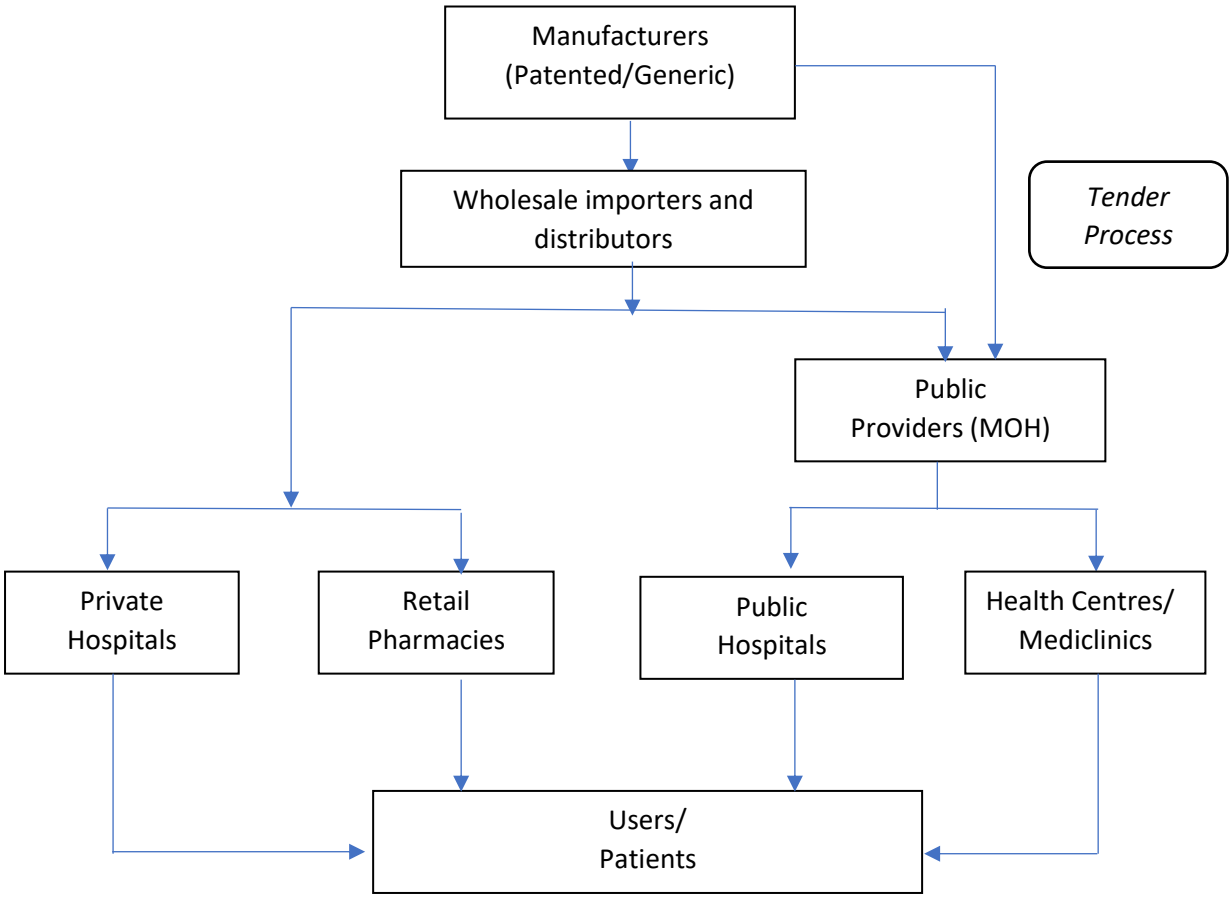
2.11. Having provided a brief overview of the health sector in Mauritius, the section below describes the pharmaceutical industry in terms of its supply chain and some market statistics on importation of pharmaceutical products.

i. The Supply chain

2.12. Based on interaction with the various stakeholders, it is gathered that players in the local pharmaceutical industry are principally involved at wholesale importation and distribution and at retail distribution levels. Currently, there is no pharmaceutical manufacturing company that caters for the local market as such.

2.13. Figure 1 illustrates a simplified supply chain for pharmaceutical products in Mauritius.

Figure 1: Simplified Pharmaceutical Supply Chain



2.14. As depicted in the supply chain above, pharmaceutical products are made available to users/patients in both public and private healthcare institutions. In the public network, pharmaceutical products are provided free of charge at all public hospitals, health centres and mediclinics. In this regard, the Ministry of Health procures pharmaceutical products based on national and international competitive tenders. In most cases, the majority of medicines are procured from local wholesale importers and distributors. For instance, for the fiscal year 2019/20, the Ministry of Health spent around Rs 1.1 billion on medicines, drugs and vaccines[7], representing around 74% of its supplies from local wholesale pharmacies. Direct imports made up the remaining 19% and the residual 7% were sourced from international suppliers.

2.15. In the private channel of healthcare distribution, patients purchase medicines mainly from retail pharmacies which are supplied by wholesale pharmacies. In 2019, it is estimated that around Rs 4 billion worth of pharmaceutical products were supplied in the private chain, the majority of these being prescription medicines supplied through retail pharmacy outlets to users. Private hospitals also procure most of their supplies from local wholesale pharmacies and to a much lesser extent rely on direct imports.

[7] Submitted by the Ministry of Health

2.16. As established in the supply chain, there are three distinct levels namely manufacturing, wholesale importation and distribution and retail distribution which will be examined in further detail.

a. Manufacturing

2.17. At local level, it has been gathered that there is currently only one licensed manufacturer of pharmaceutical products in Mauritius, namely Ajanta Pharma (Mauritius) Ltd which possesses a WHO-Good Manufacturing Practice (GMP) compliant manufacturing facility. Incorporated in 17 October 1994, Ajanta Pharma (Mauritius) Ltd is a wholly owned subsidiary of Ajanta Pharma Ltd, an Indian-based specialty pharmaceutical company engaged in the development, manufacturing and marketing of quality finished dosages of branded generics and generics[8]. Issued with an Export Enterprise Certificate, Ajanta Pharma (Mauritius) Ltd exports a major part of its production to African countries[9]. As at December 2018, the company had generated a turnover of Rs 636.4 million[10].

2.18. As such, pharmaceutical manufacturing companies supplying their products in Mauritius are essentially international.

b. Wholesale importation and distribution

2.19. As emphasised earlier, we rely mainly on importation for our supply of pharmaceutical products. Wholesale pharmacies in Mauritius are engaged in the wholesale importation and supply of pharmaceutical products to public as well as private channels of distribution. There are currently 40 registered wholesale pharmacies in the country and some of these also operate retail outlets. It may also be noted that 6 of the 40 wholesale pharmacies supply mostly veterinary products.

2.20. Wholesale pharmacies are the largest importer of pharmaceutical products in Mauritius with a share of 94% in 2019. Other importers include the government mainly through the Ministry of Health; retail pharmacies; private clinics; and research companies.

2.21. Table 3 illustrates the evolution in the share of importation of pharmaceutical products by category of importers between 2017 and 2019.

Table 3: Importers of pharmaceutical products, 2017-2019

Importers	2017	2018	2019
Wholesale pharmacies	94.0%	93.5%	94.1%
Government	4.3%	4.8%	4.0%
Private Clinics	0.0%	0.1%	0.1%
Others	1.8%	1.7%	2.0%

Source: Computed from data from MRA

[8] Ajanta Pharma Ltd, accessed from < http://www.ajantapharma.com/AnnualReports.aspx >.
[9] Submission during meeting with Department of Pharmaceutical Services on 07th August 2014.
[10] See Registrar of Companies. Available at: https://companies.govmu.org:4343/MNSOnlineSearch

c. Retail distribution

2.22. Pharmaceutical products are provided free of charge to patients in all public healthcare institutions. For outpatients, medicines are dispensed by trained pharmacists at the pharmaceutical dispensing units within the public healthcare network.

2.23. In the private channel of distribution, pharmaceutical products are sold by registered retail pharmacies. These pharmaceutical retail outlets are administered by registered pharmacists-in-charge on the private licensed premises. In 2019, there were 354 registered retail pharmacies in Mauritius.

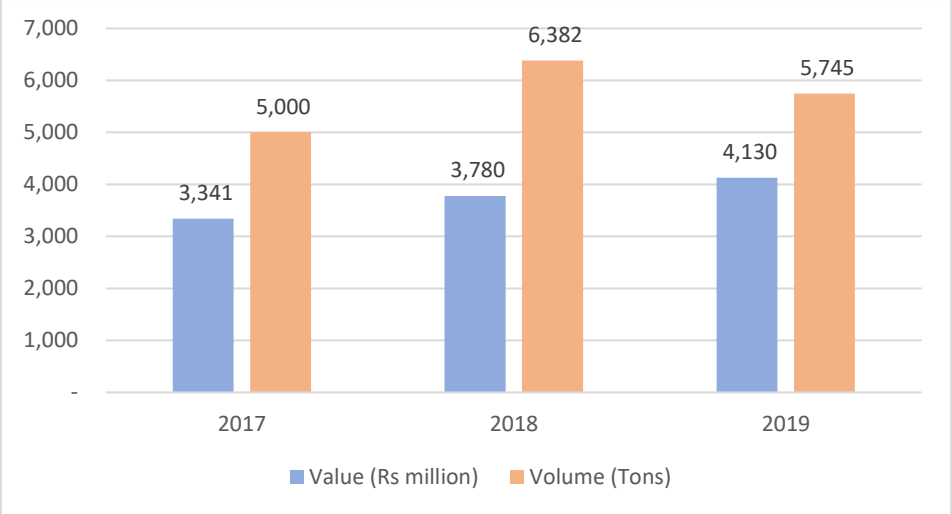
ii. Market statistics

2.24. As highlighted earlier, importation is the main source of supply of pharmaceutical products in Mauritius. In 2019, the total CIF (costs, insurance and freights) value of pharmaceutical products imported into the country for local distribution amounted to around Rs 4.1 billion[11] (an additional Rs 800 million of pharmaceutical products was imported but for re-exportation). It is estimated that the market value of the products imported and supplied to both public and private healthcare institutions is likely to be above Rs 5 billion.

2.25. It has also been observed that the CIF value of pharmaceutical products imported for local distribution has been increasing in line with the increasing demand for healthcare services. For instance, between 2017 and 2019, this value has risen from Rs 3.3 billion to Rs 4.1 billion. As regards volume, around 5,745 tons were imported in 2019 compared to around 5,000 tons in 2017. Over the period 2017-2019, this represents an increase of 24% and 15% in terms of value and volume, respectively.

2.26. Figure 2 shows the evolution in the importation of pharmaceutical products between 2017 and 2019.

Figure 2: Imports of pharmaceutical products, 2017-2019

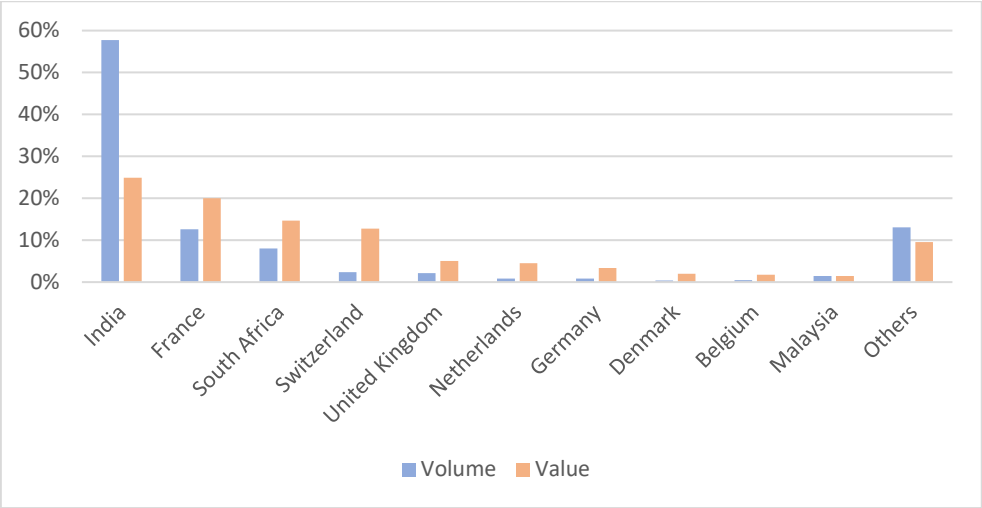


Source: Compiled from Trade Statistics and MRA

2.27. In 2019, pharmaceutical products were imported into Mauritius from 66 countries for inland supply as well as for re-exportation. The products intended for local supply were sourced from 57 countries, with India being the principal one. Figure 3 illustrates the shares of pharmaceutical products imported by country of origin.

[11] Trade Statistics, Statistics Mauritius and data from the MRA

Figure 3: Imports of pharmaceutical products in 2019, by country of origin



Source: MRA

2.28. Imports from India represented 58% of the total volume and 25% of the value of total imports. France and South Africa followed in terms of the major source of imports with shares of 13% and 8% in volume and 20% and 15% in value terms, respectively. Imports from the remaining 54 countries made up for 22% of the volume and 40% of the value of pharmaceutical products.

3. The Regulatory framework for the pharmaceutical industry

3.1. Like in other countries, the pharmaceutical industry in Mauritius is highly regulated. There are various regulations which collectively are aimed at ensuring the availability, safety, efficacity and affordability of pharmaceutical products for users.

A. Enabling Legislations

3.2. The principal legislations are the Pharmacy Act 1983[12] (the "Pharmacy Act"), the Pharmacy Council Act 2015[13] (the "Pharmacy Council Act"),the Consumer Protection (Price and Supplies Control) Act 1998[14] (the "Consumer Protection (Price and Supplies Control) Act") and various regulations made by the responsible Minister through those Acts.

i. The Pharmacy Act 1983

3.3. The Pharmacy Act provides for the main framework for regulating the manufacturing, importation, distribution and sale of pharmaceutical products in Mauritius.

3.4. Since its initial enactment, the Pharmacy Act has been revised by the Economic and Financial Measures (Miscellaneous Provisions) Act 2013[15], the Pharmacy Council Act, the Business Facilitation (Miscellaneous Provisions) Act 2019[16] and the Covid-19 (Miscellaneous Provisions) Act 2020[17]. As a whole, these revisions were aimed at formalising the registration and commercialisation process of pharmaceutical products supplied in Mauritius.

3.5. Section 3 of the Pharmacy Act establishes a Pharmacy Board (the "Board") which is entrusted with several functions. Those are *inter alia* to:

- exercise control over the manufacturing, importation, distribution, sale and possession of any drug or poison, dangerous drug, and psychotropic substance;
- license any person wishing to operate a pharmacy; and
- more generally, take such measures as the Board thinks fit to ensure the implementation of the Pharmacy Act.

3.6. The statutory functions of the Board are exercisable subject to the approval of the Minister[18]. The Board is assisted by several committees established by the Pharmacy Act in carrying out its functions; notably an 'Education Committee' (Section 6), a 'Trade and Therapeutics Committee' (Section 7), a 'Poisons Committee' (Section 8) and a 'Planning Committee' (Section 9).

