MARKET STUDY

PHARMACEUTICAL SECTOR IN MAURITIUS

MS/004

Report of the Executive Director

08 June 2021

competition commission

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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 of 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 advertising of pharmaceutical products is 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, also known as information failure, which occurs when one party to an economic transaction possesses greater material knowledge than the other party. Such circumstances 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, freight, and local charges as part of the mark-up system must 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, may 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 can potentially reduce intra-brand competition and forecloses potential competitors from the market. Thus, another potential reason for higher prices of pharmaceutical in Mauritius, along with mark-up regime and the volatility in exchange rate, 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, parallel importation of pharmaceutical products may be considered as a potential avenue. That being said, the right institutional and legal framework must be thoroughly assessed by the concerned authorities and policy makers to guard against the various health and safety risks in relation to the supply chain, liability issues ensuing from such health and safety risks, increased risk of counterfeit products on the market and money laundering risks.

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. As part of process of undertaking the Study, the Executive Director has engaged into consultation with the various stakeholders by inviting them to submit their written views on a preliminary Report. The views and comments received from inter alia wholesale pharmacies, consumer association, professional pharmacy societies, ministries, government departments and other regulators have been appraised on the basis of their relevance, pertinence, and coherence, and reflected in this Report of the Executive Director ('the Report'). The list of submissions for which the concerned stakeholders have provided their consent for publication is provided at Annex A, I-VII of the Report.

1.4. The comments, views and suggestions received can be categorised in twofold, namely those made on the analysis and recommendations enumerated in the present Report, and those proposing new suggestions and recommendations. There are certain averments and comments made which falls outside the purview of competition law, but which are nonetheless reproduced for the sake of completeness.

1.5. The recommendations arising from this market study can provide a basis for consideration of potential changes in the regulatory framework to improve the conditions of competition in the supply of pharmaceutical products in Mauritius. In bringing any regulatory changes, Government may take any wider public interest concern into account.

A. Motivation and Scope of the Study

1.6. 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.

1.7. 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.

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

1.8. 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. 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 sector 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 the 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 the country. 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].

[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.

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

Table 1: Health professionals and infrastructure, 2011 and 2018

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	38	470	508
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, 508 pharmacists and 4,400 qualified nurses and midwives in Mauritius. 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 around 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	**11.3**	**12.3**	**14.1**	**14.4**	**15.1**	**17.4**	**21.5**	**23.5**	**25.1**	**26.1**

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 12.8 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