3.7. The Board is statutorily composed of:

- the Chief Medical Officer (the 'Director General Health Services'), who is also the Chairman of the Board;
- the Chief Government Pharmacist (the 'Director of Pharmaceutical Services');
- 5 pharmacists appointed by the Minister; and

[12] Act No. 60 of 1983
[13] Act No. 13 of 2015
[14] Act No. 12 of 1998
[15] Act No. 27 of 2013 (Section 34)
[16] Act No. 14 of 2019 (Section 25)
[17] Act No. 1 of 2020 (Section 41)
[18] Section 4 of the Pharmacy Act 1983

- a law officer designated by the Attorney-General.

3.8. The 5 pharmacists are appointed by the Minister for an initial period of two years and are eligible for re-appointment. The Pharmacy Act also provides for a government pharmacist (designated by the Minister) to act as the Registrar of the Board. The Registrar is responsible for implementing the decisions taken by the Board, after approval of the Minister in accordance with the provisions of the Pharmacy Act[19].

ii. The Pharmacy Council Act 2015

3.9. The Pharmacy Council Act transfers the regulatory function regarding the pharmacist profession to a recently established professional body – the 'Pharmacy Council' (the "Council"). The Council aims to provide a better regulation of the profession of pharmacists in Mauritius.

3.10. Fully operational since November 2017, the Council has the main functions of:

- controlling access to the profession of pharmacist through proper registration procedures, approved training and examinations for pre-registration trainees and the publishing of an annual official list of pharmacists,
- ensuring that pharmacists are fit to practise by providing for continuing professional education, and
- maintaining discipline through guidelines contained in a Code of Practice and through clear disciplinary procedures in cases of pharmacists' default.

3.11. As per the Pharmacy Council Act, the Council consists of 15 members as follows:

- 3 elected pharmacists from the public sector;
- 5 elected pharmacists from the private sector,
- 1 representative of pharmacist posted at the Ministry of Health;
- 1 representative of the Prime Minister's Office;
- 1 representative of the Attorney General Office;
- 1 representative of a tertiary education sector, to be appointed by the Minister; and
- 3 other persons to be appointed by the Minister, where 2 shall be registered pharmacists and not from the public sector.

iii. The Consumer Protection (Price and Supplies Control) Act 1998

3.12. The Consumer Protection (Price and Supplies Control) Act makes provision for the control of trading practices and prices in Mauritius and establishes a Profiteering Division at the Supreme Court, which shall have the exclusive jurisdiction to try any person charged with an offence under this Act.

3.13. In substance, the Act grants powers to the Minister, to whom responsibility for the subject of commerce and consumer protection is assigned, to oversee prices of goods denoted as

[19] Submission during meeting with Deputy Director of Pharmaceutical Services and Registrar of Pharmacy Board on 07th August 2014.

"controlled goods"[20]. More precisely, the responsible Minister can either fix the price directly[21] or determine the maximum mark-up[22] that a controlled good is subject to.

3.14. Pharmaceutical products are classified as controlled goods whereby the maximum mark-up is fixed through the Consumer Protection (Consumer Goods) (Maximum Mark-up) Regulations 1998[23].

3.15. Accordingly, it can be observed that regulatory control is exercised in a comprehensive manner through the Pharmacy Act, the Pharmacy Council Act and the Consumer Protection (Price and Supplies Control) Act at three levels, namely the:

a. registration of pharmaceutical products,

b. licensing of economic operators, and

c. pricing of pharmaceutical products.

B. Registration Framework of Pharmaceutical Products

i. The Requirement for Registration of Pharmaceutical Products

3.16. The Pharmacy Act widely defines 'pharmaceutical products' as "a drug, medicine, preparation, poison or therapeutic substance"[24] while excluding "any pharmaceutical product based on the principles of ayurvedic or Chinese or homeopathic medicine and certified as such by the Board"[25] from the purview of its ambit.

3.17. The Board is mandated to regulate entry of pharmaceutical products on the Mauritian market. Prior to the amendments brought to the Pharmacy Act in 2016, the Pharmacy Act did not specifically require the registration of pharmaceutical products but prohibited the importation of any pharmaceutical product without a permit delivered by the Board[26]. These amendments instituted a practice of requiring the registration of any pharmaceutical product for commercialisation in Mauritius or individual consumption.

3.18. Sections 25 and 36C of the Pharmacy Act, as amended under the Economic and Financial Measures (Miscellaneous Provisions) Act 2013, have introduced a formal registration process for both imported and locally manufactured pharmaceutical products respectively.

3.19. The reasons put forward by the Department of Pharmaceutical Services of the Ministry of Health in support of the introduction of the proposed registration process[27] were to:

a. control the number of generics entering the market given the relatively small size of the pharmaceutical sector in Mauritius;

b. ascertain the source of the different pharmaceutical ingredients and ensuring the traceability of the end-product (across all stages of the manufacturing process);

[20] A list is available in the First & Second Schedule of the Consumer Protection (Price and Supplies Control) Act
[21] Section 3 of the Consumer Protection (Price and Supplies Control) Act
[22] Section 4 of the Consumer Protection (Price and Supplies Control) Act
[23] GN No. 150 of 1998
[24] Section 2 of the Pharmacy Act.
[25] Section 46(b) of the Pharmacy Act.
[26] Prior version of Section 25 of the Pharmacy Act
[27] Submission of factual meeting dated 17th February 2016 with representative of Pharmaceutical Services Department.

c. ensure that proper product handling mechanisms and distribution channels are put in place to safeguard the therapeutic equivalence of the product thereby collectively helping to secure good quality products for consumers;

d. standardize the registration system with international good practices (especially among Southern African Development Community (SADC) member states); and

e. meet administrative costs involved in the market authorization process (which is a service currently being provided free of charge).

ii. Pharmaceutical Products Registration process

3.20. Any person wishing to register an imported pharmaceutical product or a locally manufactured pharmaceutical product is required to make an application, in duplicate, to the Board as per the prescribed form (as set out in First Schedule of the Pharmaceutical Product (Fees) Regulations 2016[28]). The application form must be accompanied by a non-refundable processing fee and the corresponding registration file, in duplicate, containing all the technical information and specifications in the Common Technical Document (CTD) Format[29]. The registration file should normally contain the following information:

a. authorisation from Licensing Authority of country of origin;
b. the manufacturer's WHO certification of Good Manufacturing practice amongst others.
c. Certificate of Analysis (COA) and Certificate of Pharmaceutical Products (COPP);
d. label to specify country of origin (manufacturer and country marketing the product);
e. description of processes of manufacture (including those not carried out in country of origin);
f. information regarding full composition of the drug (including raw material sourcing and their quality control);
g. information on registration status in country of origin and other countries;
h. all quality and safety processes including quality control process, in process testing, stability testing, bio-equivalence/bio-availability studies, pharmacological tests and toxicology tests.
i. price of drugs-ex-factory/retail price in country of origin, and wholesale/retail price in Mauritius; and
j. a minimum of two samples.

3.21. Upon submission of the application (including a complete registration file) and payment of the processing application fee, a receipt is delivered to the applicant. The Board will then refer the application to the Trade and Therapeutics Committee for its recommendations[30], following which; the Board may approve or reject the application. Where a complete

[28] GN No. 47 of 2016.

[29] The CTD format is an internationally agreed format for the preparation of applications for registrations of new medicines and was developed by respective medicines regulatory authorities in the EU, U.S. and Japan. The CTD assembles all the Quality, Safety and Efficacy information in a common format and is intended to assist in the implementation of good review practices. (Source: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, 2017)

[30] The Trade and Therapeutics Committee, established under Section 7 of the Pharmacy Act, shall advise the Board on '*any matter relating to the manufacture and importation of pharmaceutical products; any area which is in need of a pharmacy; the compilation and maintenance of a National Drugs Formulary; any reported adverse effect caused by any drug and measure requiring to be taken to protect public health*'. (Section 7(1) of the Pharmacy Act).

registration dossier is submitted to the Board, the registration process is normally completed within a month[31].

3.22. Under the new registration process, the manufacturer/pharmaceutical laboratory is considered as the person applying for registration (i.e. the applicant) and, upon approval of registration, it is the applicant who becomes the 'owner of registration'. However, for administrative purposes, the registration process requires the applicant to assign one wholesale pharmacy to act as its 'legal technical representative'. The legal technical representative acts on behalf of the applicant and represents the manufacturer/laboratory during the registration process and is responsible vis-à-vis the Board on pharmacovigilance issues. As part of the registration process, the applicant also needs to specify details of its 'authorised distributor(s)' in Mauritius once the product is registered[32].

3.23. Where the Board approves the application, the applicant pays the prescribed registration fee and a receipt is delivered to the applicant. The Board will then register the pharmaceutical product and issue to the applicant a certificate of registration, on such conditions that it may determine. The certificate of registration is valid for a period of one year and may be renewed subject to payment of the renewal fee.

3.24. Section 2 of the Pharmacy Act, as amended by the Business Facilitation (Miscellaneous Provisions) Act 2019, mandates the Permanent Secretary of the Ministry of Health to issue guidelines:

a) setting out the requirements, the applicable law and the procedure for an application for, or renewal of, clearance, a licence or permit;
b) available for consultation at the Ministry;
c) posted on the website of the Ministry;
d) listing every fee leviable under the regulations;
e) listing every pharmaceutical product registered for import with the Board, together with their corresponding importers;
f) listing every person eligible to import any poison; and
g) listing every licensee;

3.25. In addition to drug registration, certain category of medicines and pharmaceutical products as well as chemicals (dangerous drugs) require a licence for their import or export. These include:

a) antibiotics, vaccines and any therapeutic substance, listed in the Sixth Schedule of the Pharmacy Act; and
b) dangerous drugs as defined under section 3 of the Dangerous Drugs Act 2000 (to ensure that the goods are destined for legitimate use (medicinal, scientific, educational).

3.26. For each consignment of antibiotic, vaccine and therapeutic substance imported into Mauritius, the importer is required to submit an application for a permit as specified under section 25 of the Pharmacy Act indicating the name of the product(s) and quantity in respect of each product being imported. An import permit is then delivered within 24 hours to the

[31] Submissions of representative of the Ministry of Health during a meeting held on 25.05.2017.
[32] Supra note 31.

importer. The permit is issued at time of arrival of the product(s) in the country, on a consignment basis. In the absence of a valid import permit granted to the importer, Customs may seize and detain a consignment of imported pharmaceutical products.

iii. The Board's Pharmaceutical Products Registration Requirements and Standards

3.27. The Board has product registration guidelines[33] which outline the technical documents that an applicant is required to submit and the factors which the Board will normally consider when assessing an application.

3.28. The Department of Pharmaceutical Services has submitted that when determining an application, the Board considers different factors such as:

a) **Quality:** The quality of a product may be ascertained through production of technical documents such as certificates issued for products moving in the international commerce (COPP, WHO Good Manufacturing Practice). Although laboratory facilities are available in Mauritius for quality control testing, the laboratory is not a functional aspect of the Board[34]. The Board does not systematically submit samples of pharmaceutical products for drug testing/analysis for the purposes of product registration[35];

b) **Efficacy**: Products should have been approved in country of origin after clinical evaluation. Bioequivalence against original drugs (Innovator) may be required for critical products.

c) **Safety**: Benefit to risk ratio must be acceptable. Products, which have been banned, adversely reported or restricted for use in other countries may be refused registration.

d) **Nature of product**: Preparations that have no proven therapeutic value (*ampoule buvables*, tonics, etc.), those that are liable to abuse (e.g. Benzodiazepines), or for which there already exist too many on the market (e.g. analgesics, antacids, anti-inflammatory) may also be refused registration.

e) **Number of existing products already on the market**: too many similar productswith no advantage in price or pharmacological action over comparable existing products of the same therapeutic class are not considered; and

f) **Price**: Price has to do with compliance to treatment, affordability, and availability. Similar products of proven value at lower or comparable prices may be considered. Although certain life-saving drugs, e.g. clot-busters, cancer drugs, anti-retrovirals are costly; their registration may however be prioritised in the interest of public health[36]. It has been further submitted that that there should be no monopoly for any single product or class of products[37].

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[33] Although the Competition Commission has, upon request, been provided with basic information relating to the product registration guidelines (by way of oral and written submissions), it is not clear whether the guidelines are publicly available (whether gazetted, published on a relevant website or otherwise) or provided to (potential) importers of pharmaceutical products.

[34] WHO, 'Mauritius Pharmaceutical Country Profile (July 2011), p. 15-16. According to *Ministry of Health*, samples are collected by government inspectors for undertaking post-marketing surveillance testing. For the period 2009 – 2011, approximately 120 samples were taken for quality control testing. Of the samples tested, 2 (i.e. 1.7 %) failed to meet the quality standards.

[35] Submission of Meeting with Deputy Director of Pharmaceutical Services and Registrar of Pharmacy Board on 07th August 2014, para 8.

[36] Information submitted by the Department of Pharmaceutical Services, dated 07.08.2015.

[37] Supra note 36

3.29. The Board also assesses the standards under which pharmaceutical products are manufactured or imported in Mauritius.

3.30. Firstly, the Board requires that all pharmaceutical products submitted for registration conform to 'specified standards' i.e. standards contained in British, French, United States or European Pharmacopoeia ('BEUF standards')[38], as defined under the Pharmacy Act[39], in order to ensure that pharmaceutical products on the market meet required quality standards. The Pharmacy Act prohibits any person from selling any pharmaceutical product that does not conform to a prescription or to specified standards.

3.31. Secondly, certain pharmaceutical drugs (in particular, highly critical drugs) need to be licensed in countries that are members of 'Pharmaceutical Inspection Convention' (PIC countries) where scientific evaluation is strict as a means of ensuring their quality[40].

iv. The Registration fees

3.32. The fees payable under the new registration regime have been prescribed under The Pharmaceutical Product (Fees) Regulations, in force since 01 April 2016.

3.33. As shown in Table 4, the above regulations provide a flat fee for registration of a pharmaceutical product, notwithstanding its type (originator, branded generic or generic).

[38] According to the WHO, '[a] pharmacopoeia, pharmacopeia, or pharmacopoea, in its modern sense, is a legally binding collection, prepared by a national or regional authority, of standards and quality specifications for medicines used in that country or region (…) The role of a modern pharmacopoeia is to furnish quality specifications for active pharmaceutical ingredients (APIs), FPPs and general requirements, e.g. for dosage forms'. WHO, 'Review of World Pharmacopoeias' (Working document QAS/12.512/Rev.1), March 2013 <http://www.who.int/medicines/areas/quality_safety/quality_assurance/resources/InternationalMeetingWorldPharmacopoeias_QAS13-512Rev1_25032013.pdf >

[39] Section 2 of the Pharmacy Act.

[40] The Pharmaceutical Inspection Convention of 1970 is a legally binding treaty between countries aimed at *inter alia* harmonising Good Manufacturing Practice (GMP) requirements, establishing uniform-mutual recognition inspections, and allowing member countries to have mutual confidence in the results of inspections carried out by inspectors of other member countries. In 1995, The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was founded as an extension of the PIC 1970 to provide a more flexible and informal co-operative arrangement between regulatory authorities in the field of GMP of medicinal products. As at 31 December 2016, PIC/S comprised 49 Participating Authorities from all continents.

Table 4: Overview of registration-related fees of pharmaceutical products

Pre-Registration Fees	Quantum (Rs)
Non-refundable processing fee	2,500
Registration fee for imported pharmaceutical product	5,000
Registration fee for locally manufactured pharmaceutical product	5,000
Post-Registration Fees	**Quantum (Rs)**
Annual renewal fee for imported pharmaceutical product	2,000
Annual renewal fee for locally manufactured pharmaceutical product	2,000
Change in Shelf Life	2,000
Change in Manufacturing Site/Distribution Channel	2,000
Extension in Line of Product	2,000
Change in Trade Name	2,000
Change In/Additional Pack Size	1,000
Change in Pack Design (Primary Pack)	1,000
Change in Pack Design (Secondary Pack)	1,000
Change in Packing Material	1,000
Change in Label Design	1,000

Source: Second and Fourth Schedules of Pharmaceutical Product (Fees) Regulations of 2016[41]

C. Import of Pharmaceutical Products Under the Current Intellectual Property Regime

i. The Patent, Industrial Designs and Trademarks Act 2002

3.34. The intellectual property ("IP") protection framework for pharmaceutical products in Mauritius is found in the Patent, Industrial Designs and Trademarks Act 2002[42] (the "PIDTA"). Given the relatively low or no domestic pharmaceutical R&D and manufacturing capability, patents are rarely applied for in respect of IP protection of pharmaceuticals. Thus, trademark registration of pharmaceutical brands in relation to import is the most prominent form of IP protection in Mauritius[43].

3.35. According to the Acting Controller of the Industrial Property Office, pharmaceutical products are grouped under Class 5 of the *International Classification of Goods and Services for the Purposes of the Registration of Marks*[44]. The registration of a trademark grants its registered owner the exclusive right to use that mark[45]. Any interested person, other than the registered owner, who intends to use a registered mark, in relation to any goods or services for which it has been registered, shall first require the agreement of the owner[46]. The registration of a mark is valid for a period of 10 years (from the filing date of the application for registration)

[41] GN No. 47 of 2016
[42] Act 25 of 2002
[43] Submission of meeting held on 13th February 2014 with the Acting Controller of the Industrial Property Office.
[44] Submission of Factual Meeting held on 13th February 2014 with the Acting Controller of the Industrial Property Office. The International (Nice) Classification of Goods and Services for the Purposes of the Registration of Marks was established by an Agreement concluded at the Nice Diplomatic Conference, on June 15, 1957 (Nice Agreement). Although not party to the Nice Agreement, Mauritius nevertheless applies the classification provided therein for the purposes of national registration of trademarks.
[45] Section 36(1) of the PIDTA.
[46] Section 40(1) of the PIDTA.

and may be renewed for consecutive periods of 10 years upon payment of a renewal fee and on such condition as may be prescribed[47].

3.36. The enforcement of protection of registered trademarks against parallel import, counterfeiting and piracy is done mainly at the level of MRA Customs, through the Customs and Border protection of IP rights (pursuant to section 66A-E of Customs Act 1988)[48]. The procedure set forth therein enables a right holder (or his nominated representative) to apply in writing and subject to the approval of the Director-General of the MRA, for Customs to suspend clearance of goods suspected of infringing their IP rights. The validity period of an application for suspension is for a maximum of two years.

3.37. When MRA Customs identifies goods suspected of infringing IP rights for which an application for customs action has been filed, it suspends the release of the goods and detains them. The right holder is informed of the suspension and invited to inspect the suspect goods. The term of the suspension is of 10 working days (or 3 working days in case of refrigerated goods) and may be extended up to a maximum of another 10 working days if necessary. Within these terms, the right holder must assess whether or not the suspect goods infringe his IP rights, inform the Director-General of MRA, for Customs, in writing, confirming the infringement and take the necessary legal action. Where no written objection is submitted within the prescribed delays, MRA Customs may release the detained goods.

ii. Parallel Importation

3.38. An interesting phenomenon observed across all jurisdictions worldwide in regard to the importation of pharmaceutical products is known as parallel import. Unlike counterfeiting or piracy, parallel imports are defined as genuine goods produced or sold abroad with the consent of the owner of the applicable IP right – copyright, trademark or patent – that are subsequently sought to be imported into the domestic market without the consent of the intellectual property right owner[49].

3.39. The legal principle underlying the concept of parallel importation refers to the 'territorial exhaustion of rights'. Under an international exhaustion regime, once the intellectual property right has been registered and the product sold, the rights are exhausted on that product and any person can source the product from any other country in which the product is commercialised so as to import and sell the product in Mauritius. On the other hand, a national exhaustion regime dictates that the intellectual property right is deemed to expire only in the country of first sale, making it possible for the right holder to prevent resale of its product in other markets.

3.40. It is worth noting that Article 6 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) has provided WTO Members with leeway in deciding upon the exhaustion regime which best fits their domestic policy objectives.

3.41. While the PIDTA allows the parallel importation of patented products, it does not, at present, cater for the international exhaustion of rights relating to marks/trademarks. For industrial design and trademarks, the PIDTA establishes a national exhaustion regime such that parallel

[47] Section 41 of the PIDTA.
[48] Mauritius Revenue Authority, Customs and Border Protection of Intellectual Property Rights, < http://www.mra.mu/download/NoticetoRightHolders1512014.pdf >
[49] OECD, Policy Roundtable Paper (2009) 'Competition and Regulation Issues in the Pharmaceutical Industry', DAFFE/CLP (2000)29 available at < http://www.oecd.org/competition/sectors/1920540.pdf >.

importation of a good registered for trademark protection would in principle be against the PIDTA[50] unless authorised by the owner of the registered mark.

3.42. Notably, Section 21 of the PIDTA in relation to rights conferred by a patent, provides that "any right under the patent shall not extend to acts in respect of articles which have been put on the market **in Mauritius or in any other country** by the owner of the patent…" [emphasis added] On the other hand, Section 40 of the PIDTA, in relation to trademarks, provides that "the rights conferred by registration of a mark shall not extend to acts in respect of articles which have been put on the market in Mauritius by the registered owner.".

3.43. To illustrate this notion of national exhaustion regime adopted in Mauritius, the Supreme Court of Mauritius dealt with the issue of parallel importation of a pharmaceutical product registered for both trademark protection and Customs border protection in the case of ***Reckitt & Colman (Overseas) Ltd v. M.N. Dauhoo and The Mauritius Revenue Authority***[51].

3.44. In this case, the plaintiff, who was the owner of the registered trademark "Strepsils" in Mauritius, had been informed by the Mauritius Revenue Authority (Customs) that the defendant, a wholesale importer of pharmaceuticals, had imported into Mauritius containers antiseptic lozenges bearing the mark "Strepsils" without the consent or authorisation of the trademark owner. The Court held that parallel importation, as it stands currently under the law, can only be possible with the consent, express or imply, of the trademark owner.

D. Licensing Framework of Economic Operators

3.45. The Pharmacy Act establishes distinct provisions for regulating market players operating along the pharmaceutical supply chain in Mauritius. Control is exercised in terms of licensing at the level of manufacturing, importation, wholesale trade and retail trade.[52]

i. Manufacturing

3.46. At the manufacturing level, the Pharmacy Act mandates the Board to assess both the production facility[53] and the manufacturing process[54] for the purpose of licensing any pharmaceutical manufacturing operations. Under the Pharmacy Act, the term 'manufacture' in relation to a pharmaceutical product, is given a broad definition to include "[to] compound, formulate, fill, package and label or perform any other operation"[55].

3.47. With respect to licensing a pharmaceutical manufacturing facility, the Board exercises regulatory oversight over the installations to be made, details of the type of machinery and energy sources, details of pharmaceutical products sought to be manufactured, among others[56]. In considering an application made in this regard, the Board may have recourse to the advice/recommendations of the Planning Committee. The Board grants any approval on payment of the prescribed fee and on such terms as are deemed necessary. Where the Board

[50] In the case of Polo Lauren Co V Tejoo M N 2012 SCJ 134, the Supreme Court, quoting from Section 40(5) of the PIDTA, clearly stated that '*nobody can put on the local market goods bearing a trademark registered under our law unless authorized by the owner of the trademarks*'.
[51] 2012 SCJ 495.
[52] Part IV and VII of the Pharmacy Act deals with Pharmaceutical Trade and the Manufacture of Pharmaceutical Products respectively
[53] Section 35 of the Pharmacy Act.
[54] Section 36 of the Pharmacy Act.
[55] Section 2 of the Pharmacy Act.
[56] Section 35(2) of the Pharmacy Act.

refuses to issue a license for building a manufacturing facility, the Board has the explicit duty to notify the applicant of the reason(s) of its refusal[57].

3.48. Regarding the manufacturing process, the applicant must furnish documents regarding (i) "the formula of each pharmaceutical product to be manufactured, (ii) the technical description of the production process, and (iii) details of quality control"[58]. The Board will assess the application only upon the fulfilment of these prerequisites and may even require the applicant to provide such other information that the Board deems necessary for the purpose of assessing the application.

3.49. The Pharmacy Act also prescribes three mandatory criteria to be met by the applicant, failing which the application will not be granted. These factors include adequate facilities for manufacturing sterile preparations, appropriate quality control both at the level of the therapeutic substance and the finished product, the supervision of the manufacturing process by a pharmacologist, pharmacist or chemist possessing relevant experience[59].

3.50. Even when a person has been licensed to manufacture pharmaceutical products, the Pharmacy Act imposes several duties upon the licensee to ensure: (i) constant supervision of the factory by a properly qualified person, (ii) adequate quality control; and (iii) proper storage, records-keeping and sampling facilities[60].

3.51. The recent revisions to the Pharmacy Act by the Covid-19 (Miscellaneous Provisions) Act 2020[61] provide the framework for the marketing authorisation process and commercialisation of pharmaceutical products manufactured in Mauritius. Under the new Sections 36A, 36B and 36C, a manufacturer licensed under the Pharmacy Act is not allowed to sell a manufactured pharmaceutical product, whether on the local market or not, unless it is registered with the Board.

ii. Importation

3.52. The revised Sections 25 and 25A deals with the requirements to be fulfilled concerning the import of pharmaceutical products. Any person who wishes to carry out such import must first make an application for registration of the pharmaceutical product with the Board. In the event that such an application is successful, clearance[62] must then be obtained from the Board in regard to the consignment of the pharmaceutical product crossing the Mauritian border. When this two-fold process is complied with, only then a pharmaceutical product may be commercialised through wholesale or retail trade.

iii. Wholesale trade

3.53. Concerning the wholesale trade of pharmaceutical products, the Pharmacy Act prohibits the operation of a wholesale pharmacy unless: (i) the person operating the pharmacy holds a duly issued license; (ii) there is a pharmacist-in charge of the wholesale pharmacy on a full-time basis; and (iii) the premises used for the wholesale pharmacy are distinctly separate from those of any other pharmacy[63] (including a retail pharmacy).

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[57] Section 35(5) of the Pharmacy Act.
[58] Section 36(2) of the Pharmacy Act.
[59] Section 36(5) of the Pharmacy Act.
[60] Sections 37-39 of the Pharmacy Act
[61] Act No. 1 of 2020
[62] Section 26A(1) of the Pharmacy Act
[63] The Pharmacy Act defines pharmacy to include 'any premises where, subject to [the Pharmacy Act], any pharmaceutical product may be dispensed, sold, exposed or offered for sale'.

3.54. As per guidelines issued by the Board[64], wholesale pharmacies are also required to meet the set standards for the warehousing infrastructure, safe handling, storage and distribution of pharmaceutical products, as a licensing condition.

iv. Retail trade

3.55. Section 17 of Pharmacy Act prohibits the sale by retail of any medicine or drug in any place other than a pharmacy. However, there exists strict exceptions to this provision, notably Section 17(3) and (4), whereby a medical practitioner is authorised to perform such sale if he/she "does not keep open shop and there is no pharmacy within a distance of 3 miles from the place where he attends a patient" or if the Minister makes regulations[65] authorising such sale.

3.56. All retail pharmacies require a licence obtained from the Board to operate in Mauritius. Unlike some countries[66] where doctors and manufacturers are not allowed to own a pharmacy due to a conflict of interest as prescribers, in Mauritius, there is no such restriction on the ownership of a pharmacy[67]. Any individual or legal entity may, in principle, own pharmacies in Mauritius.

3.57. Following receipt of a written application for operating a retail pharmacy, the Board will usually require the Trade and Therapeutics Committee (TTC) to carry out on-site visit(s)/inspection(s) of the proposed retail outlet. The process usually involves a first on-site visit from members of the TTC to assess the location and the building structure, following which the TTC sends its recommendations to the Board. The members of the TTC will usually conduct a second visit with a view to ensuring that the premise is ready to operate as a full-fledged pharmacy so that the Board may grant a licence to operate the pharmacy. It can take a minimum of six months to process an application for the registration of a retail pharmacy[68].

3.58. Section 18(4) of the Pharmacy Act lists three criteria which the Board is required to take into account when considering such an application, namely:

a. the number of pharmacies in the area in which the applicant intends to operate;
b. the needs of the area for an additional pharmacy; and
c. the recommendations of the TTC[69].

3.59. In September 2017, the Ministry of Health published updated guidelines for opening of a retail pharmacy[70]. The guidelines establish infrastructural requirements and set out demographic and geographic criteria that the Board will consider under section 18(4)(a) and (b) of the Act respectively.

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[64] The Competition Commission has, as at date, not received a copy of the relevant guidelines issued by Board (regarding wholesale pharmacy licensing) despite several requests made to the relevant department at the Ministry.
[65] The General Retailers (Sale of Simple Medicines) Regulations 1989 allows any person who holds a General Retailer's Licence to sell pharmaceutical products denoted as "simple medicines". These are the list of pharmaceutical products set out in the First and Second Schedule of the Regulations.
[66] The countries are Iceland, Ireland, Norway and Sweden.
[67] OECD, Competition Issues in the Distribution of Pharmaceuticals (DAF/COMP/GF(2014)6)(18 March 2014), p. 4< http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/GF(2014)6&docLanguage=En >
[68] Submission of Meeting with Deputy Director of Pharmaceutical Services and Registrar of Pharmacy Board on 07th August 2014.
[69] Section 18(4) of the Pharmacy Act.
[70] Ministry of Health and Quality of Life Guidelines 'Guidelines for opening of pharmacies (Retail)' (11.09.17).

3.60. In applying "the number of pharmacies in the area in which the applicant intends to operate" criterion, the Board will have regard to the pharmacy to population ratio, which is one pharmacy for 2000 inhabitants.

3.61. Regarding "the needs of the area for an additional pharmacy" criterion, the Board now requires that the minimum distance between the proposed pharmacy and an existing one must be 200 meters apart in a linear direction.

3.62. The above two criteria will not be applicable with regards to applications for the opening of a pharmacy in shopping malls and smart cities.

3.63. Furthermore, the Board has established both indoor and outdoor design requirements for a retail pharmacy, in terms of the minimum area, floor space and height requirements, separate storage and dispensing areas[71]. Also, the pharmacy should be separate from any other business by a concrete partition.

3.64. The guidelines prohibit the applicant from subletting any part of the pharmacy to any doctor, other healthcare professional or any other business. Any doctor's surgery should be completely separated from the pharmacy by a concrete partition. The name of the pharmacist-in-charge should be clearly displayed and must be updated immediately when there is a change.

3.65. The guidelines further state that the use of a signboard to feature an advertisement is prohibited. This goes in line with the general advertising prohibition contained at section 41 of the Pharmacy Act[72].