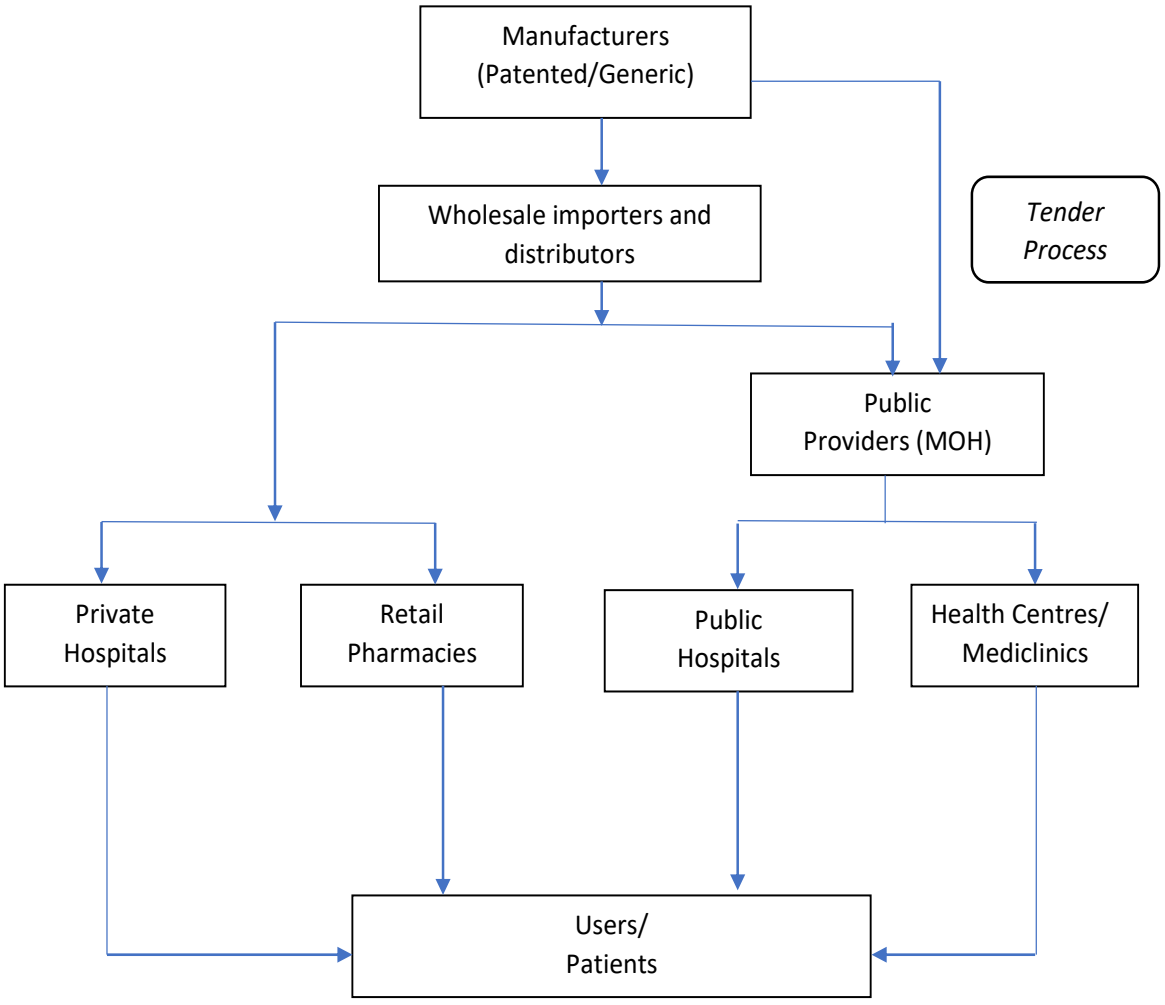
2.11. Having provided a brief overview of the health sector in Mauritius, the section below describes the pharmaceutical industry in terms of its supply chain and some market statistics on importation of pharmaceutical products.

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.

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 on 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 of 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.

[7] Submitted by the Ministry of Health
[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

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

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

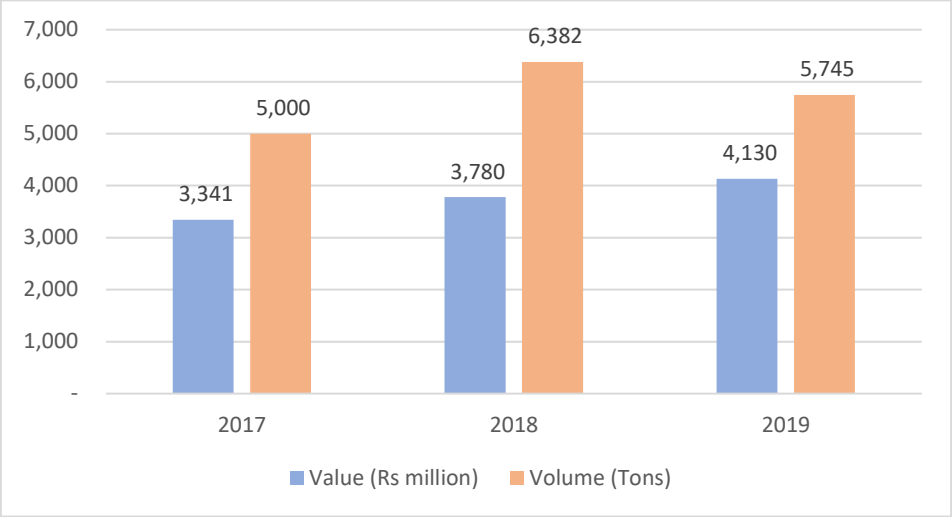
2.24. As highlighted earlier, importation is the main source of supply of pharmaceutical products in Mauritius. In 2019, the total CIF (costs, insurance, and freights) value of pharmaceutical products imported into the country for local distribution amounted to Rs 4.1 billion[11] (an additional Rs 800 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.