3.66. Any license (manufacturing, wholesaling or retailing) granted by the Board is valid for a one-year period upon payment of the relevant fee and the license is renewable on a yearly basis (upon payment of a renewal fee). Table 5 shows the evolution of the respective fees applicable at different levels of the pharmaceutical trade in Mauritius. It can be observed that the annual fees considerably increased in 2010.

[71] According to the amended Ministry of Health guidelines, *'the area of the pharmacy should be of minimum 25 square metres; it shall consist of at least two adjoining rooms, each having a minimum floor space of 134.5 square feet and a minimum height of 2.75 metres; one room of the pharmacy shall be used as a service room and either two other rooms or one other room divided into two sections by a partition of not less than 2 metres in height for dispensing and for storage respectively;*
and the height of a mezzanine is to be equivalent to 2.75 metres, if floor space is to be included in the area of the pharmacy.

[72] According to section 41 of the Act, no person shall advertise any pharmaceutical product intended for human or veterinary use except in such technical or professional publications, as may be approved by the Board.

Table 5: Evolution of Licensing Fees in Pharmaceutical Trade, 1985 - 2020

Type of Licence	Annual Fees Applicable 1985 (Rs)	Annual Fees Applicable (1985-2009) (Rs)	Annual Fees Applicable (2010 - present) (Rs)
Registration of Pharmacist	250	303	1000
Licence for Retail Pharmacy in Town	920	324	4100
Licence for Retail Pharmacy in an area, other than a town	60	164	2100
Licence for Wholesale Pharmacy	400	904	5100
Licence for Manufacture of Pharmaceutical Products	200	452	5100

Source: Department of Pharmaceutical Services

E. Price Regulation of Pharmaceutical Products

i. Evolution of the pricing control mechanism in Mauritius to date

3.67. A mark-up system regarding pharmaceutical products was first introduced under Section 5 of the Supplies Control Act 1974[73] by the Medicines (Maximum Mark-up) Regulations 1977[74] and then replaced by the Medicines (Maximum Mark-up) Regulations 1981[75]. In essence, the wholesale and retail components of pharmaceutical products prices are regulated by establishing maximum allowable mark-ups. Such a system is aimed at ensuring the affordability of pharmaceutical products while allowing room for wholesalers/retailers to cover relevant costs and also earn an element of profit.

3.68. The Supplies Control Act 1974 was then repealed and replaced by the Consumer Protection (Price and Supplies Control) Act 1998. Consequently, The Medicines (Maximum Mark-up) Regulations 1981 was revoked by the Consumer Protection (Consumer Goods) (Maximum Mark-up) Regulations 1998.

3.69. Pharmaceutical products were thereby classified as a "controlled good" for which the responsible Minister may determine the maximum mark-up. The Price Fixing Unit of the Ministry of Commerce and Consumer Protection is the relevant body responsible for controlling the prices of pharmaceutical products in Mauritius as of now.

3.70. Provision is made by the Consumer Protection (Consumer Goods) (Maximum Mark-Up) Regulations 1998 not only for wholesale and retail components of pharmaceutical products prices by establishing maximum allowable mark-ups but also for a special allowance of 5% for wholesale importers to meet costs such as bill of entry fees, transport and storage costs, handling and clearance charges.

3.71. The new categorisation was in terms of pharmaceutical products and simple drugs with maximum mark-up, inclusive of special allowance, set at 50% and 45% respectively.

3.72. In 2004, the maximum mark-up for both pharmaceutical and simple drugs was reviewed and set at 35% with a special allowance of 2% on landed costs. Duties are neither levied on

[73] Act No. 20 of 1974
[74] GN No. 68 of 1977
[75] GN No. 338 of 1981

imported Active Pharmaceutical Ingredients (APIs) nor are prices of finished pharmaceutical products subject to any form of taxes (i.e. import duty and VAT).

3.73. Table 6 shows the evolution of the new mark-up system applicable on pharmaceutical products since 1998.

Table 6: Evolution of mark-up system from 1998 to date

Regulation	Effective Period	Product categorisation	Maximum Mark-up (%)	Special Allowance (%)
The Consumer Protection (Consumer Goods) (Maximum Mark Up) Regulations 1998	8th September 1998 to 18th June 2004	Pharmaceutical products	45	5
		Simple Drugs	35	5
The Consumer Protection (Consumer Goods) (Maximum Mark Up) (Amendment) Regulations 2004[76]	18th June 2004 to date	Pharmaceutical products and simple drugs	35	2

Source: Compiled

3.74. Table 7 illustrates the price structure of a pharmaceutical product using a hypothetical manufacturer's selling price (MSP) of Rs100:

Table 7: Illustrative Price Mark-Up system in Mauritius

Cost Element	From 1998 to 2004		After June 2004	
	Mark Up (%)	Price (Rs)	Mark Up (%)	Price (Rs)
MSP		**100**		**100**
Customs Duty	5	5	0	0
Special Allowance	5	5	2	2
Landed Cost		**110**		**102**
Wholesale Mark-Up	14	15.40	11	11.22
Wholesale Price		**125.40**		**113.22**
Retail Mark-Up	27	33.85	21.6	24.48
Retail Price		**159.25**		**137.70**

Source: Price Fixing Unit

3.75. It is to be noted that the Consumer Protection (Consumer Goods) (Maximum Mark-Up) Regulations 1998, establishes two regimes for the purpose of determining the cost price of a pharmaceutical product (subject to the approval of the Minister):

i. where the maximum prices are fixed on a consignment basis, the importer shall use the currency conversion rate prevailing on the date of submission of the required form to the Minister; and

[76] GN No. 82 of 2004

ii. where the maximum prices are fixed for a minimum period of 6 months, the importer shall use the currency conversion rate approved in writing by the Minster.

4. Conditions of Competition

4.1. The previous sections provided an overview of the pharmaceutical industry in Mauritius in terms of the supply chain, key market players and the governing regulatory framework. Against this background, an assessment of the prevailing competition conditions is undertaken. The assessment is based on the analysis of the market structure and concentration levels across the supply chain and discussion of potential issues that could be arising from the regulatory framework with respect to commercialisation and pricing of pharmaceutical products; and the licensing of economic operators in the industry.

A. Market structure and concentration

4.2. An assessment of the market structure across the pharmaceutical supply chain in terms of the number of players and concentration levels provides a broad indication of the competition dynamics within the concerned markets. In general, higher number of players in a market and lower concentration level tend to indicate conducive conditions of competition.

4.3. With regard to market concentration, two estimates used are: the concentration ratio (CR) and the Herfindahl-Hirschman index (HHI).[77] The CR measures how much of market share is accounted for by the top firms (for example, the top 3, 4, or 10 firms). The HHI, on the other hand, measures the size of firms in relation to the industry and is an indicator of the level of competition in that industry. Both measurements indicate the level of market fragmentation and potential market power. An HHI of close to zero indicates perfect competition where no firm has any influence over market price, while an HHI of 10,000 shows that there is only one firm in the market. An HHI of less than 1,500 denotes an unconcentrated (competitive) market; between 1,500 and 2,500 denotes a moderate level of concentration; and over 2,500 denotes a highly concentrated market.[78]

4.4. As market concentration is in relation to market shares, it is therefore imperative to define the relevant market(s) in which firms compete from the product and geographic dimensions. Conventionally, this is done by undertaking the substitution analysis on both the demand and supply sides. In relation to pharmaceutical products, however, this approach of delineating the relevant market is found to be inappropriate for various reasons.

4.5. Unlike other commodities, substitution between pharmaceutical products is less likely. This is because medicines used in the treatment of a particular health condition cannot be substituted with medicines used in the treatment of another health condition. For instance, following an increase (even substantial) in the price of a drug to lower blood pressure, users would not shift to anti-fungal drugs. In other words, products need to have same therapeutic value to be considered as interchangeable.

4.6. In this regard, the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system provides a useful framework for the assessment of substitutability of

[77] The Herfindahl-Hirschman index is a commonly accepted measure of market concentration. It is calculated by squaring the market share of each firm competing in a market, and then summing the resulting numbers. The HHI figure can range from close to zero to 10,000. Empirical evidence suggests that, other things being equal, the concentration of firms in a market is an important element of market structure and a determinant of competition. The higher the HHI, the higher is the market's concentration and the closer the market is to being a monopoly.

[78] DOJ-FTC Guidelines on Horizontal Mergers.

pharmaceutical products. The WHO ATC system classifies drugs in 5 categories, with ATC 1 being the widest and ATC 5 being the most specific: ATC 5 indicates the chemical substance of a particular drug and is commonly used to determine substitution of products for defining the relevant market and establishing dominant position in the market. If the example of cardiovascular drugs is taken, ATC 1 indicates the cardiovascular system. ATC 2 shows the therapeutic main group such as anti-hypertensive medicines used for the treatment of high blood pressure. ATC 3 is the therapeutic/pharmacological subgroup, for instance, plain ACE inhibitors (such as benazepril, enalapril, ramipril, lisinopril and perindopril) as opposed to other anti-hypertensives such as beta blockers, diuretics, calcium channel blockers and angiotensin-II receptor blockers, which form their own individual subgroups. For ACE inhibitors, there is an overlap between ATC 3 and 4. At ATC 5, which indicates the chemical substance, an example would be perindopril alone. At this level, the only substitute for the drug would be its bioequivalent generic.

4.7. In practice, even substitution between chemical substances with same therapeutic value (originator drug and its bioequivalent generics) may not be evident for various reasons. One of them could be attributed to prescription patterns. In most cases, it is doctors who decide on the choice of medicines rather than users themselves. In their prescription decisions, doctors tend to give higher weight to product attributes rather than price. For instance, doctors tend not to switch medicines for cheaper substitutable molecules on account of risks of provoking side-effects. This phenomenon is often referred to as 'the doctors' inertia'. Similarly, doctors' choice of medicines may be influenced by branded drug manufacturers' marketing efforts. It is common practice for their sales representatives to discuss product claims and clinical evidence with physicians and provide them with samples.[79]

4.8. It follows from the above discussion that there potentially exist several relevant markets in relation to the supply of pharmaceutical products. It requires an in-depth substitution analysis to define those relevant markets based on actual market information on, inter alia, molecules with equivalent therapeutic value and doctors' prescription patterns. Such an exercise is beyond the scope of this study given the complexity, competence, and resources required to do so.

4.9. For the purpose of the Study therefore, the assessment of the structure and concentration level will be done at the broader levels in the pharmaceutical supply chain.

4.10. As highlighted earlier in Figure 2, the pharmaceutical supply chain consists of three levels, namely manufacturing, wholesale and retail. At manufacturing of pharmaceutical products level, it is gathered that Ajanta Pharma (Mauritius) Ltd is the only active firm in Mauritius. However, the latter is mainly involved in exportation of its products and as such does not influence the local competition dynamics for the supply of pharmaceutical products. Thus, the market structure and concentration analysis focuses at the wholesale and retail levels.

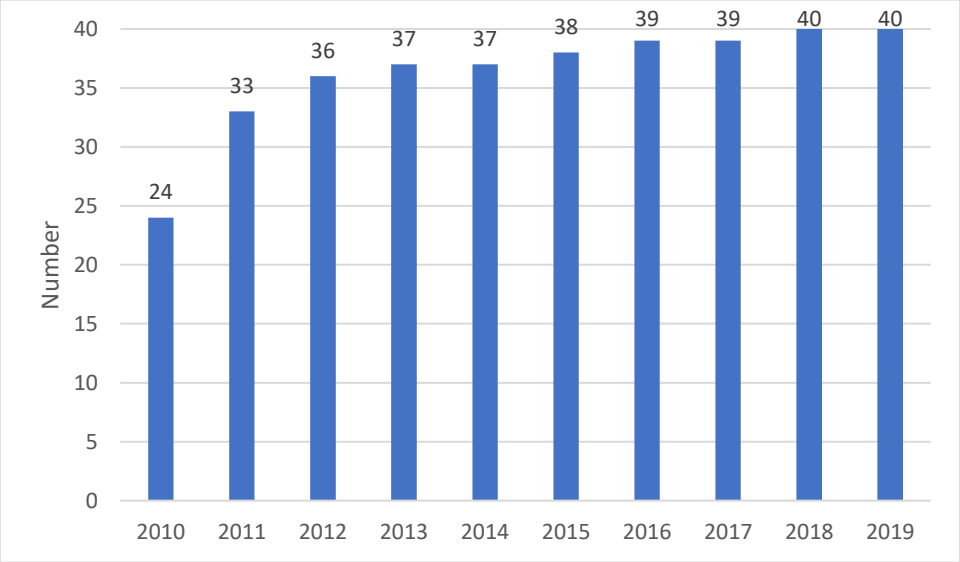
[79] Competition and Regulation Issues in the Pharmaceutical Society 2000, OECD Policy Roundtables, DAFFE/CLP (2000)29, 6 February 2001, para 4.6, page 45: https://www.oecd.org/competition/sectors/1920540.pdf

a) The wholesale pharmacy market

4.11. At the level of wholesale supply of pharmaceutical products, wholesale pharmacies import originator and generic products from international pharmaceutical companies and supply these to both public and private healthcare institutions in Mauritius.

4.12. The number of registered wholesale pharmacies has progressively increased from 24 in 2010 to 40 in 2019, as illustrated in Figure 4 below.

Figure 4: Evolution of number of wholesale pharmacies, 2010-2019



Source: Compiled from Department of Pharmaceutical Services

4.13. The increase in the number of wholesale pharmacies by 16 over the period 2010-2019 tends to indicate that barriers to entry in the wholesale pharmaceutical market are not too high. As indicated earlier, wholesale pharmacies require a licence to operate their business which is conditioned on having a full-time pharmacist in-charge, warehousing infrastructure, safe handling, storage and distribution of pharmaceutical products. These conditions for operating as wholesale pharmacies do not appear to be constraining, as evidenced by the increase in the number of players in the market.

4.14. Table 8 illustrates the indicative share of supply for wholesale pharmacies over the period 2017-2019, with particular emphasis on those having more than 5% share.

Table 8: Share of supply of wholesale pharmacies for the period 2017-2019

Wholesale Pharmacies	2017	2018	2019
IBL Ltd	24-26%	23-25%	19-21%
MSJ Ltd (Unicorn)	16-18%	18-20%	18-20%
Pharmacie Nouvelle Ltd	11-13%	11-13%	10-12%
Scott Health Ltd	10-12%	8-10%	11-13%
Anichem Pharmacy	5-7%	5-7%	5-7%
Ste A.E. Patel & Co	4-6%	4-6%	4-6%
Other wholesale pharmacies	23 -25%	24-26%	26-28%

Source: Compiled from data from the MRA

4.15. It is observed that 4 wholesale pharmacies, namely IBL Ltd, Unicorn, Pharmacie Nouvelle Ltd and Scott Health Ltd, maintained considerable proportions of their share supply over the period 2017-2019. Those of Anichem Pharmacy and Ste. A.E Patel & Co., individually around 5%, were also

found to be significant relative to the remaining 34 wholesale pharmacies. The latter had a combined share of supply in the range of 26-28% by 2019.

4.16. Analysis of the concentration ratios shows that the degree of market concentration has progressively been on the decline (see Table 9) between 2017 and 2019.

Table 9: Evolution of concentration ratios

Concentration ratios	2017	2018	2019
Herfindahl-Hirschman Index (HHI)	1,303	1,302	1,126
Three-firm (%) – CR3	53.9	55.4	50.6
Four-firm (%) – CR4	65.1	64.2	61.2

Source: Compiled based on MRA figures

4.17. With an HHI of less than 1,500, the wholesale market falls in the unconcentrated category. However, as highlighted earlier, the actual market shares of wholesale pharmacies, in particular the 4 major ones, are likely to be higher if the various relevant markets are defined according to ATC 5, i.e. terms of chemical substance and their bioequivalent generics.

4.18. Notwithstanding an in-depth definition of the relevant markets, a closer examination of the share of supply of individual wholesale pharmacies tends to demonstrate that there could be higher concentration levels in the wholesale market. The bulk of pharmaceutical products that are supplied by 4 major firms namely, IBL Ltd, MSJ Ltd (Unicorn), Scott Health Ltd and Pharmacie Nouvelle Ltd with amounts to around 60% over the period 2017-2019. The remaining 36 wholesale pharmacies, a 90% representation of the wholesale market, supplied less than 30% of pharmaceutical products.

Table 10: Distributors of top international pharmaceutical companies

Local wholesale companies	Top International pharmaceutical companies
IBL Ltd	Johnson & Johnson, Roche, Pfizer, Bayer, Novartis, AbbVie, Novo Nordisk, Takeda Pty Ltd, Pfizer, Bayer, GlaxoSmithKline, Amgen, B. Ingelheim
MSJ Ltd (Unicorn)	Bayer, Novartis, GlaxoSmithKline, Merck & Co, Sanofi, Astra Zeneca
Pharmacie Nouvelle Ltd	Gilead, B. Ingelheim, Pfizer, GlaxoSmithKline, Abbott Laboratories, Merck & Co, Eli Lilly, B. Ingelheim
Scott Health Ltd	Johnson & Johnson
Chemical & Technical Suppliers (I.O)	Johnson & Johnson, Amgen
Ste A.E.Patel & Co	Roche, Merck & Co
The Mauritius Pharmacy (Seegobin) Ltd	GlaxoSmithKline, Merck & Co
Vetopharma Ltd	Bayer, B. Ingelheim
Inicia Ltd	B. Ingelheim
Anichem Ltd	B. Ingelheim

Source: Compiled from MRA data

4.19. Another indication of the market position of these 4 wholesale companies and potential concentration level can be viewed in terms of the branded products they import and distribute. These 4 firms are distributors for 14 of the top 16 international laboratories that supply their

products in Mauritius. Table 9 illustrates the local wholesale pharmacies which are distributors for the top international pharmaceutical companies.

4.20. It is also observed that most of the top pharmaceutical products have more than one local distributor, i.e. they have co-distributors. Only 5 out of the 14 top pharmaceutical companies have an exclusive distributor. Actual imports data, however, tend to show that the majority of the products imported from a particular international pharmacy is by its primary local distributor which serves as its legal technical representative rather than the co-distributors[80].

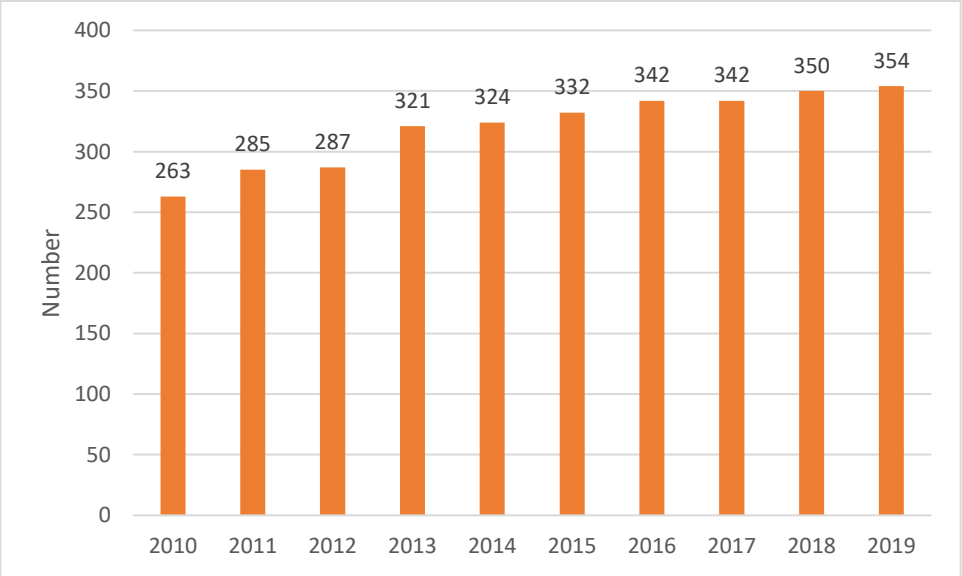
4.21. In conclusion, the wholesale pharmacy market tends to show competition in terms of the increasing number of players in the market and volume of products supplied. However, to ascertain the actual level of concentration, an in-depth assessment of the various individual markets is required. Such an exercise is outside the scope of this Study.

b) The retail pharmacy market

4.22. In the private channel, retail pharmacies generally obtain their supply of pharmaceutical products from wholesale pharmacies. The latter also supply private hospitals for their requirement of drugs dispensed at the point healthcare delivery.

4.23. Over time, the number of retail pharmacies in Mauritius has followed an increasing trend. As depicted in Figure 5, the number increased from 263 in 2010 to reach 354 in 2019 or by 91 outlets over the 10-year period.

Figure 5: Evolution of number of retail pharmacies, 2010-2019



Source: Compiled from submissions of Department of Pharmaceutical Services

4.24. The number of retail pharmacies in Mauritius is currently well above the WHO recommended ratio of one pharmacy for every 5000 inhabitants. In the year 2019, for instance, the pharmacy to population ratio in Mauritius is estimated to be approximately 1: 3500 inhabitants.

4.25. To assess concentration at retail level, an analysis of the geographic dimension is essential. This is because consumers would buy their pharmaceutical products based on immediacy and convenience rather than shopping around the whole island. As such, there are likely to be several relevant markets. Assessing the degree of concentration at retail level may though not be a fruitful exercise in so far as prices of pharmaceutical products are regulated and current

[80] Based on information gathered from MRA.

regulations impose restrictions on advertising. Nonetheless, an assessment of pharmacy to population ratio at district level is undertaken for a better view of pharmacy coverage and somehow a proxy for concentration.

Table 11: Retail pharmacy to population ratio

District	Estimated resident population (2018)	Number of retail pharmacies	Pharmacy to population ratio
Black River	82,961	13	6,382
Flacq	138,701	31	4,474
Grand Port	112,853	26	4,340
Moka	83,676	22	3,803
Pamplemousses	141,261	25	5,650
Plaines-Wilhems	367,576	124	2,964
Port-Louis	118,815	63	1,885
Rivière du Rempart	108,034	33	3,274
Savanne	68,391	12	5,699
TOTAL	**1,222,268**	**349**	**3,502**

Source: Compiled with data from Statistics Mauritius and submissions by the department of pharmaceutical services

4.26. As illustrated in Table 11 above, the pharmacy to population ratio for most districts is within the WHO benchmark. The exceptions are Black River, Pamplemousses and Savanne districts which have slightly higher ratios. Instead, the ratio for high converging regions such as Port Louis and Plaines Wilhems are much lower, i.e. there are more pharmacies in those regions.

4.27. Based on the above figures, it can safely be concluded there is an adequate number of retail pharmacies scattered all over the island and which somehow does not raise concentration issue as such.

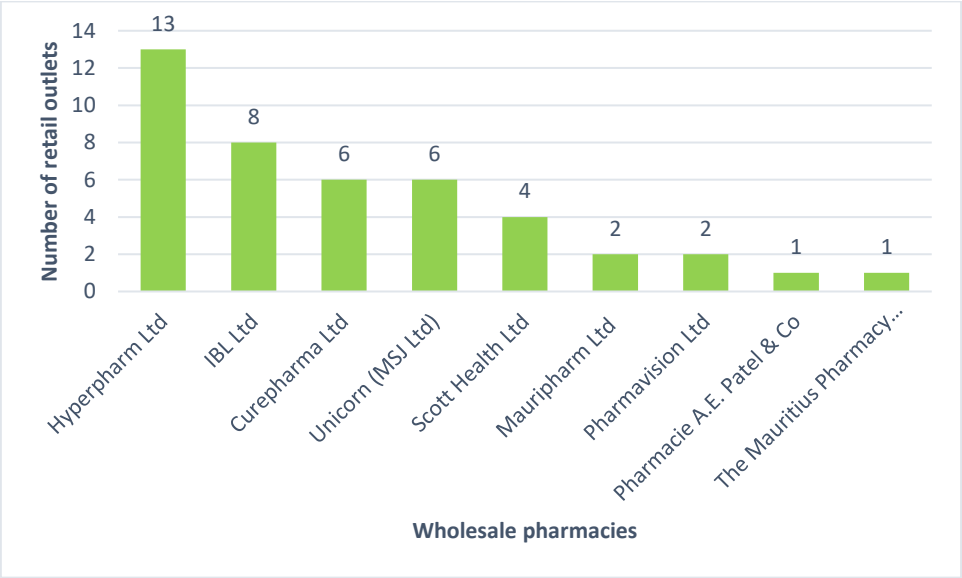
c) Vertical linkages

4.28. With respect to the functional dimension of the pharmaceutical market, the level of vertical integration across the supply chain has been analysed.

4.29. The Pharmacy Act does not place any restriction on 'pharmacy ownership' i.e. on the person(s) who are allowed to own a private pharmacy. There is also no limit on the number of retail pharmacies in a chain. Hence, any individual or legal entity may, in principle, own pharmacies in Mauritius implying that wholesale pharmacies are also legally allowed to own retail pharmacies.

4.30. In 2019, 9 wholesale pharmacies were operating a total of 43 licensed retail pharmacies, representing 12.2% of the existing base of retail pharmacies, as shown in Figure 6 below.

Figure 6: Number of retail pharmacies owned by wholesale pharmacies



Source: Compiled from companies' websites

4.31. Some concerns have been expressed surrounding the fact that wholesale pharmacies might favour their own retail outlets to gain on the full flat mark up on pharmaceutical products. Eventually, this could potentially lead to a foreclosure of access to key products which are restricted to particular retail outlets.

4.32. An analysis of the degree of vertical linkages between wholesale and retail pharmacies does not tend to support the claim that integrated wholesale pharmacies would have an economic incentive to favour their own retail outlets to the detriment of other retail pharmacies. The top 3 wholesale pharmacies own only 18 out of the 354 retail pharmacies. This represent only 5% of the retail pharmacies operating across the island. As such, there does not seem to be an incentive for integrated wholesale pharmacies to restrict supply of key products to other retail pharmacies.

B. Regulatory Framework

a) Registration and Commercialisation Framework

4.33. As discussed earlier, the amendments brought in 2016 to the Pharmacy Act have instituted a formal registration process and introduced fees for the registration of pharmaceutical products imported/manufactured in Mauritius for commercialisation purposes (see Paragraphs 3.15-3.33). However, the manner in which this new model of registration is being implemented has brought about several criticism from applicants.

i. Composition of the Pharmacy Board

4.34. It has been implied by various economic operators that the manner in which the Board is constituted may give rise to a potential instance of conflict of interest, notably through the vested interest in the wholesale market of some members. This could potentially have an incidence on competition in so far as some Board members may be privy to commercial information on

competitors and participate in the decision-making process towards the approval or non-approval of the registration of their own products and that of rivals.

4.35. In order to ascertain the veracity of the claim of conflict of interest, it is of utmost importance to examine the composition of the Board. The latter consists of 8 members from both the public and private sectors collectively. Members from the public sector are currently the Director General Health Services, the Director Pharmaceutical Services, 1 Principal Pharmacist and 1 Principal State Counsel. The remaining 4 members from the private sector are pharmacists designated by the responsible Minister. Since 2019, these appointments are made up of 4 private retail pharmacists.

4.36. This perception of a possible conflict of interest regarding the 4 private retail pharmacists as Board members may find its roots in the fact that some retail pharmacies are wholly owned subsidiaries of wholesale pharmacies. This relationship may potentially give rise to a situation whereby these private retail pharmacists, in their capacity as Board members, may give preferential treatment to registration applications made by their respective wholesale pharmacies or provide them with information not publicly available as of date, such as the list of registered pharmaceutical products.

4.37. Access to crucial information of this nature can allow wholesale pharmacies to make better informed commercial decisions in relation to import compared to their competitors with no such access regarding the registration process. This information asymmetry has the potential to undermine the level playing field on which all competitors are supposed to operate.

4.38. A parallel may be drawn to the previous importation regime before 2016 whereby only a permit delivered by the Board was required without a formal registration process in place. From the year 2005 to 2016, the then Board consisted of 2 wholesale pharmacies and 2 retail pharmacies as Board members concerning the requirement for private sector pharmacists.[81] This may be seen as a potential conflict of interest since the wholesale pharmacies sitting on the Board were involved in the application process of allocating permits to wholesale pharmacies regarding the import of pharmaceutical products.

4.39. The current composition, appointed as of 2019, has no such issue, however. The 4 private retail pharmacies present on the Board are not vertically linked to any wholesale pharmacy[82], thereby ensuring their independence.

4.40. Additionally, it can be observed that that the Board is homogeneously proportioned equally between the public and private sector, that is, 4 members from the public sector and the remaining 4 from the private sector. More specifically, with 5 independent pharmacists out of the 8 Board members, namely 1 pharmacist from the public sector and 4 solely private sector retail pharmacists who are not vertically linked with any wholesale pharmacy and as Board members, decisions taken by the Board are likely to be fair and unbiased since none of the members has any vested interest in the sale of pharmaceutical products in the wholesale market.

4.41. Nonetheless, care should be taken to consider such aspects when making upcoming appointments to the Board. The current composition of the Board does not therefore raise any competition concern at this level.

[81] Information provided by the Pharmacy Board; email dated 10th June 2020.

[82] Information provided by the Registrar of the Pharmacy Board; email dated 11th June 2020.

ii. Transparency Issue Regarding Operation of the Board

4.42. Several stakeholders have expressed concerns about the lack of transparency and predictability in relation to the Board's operating procedures. They have in particular emphasised on the absence of a clearly defined and comprehensive pharmaceutical product registration guidance document that spells out the Board's registration policies, its evaluation process and the considerations that lead the Board to approve or not approve the registration application of a pharmaceutical product. Such a situation may create business uncertainties and potentially act as a barrier to entry and thus stifle competition in the market.

4.43. One of the ways to qualitatively assess such an assertion is to probe into the grounds of refusal concerning the registration of pharmaceutical products. An analysis of this nature will bring about a clearer view as to the extent to which applicants are able to meet the threshold set by the Board. In this optic, information has been gathered from the Department of Pharmaceutical Services and compiled in Table 12 below to illustrate the numerous reasons for not approving the registration of pharmaceutical products between 2013 and 2019.

Table 12: Reasons for not approving pharmaceutical products registrations, 2013-2019

Reasons for not approving registration	2013	2014	2015	2016[83]	2017[84]	2018	2019	Total
Existing molecule on the market	2						1	**3**
Incomplete dossier	1					22	4	**27**
Innovator not yet registered				1				**1**
Innovator still under patent				1		1		**2**
Lack or no comparison with a reliable trusted generic product or innovator						2		**2**
Lack or no marketing experience in other countries						2		**2**
Lack or no comparison with a reliable trusted generic product or innovator						1	3	**4**
No added therapeutic advantage					3			**3**
No clinical evidence for efficacy						3		**3**
No clinical experience in Mauritius				4				**4**
No evidence based therapeutic benefit		4						**4**
No evidence of foreign registration				1				**1**
No reason given			1	2		2		**5**
Not yet sold in developed countries					2			**2**
Not registered in EUR or PIC or GCC country	4			3		1		**8**
Total	**7**	**4**	**1**	**12**	**5**	**34**	**8**	**71**

Source: Compiled from information submitted by Department of Pharmaceutical Services

4.44. Table 12 shows that an 'incomplete dossier' was the main reason for not approving registration between 2013 and 2019. Notably, 27 out of a total of 71 registration applications (38%) were not approved on this ground. An incomplete dossier is typically the result of missing documents such as the Bioequivalence Study, Dissolution Study, Certificate of Analysis of finished product and/or Free Sale Certificate, information on marketing experience in other countries, Registration

[83] Data submitted by the Ministry of Health pertains to period between April to December 2016.
[84] Data submitted by the Ministry of Health pertains to period between January to June 2017.

Certificate from country of origin (India), certificates to establish safety in patients and stability test among others.

4.45. This is where access to a comprehensive pharmaceutical product registration guidance document would prove to be crucial in palliating this lack of essential information regarding the minute details of every key aspect of the registration process. Having unhampered access to such a document would put applicants on a level playing field as far as fulfilling the procedural requirements of the registration process is concerned. This, in turn, would allow them to self-assess and remediate their registration applications as required in order to allow the Board to focus on the substance of the application rather than the format.

4.46. On its part, the Ministry of Health has submitted that the product registration guidelines issued by the Pharmacy Board are available for consultation at its office. While this might technically fulfil the requirement of disclosure, it should also be made available on the website of the Ministry as a means of best practice. This will have the effect of further reducing the likelihood of any possible instance of information asymmetry for applications seeking product registration.

4.47. Another anomaly noted from Table 11 regarding transparency relates to the fact that a total of 5 applications for registration were refused and apparently no reasons were given to the applicants. In fact, the duty to give reasons is one of the fundamentals of good administration. Omitting to do so deprives the applicant from understanding the rationale behind the decision-making process and thus prevent any corrective measures that might have been envisaged.

4.48. Such a state of affairs further reinforces the existing information asymmetry which prevails and may in turn cripple the applicant's commercial efforts to effectively introduce or expand competition in relation to a particular pharmaceutical product.

iii. Unavailability of the List of Registered Pharmaceutical Products

4.49. The law makes concrete provisions to this effect, notably Section 2 of the Pharmacy Act requires the Permanent Secretary of the Ministry of Health to make publicly available guidelines:

(a) setting out the requirements, the applicable law and the procedure for an application for, or renewal of, clearance, a licence or permit;

(b) available for consultation at the Ministry;

(c) posted on the website of the Ministry;

(d) listing every fee leviable under the regulations;

(e) listing every pharmaceutical product registered for import with the Board, together with their corresponding importers;

(f) listing every person eligible to import any poison; and

(g) listing every licensee.

4.50. While the registration guidelines might be available for consultation at the Ministry, the list of pharmaceutical products registered for import with the Board is neither available for consultation at the Ministry nor on its website.

4.51. The absence of accessible and periodic information on the evolution of pharmaceutical products registered by the Board creates an information asymmetry which may undermine the ability of wholesale pharmacies/importers to effectively introduce or expand competition within any particular market segment.

4.52. Wholesale pharmacies, unless being or having been a Board member, may not have sufficient industry information (such as the number of existing registrations for a particular molecule, their respective dosage forms or overpopulation of any particular class of drugs) to guide their commercial efforts and strategic decisions to bringing in new and innovative drugs on the market. For instance, 3 applications for registration (refer to Table 3) were refused by the Board because the concerned pharmaceutical products had '*no added therapeutic advantage*' while another 3 applications were denied due to an already '*existing molecule on the market*'. In the absence of the list of registered products, applicants may not necessarily be in a position to fully appreciate the decisions of the Board.

4.53. The practice of statutory bodies in other jurisdictions may provide insight as to the good administration and enforcement of the regulatory framework. For instance, the Medicines Control Authority of Zimbabwe[85] makes available on its website an updated register for approved human medicines listing information on product brand/generic name, its form and dosage, and details of the applicant and manufacturer. Similarly, the Australian Therapeutic Goods Administration[86] maintains an interactive, online database of registered drugs (the 'Australian Register of Therapeutic Goods') containing both consumer medicine information and product information and which allows any person to run searches by INN, brand name and name of applicant.

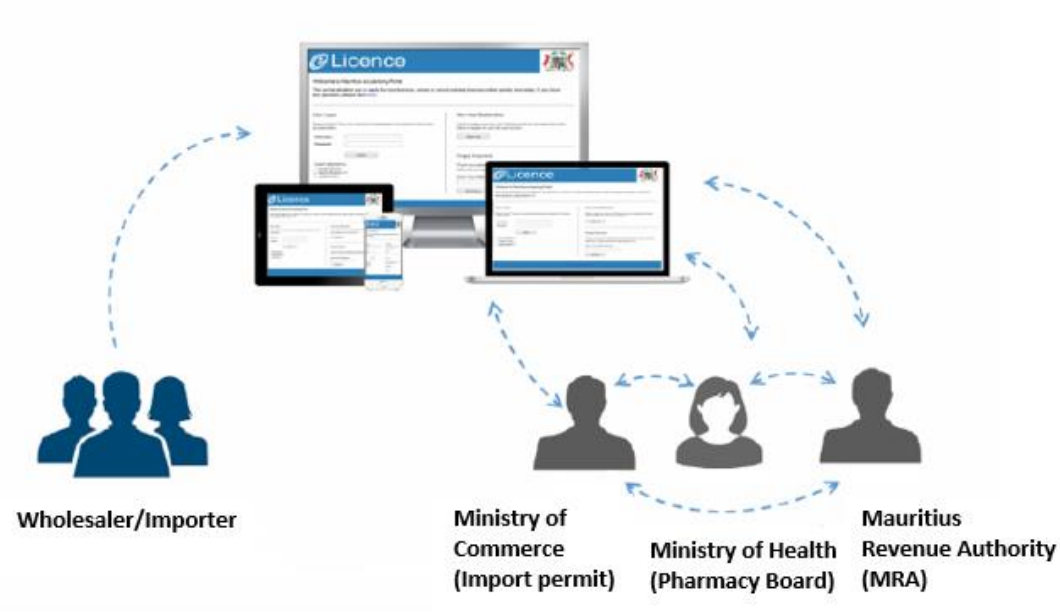
4.54. Regarding this particular issue, it should be noted that there exists a centralised platform known as the National Single Window (Mauritius Trade Link) which was launched on 26th January 2016. The Mauritius Trade link is aimed at acting as a single web-based online portal for the submission and processing of import/export permits and respective clearance from Government agencies.

4.55. The Ministry of Industry, Commerce and Consumer Protection has indicated that the Pharmacy Board is listed as one of those agencies entrenched in this platform in relation to managing cross-border trade. In fact, during an information session in August 2019 between the Mauritius Chamber of Commerce and Industry (MCCI) and the Economic Development Board (EDB), the application of the Nation Single Widow (NSW) to the pharmaceutical industry was presented to the various stakeholders. The NSW would electronically connect the regulatory authorities and wholesalers/importers.

[85] See Medecines Control Authority of Zimbabwe, Regulations and Guidelines. Available at https://www.mcaz.co.zw/index.php/downloads/category/9-regulations-guidelines

[86] See Australian Therapeutic Goods Administration, Department of Health, Australian Government,. Available at: https://www.tga.gov.au/regulation-basics

Figure 7: National Single Window



Source: MCCI & EDB information session on the Business Facilitation Act 2019, 28th August 2019

4.56. Before clearance for import is given by Board, it is a pre-requisite that the pharmaceutical product is duly registered with the Board. Through this centralised system, harmonisation of data elements across agencies (notably the MRA, the Pharmacy Board, the Ministry of Health and the Ministry of Commerce and Consumer Protection) would be greatly enhanced. Consequently, it would make the process of gathering and compiling the list of pharmaceutical products registered for import with the Board much easier and making it accessible to the wholesalers/importers through this central repository.

4.57. The Department of Pharmacy of the Ministry of Health has submitted that the project will soon be realised, and the platform will be used to publish the list of registered pharmaceutical products on the Ministry's website. The list will be a dynamic one, providing instant information on any changes made to it. Thus, it will address the information asymmetry that exists currently surrounding aspects of pharmaceutical trade in Mauritius by allowing wholesale pharmacies and importers to have adequate access to the relevant information, thereby being in full compliance with Section 2 of the Pharmacy Act.

iv. Transparency Issue Regarding Applicable Standards

4.58. Another issue raised by stakeholders regarding the registration of pharmaceutical products relates to the applicable standards. It was submitted that the Board's refusal to grant market authorisation to products which do not conform to BEUF standards, in particular to standards conforming to Indian Pharmacopoeia, was irrational. It was submitted that, should the Board restrict registration of pharmaceutical products to BEUF standards only, (a) '*95% of the pharmaceuticals currently on the market will need to be withdrawn as they neither mention any of the 4 Standards nor that of any other standard on their packaging; and (b) all the pharmaceuticals bearing no indication of appropriate standard but which have nevertheless been registered by the Ministry of Health will need to be de-registered*'[87].

[87] Submission from the Pharmaceutical Association of Mauritius, email dated 07.10.2014.

4.59. Where the Board refuses to register a pharmaceutical product of Indian Pharmacopoeia or of Indian origin (on the basis that it does not conform to BEUF standards), the Board should in principle also refuse to register a pharmaceutical product manufactured in India under British Pharmacopoeia standards. This is because pharmaceutical products manufactured in India under a pharmacopoeia, other than Indian Pharmacopoeia, are not marketed in India. It has been alleged that such products, although not marketed in the country of origin, are nevertheless registered in Mauritius[88].

4.60. That being said, there has been recent developments regarding this particular issue. Most notably, it was announced in the budget speech 2020/21[89] that the Pharmacy Act will be amended to extend the definition of "specified standards" to also include Indian Pharmacopoeia. In fact, the Finance (Miscellaneous Provisions) Act 2020[90] has already been inacted and this is likely to resolve the issue tied to the import and registration of pharmaceutical products of Indian origin.

v. Registration fees

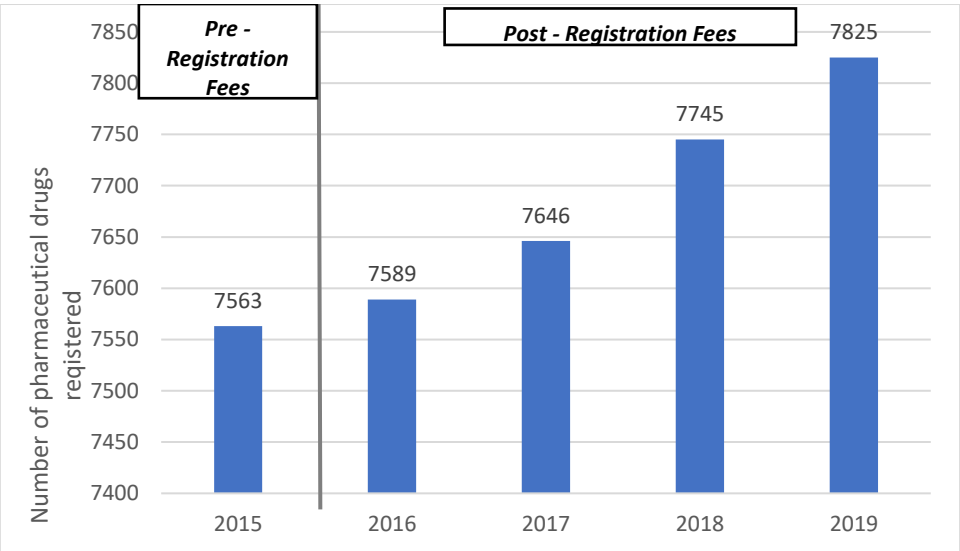
4.61. Several stakeholders, including representatives of the Pharmaceutical Association of Mauritius (PAM), the Small and Medium Pharmaceutical Wholesalers Association (SMPWA) and consumer associations have expressed concerns over the introduction of registration and several other fees (per product basis) as part of the formal registration process. According to them, the new registration fees were expected to significantly raise the costs of wholesale pharmaceutical trade, which were to the detriment of small and medium pharmaceutical importers/wholesalers. Moreover, the new requirements were to limit the number of wholesale pharmacies importing a particular pharmaceutical product, tended to promote monopolies and served as a mechanism to prohibit parallel importation of pharmaceutical products[91].

4.62. Actual figures do not support the claim of the stakeholders that the increase in registration fees led to foreclosure of small wholesale pharmacies. In fact, the number of wholesale pharmacies has not decreased in any way whatsoever but in fact increased from 39 in 2016 to 40 in 2019, albeit marginally (as shown in Figure 4). It is worth highlighting that the number of registered pharmaceutical products has increased by around 3% from 7,563 in 2015 to 7,825 in 2019.

4.63. Figure 8 illustrates the evolution in the number of pharmaceutical products registered between 2015 and 2019.

[88] Submission from the Pharmaceutical Association of Mauritius, email dated 07.10.2014.
[89] See Annex to Budget Speech, 2020-2021. Available at: http://budget.mof.govmu.org/budget2020-21/2020_21budgetannex.pdf
[90] Section 50 of Finance (Miscellaneous Provisions) Act 2020 proposes to amend the Pharmacy Act 1983 in this sense. Available at: http://mauritiusassembly.govmu.org/English/acts/Documents/2020/act072020.pdf
[91] L'Express (04 Nov. 2016), 'Pharmacies privées: une pénurie de médicaments s'annonce' < https://www.lexpress.mu/article/292949/pharmacies-privees-une-penurie-medicaments-sannonce >; Le Mauricien (08 April 2017), 'Pharmacies Privées — Médicaments: Fin des différentes sources d'importation' < http://www.lemauricien.com/article/pharmacies-privees-medicaments-fin-des-differentes-sources-dimportation >;

Figure 8: Evolution of number of drugs registered, 2015-2019



Source: Compiled from submissions of Department of Pharmaceutical Services, 2020

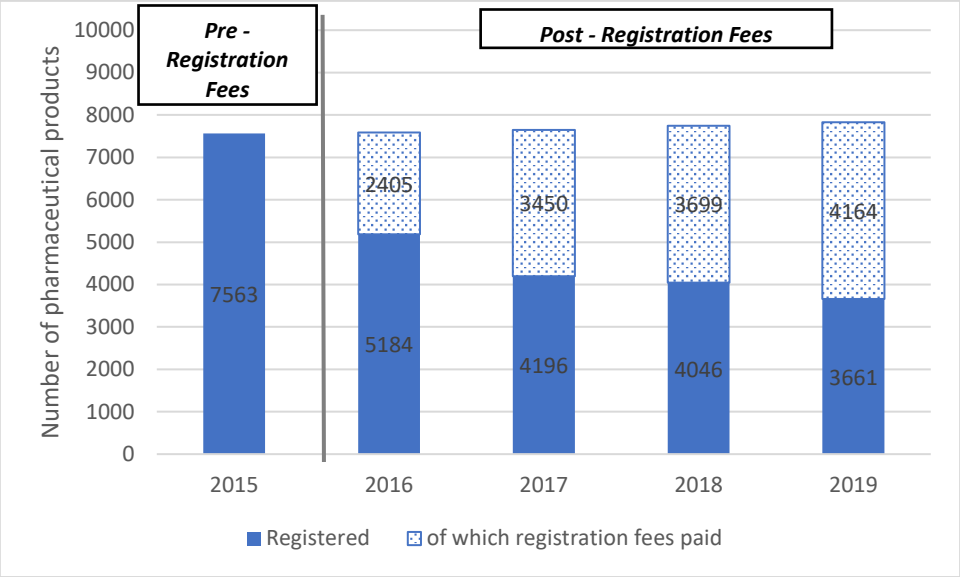
4.64. It should be mentioned that the Department of Pharmacy has indicated that data compilation on registered pharmaceutical products started formally in 2016. The numbers for the year 2015 have been compiled on a retroactive basis and may thus not provide the most reliable depiction of the number of pharmaceutical products in circulation. This is due to the fact that while a pharmaceutical product has been registered, it does not necessarily mean that it has been imported into the country.

4.65. A more accurate metric to represent this data is catered by the actual fees paid regarding registered pharmaceutical products. In order for an import to be endorsed, the registration fee or the yearly renewal must be paid. Thus, under the new regulatory regime, wholesale pharmacies/importers will only pay the fees if they are actually importing the pharmaceutical products. Thus, this data provides a clearer picture as to the number of pharmaceutical products in circulation in Mauritius.

4.66. An assessment in terms of the number of drugs registered showed that in 2019, out of the 7,825 pharmaceutical drugs that were registered, registration fees have been paid for 53% (4,164) of them. In fact, the number of registered pharmaceutical products for which the annual renewal registration fee has been paid has been increasing from 2,405 in 2016 to reach 4,164 in 2019, notably an overall increase of 73%.

4.67. Figure 9 below illustrates the number of registered products and that for which registration fees have been paid over the period 2016-2019.

Figure 9: Renewal of registration of drug compared to total number of drugs registered, 2016-2019



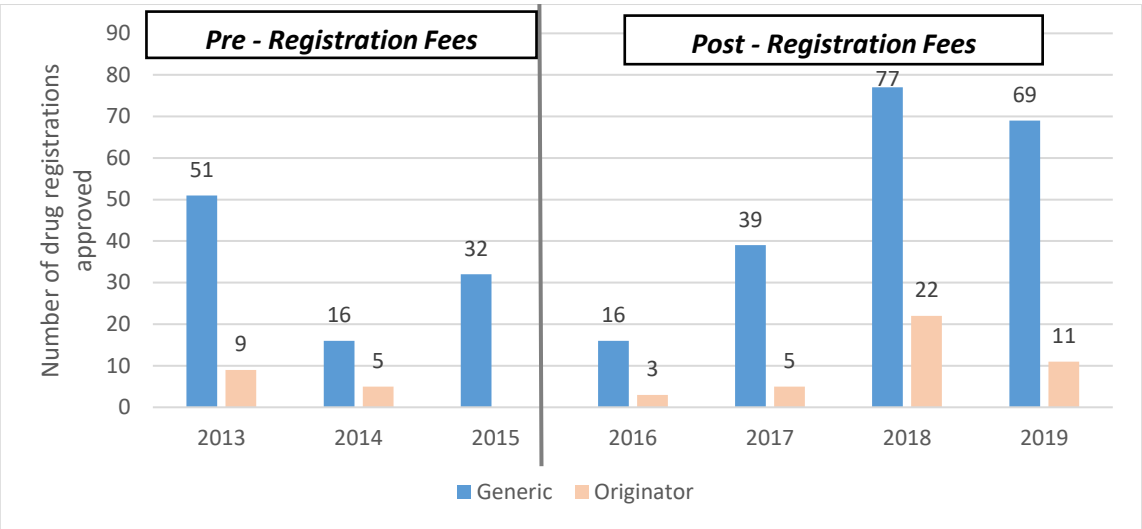
Source: Compiled from submissions of Department of Pharmaceutical Services, 2020

4.68. The SMPWA also highlighted that imposition of the new registration fees could restrict the availability and even cause the disappearance of certain pharmaceutical products such as cheaper generics (orphan/low-selling drugs) on the market. These drugs are not usually commercialised by larger wholesalers because of their low sales volume but are nevertheless imported by smaller importers.

4.69. To ascertain the claims of the SMPWA, information on registration of pharmaceutical products in terms of originator and generic were requested from the Department of Pharmaceutical Services. Analysis of the data showed that the number of pharmaceutical registrations approved by the Board on a yearly basis has fluctuated over the years. It is generally observed that the majority of pharmaceutical products entering the market pertains mostly to generics with few originators being registered for commercialisation purposes.

4.70. Data gathered for the year 2013 to June 2019 has been compiled in Figure 10. It can be seen that from 2013 to 2015, a total of 113 applications for registration were approved, out of which 99 or around 88% were generics. Similarly, for 2016 to 2019, out of 242 approved registration applications 201 or 83% were generics.

Figure 10: Breakdown of Registrations approved by the Board, 2013 – June 2019



Source: Compiled from information submitted by Department of Pharmaceutical Services

4.71. With the overall increase in the number of pharmaceutical products (which are mostly generics), there is therefore little evidence showing that the new registration fees could have potentially impacted the wholesale market in the manner claimed by the SMPWA.

b) Licensing criteria for retail pharmacies

4.72. Under the revamped guidelines issued by responsible Ministry, the Board must now consider the pharmacy to population ratio, which is one pharmacy for every 2000 inhabitants. Additionally, The Board require that the minimum distance between the proposed pharmacy and an existing one must be 200 meters apart in a linear direction (except for shopping malls and smart cities).

4.73. The introduction of a geographic dimension concerning the licensing of retail pharmacies has received a negative response from the Pharmaceutical Association of Mauritius (PAM). It submitted that the pharmacy to population ratio criteria (one pharmacy for 2000 inhabitants) established by the Board for licensing purposes would further asphyxiate an already 'saturated' retail pharmaceutical market[92]. With the new criteria, around 650 pharmacies would be allowed to operate on the market, which would further increase the pharmacy density.

4.74. While the statutory provisions and guidelines directed to location requirements and 'population needs', though exempting pharmacies established in shopping malls and smart cities, may bring about an increase of entrants on the retail market, this may not necessarily bring about overwhelmingly adverse effects as feared by current operators.

4.75. 'Control of entry' criteria are often used with the aim of ensuring a reasonable spread of pharmacies and thus, a satisfactory coverage across both urban and rural areas and/or to ensure the economic viability of pharmacies operating in the market. One of the feared ill-effects of this regulation at entry level has been denoted as being the possible localised worsening of access due to pharmacies clustering around sources of demand and driving out outlying pharmacies (in rural areas particularly).

4.76. However, one cannot make this evaluation in the vacuum of the theoretical regulatory framework. In fact, the actual purchasing patterns and behaviours of pharmaceutical users should be factored in. Geographical proximity, while certainly being an important criterion, mobility of

[92] Le Défi Media, 'Nouveaux règlements de la Santé : les pharmaciens montent au créneau' (25 September 2017) < http://defimedia.info/nouveaux-reglements-de-la-sante-les-pharmaciens-montent-au-creneau >

consumers should also be factored in. Convenience is changing the way people shop and understanding these evolving consumer shopping behaviours is crucial so that the relevant legislation is adapted to reflect current trends.

4.77. Concerning the possible driving out of retail pharmacies in rural areas, if that were to truly occur, this would create a void in this particular geographical market. As such, this would in turn make it more attractive for new entrants or established players to pursue this geographical market. Consequently, due to the natural operation of competitive forces, the market will self-rectify itself to deliver benefits of choice and access to consumers and stimulate investments and improvements in service.

4.78. As a matter of fact, as of 2019, a total number of 354 retail pharmacies were in operation which is far off the figure of 650 that was articulated. Additionally, from 2017, the year in which the geographical guidelines were devised, to 2019, the number of retail pharmacies in rural areas have increased by only 12, i.e. from 342 to 354. Consequently, the current regulatory framework in which licences for retail pharmacies is being allocated does not raise any competition concern in this sense.

c) Marketing and Advertising Restrictions

i. At the wholesale level

4.79. Some concerns have been expressed over marketing and promotional activities being practised at wholesale level in terms of free samples, financial and other incentives provided to doctors in exchange for exclusive brand prescription. While the Pharmacy Act prohibits illegal arrangements between manufacturer/wholesale distributor of pharmaceutical products and health professionals[93], some stakeholders have denounced the lack of effective monitoring of marketing practices by the responsible authority.

4.80. While monitoring of compliance with the law relative to marketing and promotional activities pharmaceutical product falls outside the purview of the Competition Commission, such alleged practices can potentially have an incidence on process of rivalry. This is because choice of prescription drugs is determined by physicians and not users. As such, doctors' preference for a particular drug as a result of the marketing efforts of a particular supplier can affect the ability of other suppliers to compete on level playing field. In consequence, users may have to pay more for higher-priced drugs prescribed by doctors instead of buying cheaper products with same therapeutic value.

ii. At the retail level

4.81. The Pharmacy Act also imposes limitation on direct-to-consumer pharmaceutical advertising[94]. Such restriction is intended to address legitimate public interest concerns. Most notably, it aims at preventing advertisers from misinforming patients by overemphasizing certain aspects of the pharmaceutical products and encouraging their over-utilization in relation to natural conditions, cosmetic issues or trivial ailments, which may result in an overmedicated society.

4.82. At the same time, it should be recognised that nowadays the public is increasingly interested in healthcare matters and willing to play a more active role in its own healthcare. In this regard, non-prescription pharmaceutical products provide a tool to practise self-care. Promoting the

[93] Section 40(1) of the Pharmacy Act 1983.

[94] Section 41 of the Pharmacy Act 1983 provides that '[n]o person shall advertise any pharmaceutical product intended for human or veterinary use except in such technical or professional publications, as may be approved by the Board'.

responsible usage of such pharmaceutical products while diminishing 'self-medication'[95] together with responsible advertising on the part of pharmaceutical suppliers become complementary tools in delimitating the boundaries of the market upon which each market player ought to compete.

4.83. In fact, consumer choice in the self-care sector requires marketplace competition founded on the development of brands and the advertising of those brands by manufacturers. In turn, the competitive marketplace provides choice for consumers and helps keep prices down. If the consumers do not wish to pay for a particular product, there are alternatives in the non-prescription segment. In this sense, advertising may prove to be an essential tool in assisting consumers on their choice and thus intensify competition in the non-prescription segment of the pharmaceutical market.

4.84. The lack of a flexible regulatory framework concerning this particular type of advertising may lead to a situation which may protect relatively inefficient incumbents from competition from new entrants. As such, there may be a need to revisit the advertising framework in respect of pharmaceutical products.

C. The Pricing of Pharmaceutical Products

4.85. As explained earlier, in the current pharmaceutical regulatory framework, the regime adopted is one in which the pricing policy is set by the government. The latter regulates the prices of pharmaceutical products at wholesale and retail levels by prescribing maximum mark-ups. Price regulation is aimed at ensuring affordability and access of medicines to the population. The current pricing structure may not only affect users of pharmaceutical products but also the incentives of market players across the supply chain in their choice of products for commercialisation.

4.86. Given that the majority of our supplies come from importation, the final price borne by users of pharmaceutical products is an aggregate of various components: manufacturer's selling price, insurance and freights, local charges and mark-ups. Wholesale and retail pharmacies have limited control over these components, except for the allowable mark-up. In the current pricing system, they have the incentive to apply that the maximum prescribed mark-ups. While price regulation is intended to control prices of pharmaceutical products, the question that arises is whether same are competitive or not. Two issues have been identified in this regard. First, whether the manufacturers' selling prices are competitive or not. The second is whether the pricing methodology based on the maximum mark-up system is optimal.

4.87. To assess whether prices of pharmaceutical products in Mauritius are competitive, reference is made to the 2008 field study[96] conducted by the Mauritius Institute of Health (the "MIH") in collaboration with the Ministry of Health. The MIH 2008 study report ('MIH Report') provides broad insights into issues related to the price, availability and affordability of selected sample of drugs.

[95] The inadvertent and irrational use of prescription drugs without the intervention and supervision of a medical doctor – an all too common practice in developing countries.

[96] Mauritius Institute of Health, 'A Report Survey on Medicine prices, Availability, Affordability, and Price Components in the Republic of Mauritius' (August 2008) available at < http://mih.gov.mu/English/Research/Documents/Research/Report.pdf >

4.88. With regard to pricing, the MIH Report based on a survey of 50 selected drugs [97] concluded that patients in the private sector pay about 324% more for originator-branded medications than for generics. It also reported that prices of drugs in Mauritius were considerably higher than their international reference prices (IRPs). [98] The IRPs are the medians of recent procurement prices offered by for-profit and not-for-profit suppliers to international not-for-profit agencies for generic products.

4.89. The MIH Report also concluded that originator medicines in the private sector were generally sold at 19.28 times their IRPs while the lowest-priced generic medicines were sold at 5.93 times their IRPs. By comparison, the median price ratio (the ratio of local price to the IRP) of originator and generic drugs in Pakistan were 3.36 and 2.26, respectively. In the public sector however, the MIH Report provided more reassuring results. The majority (about 75%) of the products procured in the public sector were 34% less than their IRPs evidencing a good level of purchasing efficiency.

4.90. To ascertain whether the pricing concern raised in the MIH report is still valid, retail prices of 6 selected medicines surveyed in 2008 were compared with their corresponding IRPs. Those 6 selected medicines were among those for which both originator brands and lowest priced generics were priced significantly higher than their corresponding IRPs. Therefore, this sample should provide meaningful insights in assessing the competitiveness of prices of pharmaceutical products in Mauritius.

4.91. The retail prices of the 6 selected pharmaceutical products were randomly collected from a few pharmacies across Mauritius. The median local unit prices of the drugs were compared with their corresponding IRPs, based on the International Drug Price Indicator Guide of 2015 (latest one available).[99]

4.92. Table 13 provides information on the MPRs of the selected drugs in 2008 (from MIH Report) and 2020 (Competition Commission's computation).

Table 13: Medicine Price Ratio, 2008 and 2020

Selected products	Generic		Originator	
	2008[100]	2020	2008[101]	2020
Albendazole	56.02	3.93	106.79	28.92
Atenolol	5.69	6.72	31.76	31.54
Carbamazepine	2.41	7.21	10.25	6.65
Glibenclamide	19.27	13.06	45.58	15.79
Metronidazole	23.30	13.12	64.03	23.39
Omeprazole	5.74	16.91	53.1	41.03

Source: MIH Report 2008 and Competition Commission's computation

4.93. Comparing the MPRs of the sample drugs between 2008 and 2020, it is observed that prices of the 6 selected originators products relative their international reference prices decreased over this period. For certain products such as Albendazole, Glibenclamide and Metronidazole, their respective MPRs have significantly fallen. For example, the MPR of the originator for Albendazole

[97] Survey of a pre-determined basket of pharmaceutical products was conducted as part of the 'Medicine Prices, Availability, Affordability and Price Components in the Republic of Mauritius' report.
[98] International reference pricing is the practice of regulating the price of a medication in one country, by comparing with the price in a "basket" of other reference countries.
[99] Available at https://www.msh.org/blog/2015/07/02/new-edition-of-international-drug-price-indicator-guide-available
[100] Source from MIH Report
[101] Supra note 100

has fallen from 106.79 in 2008 to 28.92 in 2020. Those of Glibenclamide and Metronidazole have fallen from 45.58 and 64.03 in 2008 to 15.79 and 25.39 in 2020, respectively. The decrease in the MRP of Atenolol is however insignificant.

4.94. For generics, 4 out of the 6 selected drugs experienced a decrease in their MRPs. That of Albendazole decreased significantly, from 56.02 in 2008 to 3.93 in 2020. Whereas those for Carbamazepine and Omeprazole increased in 2020 compared to their levels in 2008.

4.95. While a general improvement in the MPRs are observed compared to their 2008 levels, the retail prices charged in Mauritius remain still well above the IRPs for both generics and originators. For example, that for Omeprazole is 16.91 times for generic and 41.03 times for originator the IRP.

4.96. The IRPs should, however, for mere comparative purposes as an indication for likely competitive prices rather than the actual ones. There are several factors which could explain the higher prices of pharmaceutical products compared to their IRPs. These are in essence the manufacturer's selling price and add-on costs.

4.97. Potential higher manufacturers' selling prices can be attributed to reasons such as the smaller size of local market, lower bargaining power of buyers and volatility of Mauritian rupee vis-à-vis major international currencies. There is not much that can be done in this regard but to encourage parallel import.

4.98. As identified in the MIH Report, add-on costs represent around 40.11% to 63.90% of the final price of pharmaceutical products in the private sector. The add-on cost are notably in the form of freights, insurance, local charges and mark- up.

4.99. A discussion on how the current mark-up, volatility in exchange rates and parallel import can influence the price of pharmaceutical products is provided below.

a) Mark-up regime

4.100. Under the current legal framework, as explained in the prior section, prices of pharmaceutical products are regulated in terms of the maximum applicable mark up of 35% and a special allowance of 2% on the landed cost.[102] Price regulation in this sense is principally intended to ensure affordability and thus accessibility to medicines to the population at large. It concurrently creates an incentive for market players in the supply chain to make the product available on the market.

4.101. With a maximum mark-up system, wholesalers and retailers have strong incentives to stock and sell higher-priced pharmaceutical products, which in most cases are branded originators. This is because higher priced products result in higher quantum of profits for the operators. Even though originators and generics co-exist, the structure of current mark-up system may create an unequal playing field among equivalent therapeutic options, favouring expensive options over cheaper alternatives to the detriment of users of pharmaceutical products.

4.102. The current mark-up system also encourages retail pharmacies to sell products at the maximum allowable retail price (usually already affixed by the wholesale pharmacy on its products pursuant

[102] The landed cost includes the CIF, inspection charges, port fees such as storage, handling and insurance in port, custom clearing charges and local transport charges to the warehouse.

to its statutory obligations under Consumer Protection (Consumer Goods) (Maximum Mark-Up) Regulations 1998)[103], thereby undermining price competition between retail pharmacies.

4.103. Consequently, it can be observed that a fixed percentage mark-up has the overall tendency to undermine the very purpose it is trying to achieve; namely ensuring the affordability and availability of pharmaceutical products in a competitive manner.

4.104. In contrast, a regressive mark-up regime may provide some ground to offset those anticompetitive effects through its influence on financial incentives. Such a regime makes provision for a lower mark-up percentage for higher-priced pharmaceutical products, i.e., as price increases the mark-up percentage decreases.

b) Volatility in exchange rate

4.105. Given our cardinal reliance on importation of pharmaceutical products for local supply in Mauritius, their prices are heavily affected by fluctuations in the exchange rate. An appreciation of the Mauritian rupee vis-à-vis the major trading currencies would tend to make our imports more affordable while a depreciation of our local currency would cause imported pharmaceutical products to be more expensive. In general, this strong responsiveness of import prices of pharmaceutical products should not pose major concern as currencies are very volatile by nature.

4.106. However, what has been observed, is that the Mauritian rupee has been consistently, over time, depreciating against the currencies of our major importers. Considering the period 2008 to 2020, for instance, the Mauritian rupee has depreciated by a significant 42% against the US dollar (US $1=Rs 28.45 in 2008 to US $1=Rs 40.36 in 2020), thus explaining, to a large extent, the higher retail prices of pharmaceutical products brought. Furthermore, the current pricing mechanism of applying a maximum mark-up on the c.i.f. value of pharmaceutical products only fuels the higher cost burden borne by final consumers who pay a proportionately higher price. Hence, exchange rate volatility is of crucial importance in the pricing of pharmaceutical products in Mauritius.

c) Parallel imports

4.107. As mentioned previously, due to the national exhaustion regime adopted by Mauritius, owners of registered trademarks have the discretion to withhold their consent for parallel importation of registered pharmaceutical drugs. This can potentially lead to a situation giving rise to abusive use of IP rights. It may notably reduce intra-brand (price) competition through the preservation of market power of IP holders which may consequently foreclose potential competitors of genuine sources of supply on the market.

4.108. This was illustrated in the aforementioned case of ***Reckitt & Colman (Overseas) Ltd v. M.N. Dauhoo and The Mauritius Revenue Authority*** in relation to the parallel import of "Strepsils" branded lozenges. The defendant averred that the acts and doings of the plaintiff were detrimental to the interests of the consumers and was creating a monopoly situation in so far as "Strepsils" branded lozenges were being sold at an exorbitantly high price on the Mauritian market. The wholesale importer had averred "importing 2 to 3 consignments of "Strepsils" per year for the past 15 years from different countries. The [then] cost price [was] Rs60 per box of 24

[103] GN No. 150 of 1998. Regulation 9(1) provides as follows –
'Every importer shall, prior to making a sale or supply of a medicine, affix a label to every pack, packet or container of the medicine, indicating legibly the maximum retail price at which the medicine is to be dispensed, exposed, offered for sale or sold to consumers'.

tablets which he sold at Rs75. The plaintiff - Grays Inc. Ltd. had, for its part, been selling the said product at Rs137.50'[104].

4.109. While this constitutes a competition concern, it has no bearing whatsoever under the current regulatory framework. As a matter of fact, the Court held that fact that goods are sold cheaper elsewhere is irrelevant regarding the issue of parallel importation. The ability of the trademark owner to object to the importation of goods without its consent is a legitimate exercise of his legal rights as the law stands now, despite the fact that is at the detriment of the consumers interest in the long run.

4.110. Parallel import can not only bring a reduction in the prices of branded pharmaceutical products but can also act a complement to price control strategies. This is particularly relevant to healthcare providers whereby it may give them a strong negotiating leverage with manufacturers of branded pharmaceutical products. Increasing the bargaining power of the distributor vis-à-vis the producer will ultimately lead to more competitive prices.

[104] 2012 SCJ 494, pg. 8.

5. Conclusion and Recommendations

5.1. The Study aimed at understanding the conditions of competition in the pharmaceutical industry by reviewing the underlying market structure and concentration levels and assessing the regulatory framework with respect to the market authorisation process, the licensing of economic operators and pricing of pharmaceutical products.

5.2. The pharmaceutical industry consists mainly of wholesale pharmacies, and retail pharmacies. Wholesale pharmacies import and supply pharmaceutical products to both public and private healthcare institutions. It is observed that the number of wholesale pharmacies has increased significantly over the years from 24 in 2010 to reach 40 in 2019. While the broader wholesale pharmaceutical market is not found to be concentrated, a more in-depth assessment is required to assess actual concentration levels in the various individual relevant markets that are likely to exist given the nature of pharmaceutical products.

5.3. Potential competition concerns identified within the pharmaceutical industry arise from the current regulatory framework. Amongst, perceived conflict of interest of Board members taking part in the registration process for the approval of products. This stems from the fact that prior to 2016, wholesalers or vertically linked retail pharmacists were appointed as Board members.

5.4. There is also the lack of transparency and predictability regarding the Board's operating procedures. Most notably, the lack of clearly defined and thorough guidance on the registration pharmaceutical products can lead to information asymmetry among applicants seeking registration of products. Additionally, the up-to-date list of pharmaceutical products registered with the Board is neither available for consultation at the responsible Ministry nor on its website, despite the fact that the law already makes provision for this. Collectively, these factors can potentially lead to conditions creating business uncertainty and thus may stifle competition among wholesale pharmacies.

5.5. In regard to the pricing of pharmaceutical products, the analysis carried out tends to show that local prices are higher when benchmarked against international reference prices. However, the context of this comparison is a particular one. When this index is used as a direct benchmark of prices of pharmaceutical products in the private sector, care should be taken to also consider other defining factors of the Mauritian economy which affects the various price components.

5.6. In relation to the pricing model used for pharmaceutical products, which tends to deliver some unintended consequences. It can be argued that the current pricing model based on a maximum mark-up may provide strong incentives for wholesalers and retailers to favour higher-priced products to attract higher profits. It also incentivises operators along the supply chain to use the maximum mark-up allowable.

5.7. that Mauritius relies essentially on imports, prices of pharmaceutical products are wholly influenced by the exchange rate. The Mauritian rupee, having considerably depreciated over the years, led to high retail prices after accounting for the full flat mark-up.

5.8. The prevailing national exhaustion rights regime is another aspect of the pricing component of pharmaceutical products. In fact, the current regulatory framework might impede competition at wholesale level in the event that registered trademarks owners withhold their consent for parallel importation, which is usually more often the case than not. A probable effect thereafter is the foreclosure of competition from new potential entrants supplying the market with genuine supply. This, in turn, supresses intra-brand competition to the detriment of end-users.

5.9. In light of the foregoing, the Executive Director recommends the following:

A. Facilitation of access to information in relation to the Pharmacy Board's registration process, criteria and applicable standards

5.10. The Pharmacy Board plays a very important role in regulating the entry of pharmaceutical products and licensing pharmacies in Mauritius. It is vital that clearly defined and comprehensive drug registration guidance in relation to the board's policies and evaluation process is made available to registration applicants. This would bring more transparency and accountability into the process and enable applicants to better understand the decisions of approval or non-approval of registration of products by the Board.

5.11. In this optic, The National Single Window (Mauritius Trade Link) can be used to achieve greater accountability and transparency. This centralised system will allow harmonization of data elements across agencies (notably the MRA, the Pharmacy Board, the Ministry of Health and Wellness and the Ministry of Commerce and Consumer Protection). Consequently, it would make the process of gathering and compiling the list of pharmaceutical products registered for import with the Board much easier and making it accessible to the wholesalers/importers through this central repository.

5.12. Thus, the availability of these guidance documents, the up-to-date list of pharmaceutical products registered with the Board together with unconflicted Board members is likely to promote information symmetry among operators. This will enable them to make better informed commercial decisions through a fairer and more transparent decision-making process by the Board.

B. Reviewing the pricing control policies

5.13. The fixed mark-up system, as applied in Mauritius, remains the prominent methodology for price determination in most low and middle-income countries, particularly in Africa. In contrast, the regulation of mark-ups in most European countries and high-income countries caters for a wider combination of strategies which introduce flexibilities in the regulations[105].

5.14. For instance, separate strategies may apply for branded originators and generic medicines; medicines on the national essential medicines list and those not on the list; reimbursable and non-reimbursable medicines[106]. Cyprus and Luxembourg, for example, have different wholesale margins for different classes of drugs, be it locally manufactured versus imported, or depending on the country of origin. Regressive mark-ups, which consist of a fixed percentage that decreases as the corresponding price increases, are popular in most European countries for both wholesale and retail operations[107]. Indonesia is another example where mark-ups for originator brands are lower than those for generic products; thereby promoting lower cost generics by allowing for higher a return[108]. The WHO Guideline[109] also considers regressive mark ups rather than fixed percentage mark-ups given the incentive that the latter provides for higher-priced products to receive a lower net margin.

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[105] For instance, Australia employs a combination of regressive percentages plus fixed fees plus a dispensing fee, and New Zealand employs a limited progressive percentage mark-up plus a dispensing fee (Source: WHO/HAI, 2011).

[106] In Latvia, different mark-ups apply to reimbursable and non-reimbursable medicines. These result in lower prices for reimbursed products and lower co-payments for patients with the effect of reducing pharmaceutical expenditure for the third-party payer. Source: WHO/HAI, The Regulation of Mark-ups in the Pharmaceutical Supply Chain (2011), p. 22.

[107] Kanavos, Willemien and Vogler (2011).

[108] WHO/HAI, The Regulation of Mark-ups in the Pharmaceutical Supply Chain (2011), p. 22.

[109] See WHO Guideline on Country Pharmaceutical Pricing Policies (2015). Available at: <http://apps.who.int/medicinedocs/documents/s21016en/s21016en.pdf>

5.15. The mark-up system also directly impacts on the profitability of operators in the wholesale and retail pharmaceutical business. Private operators have expressed concerns over the commercial viability of the pharmaceutical sector as a result of the reductions in mark-up allowances in 2004. To the extent that further reductions in mark-up allowances would be met by lobbying or resistance from the operators, the Government could consider imposing service criteria such as requiring wholesalers and retailers to carry a minimum ratio of unbranded generic medicines to originator medicines. This would ensure affordability of drugs in Mauritius without disrupting the commercial viability of operators.

5.16. It is therefore important that regulation of chain mark-ups is studied after considering the variables that determine medicines prices and the characteristics of each level of the supply chain. The Ministry of Commerce and Consumer Protection is also encouraged to monitor prices by undertaking price comparison and publishing same on a regular basis. This will encourage price transparency at all levels.

5.17. As recommended by the WHO, international or external reference pricing should be part of an overall strategy, in combination with other methods, for setting the price of a medicine. In developing such a system, countries should define transparent methods and processes to be used.

C. Consider amending the law for parallel imports

5.18. It is undeniable that a robust IP rights regime is essential to foster creative effort and innovation. This is particularly crucial in the pharmaceutical industry given that constant endeavours towards research and development is required for the advancement of new medications. Furthermore, a strong IP rights enforcement promotes the overarching objective of public safety as it helps consumers to make an informed choice in relation to the authenticity, reliability and effectiveness of their purchases. In this sense, IP rights aims at ensuring a standardised benchmark in terms of quality of a pharmaceutical product.

5.19. That being said, the overlap of parallel imports and IP rights in the context of the Mauritian pharmaceutical industry is a peculiar one. As indicated earlier, Mauritius relies primarily on imports in relation to pharmaceutical products. Parallel imports, as it stands currently, involves the importing of a pharmaceutical product produced genuinely under the protection of a trademark, patent, or copyright from another market and then distributing it outside the distribution network set up by the manufacturer or the authorised local distributor in Mauritius.

5.20. As it can be observed, parallel import does, in no manner whatsoever, relates to counterfeit pharmaceutical products. Consequently, in general, neither does it jeopardize the protection of human health and life nor does it flout industrial and commercial property as the concerned pharmaceutical product is one of genuine origin. Instead, parallel import has the effect of promoting intra-brand (price) competition and opening the market for genuine sources of supply.

5.21. In this respect, amendments are proposed to be brought to the current legal framework to allow for the parallel import of pharmaceutical products as consumers can only stand to gain in the long run in terms of ensuring competitive prices and authenticity altogether.