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

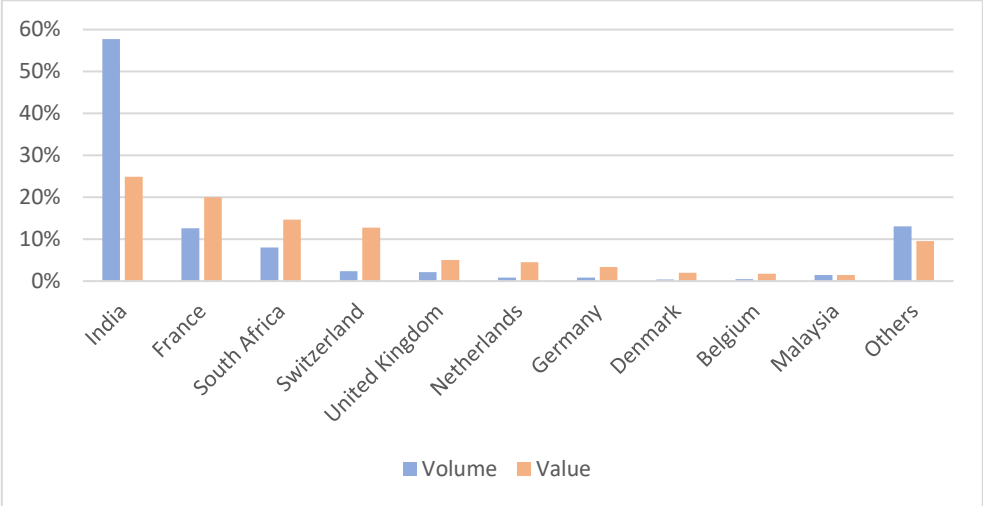
Figure 2: Imports of pharmaceutical products, 2017-2019



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.

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 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. During the consultative process, stakeholders have highlighted that certain issues of general nature regarding the trade of pharmaceutical products but also products falling outside the ambit of the Pharmacy Act. These submissions are summarised below:

- The law does not make any distinction between generic and branded products. However, the entry of generics is often constrained in so far as registration of several products have been refused. The reason put forth by the Pharmacy Board is that there are too many such products with the same therapeutical value on the market.
- More than 80% of pharmaceutical products available in public health institutions are not listed on the schedules of the Pharmacy Act.
- There is no legal framework to regulate:
    - health supplements,
    - cosmetics,
    - medical devices and consumables, and
    - traditional medicines (TMs).
- The Ayurvedic and other Traditional Medicines Act provides for framework governing practitioners of traditional medicine but there are no regulations to control imports and sales of TMs in Mauritius.

[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.

- The requirement for a pharmacist to be in charge at local manufacturing plant of pharmaceutical products has been questioned. It is submitted that there are various ways for quality control, including the involvement of professionals such as a chemical technologist.

3.18. 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.

3.19. 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.

3.20. 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);

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

3.21. 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.

[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.
[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)

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.

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

3.23. 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].

3.24. 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.

3.25. 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.

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

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;

3.26. 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).

3.27. 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 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

3.28. 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.

3.29. 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];

[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.

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 products with 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 there should be no monopoly for any single product or class of products[37].

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

3.31. 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[38] (hereinafter referred to as "BFUE" standards), 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.

3.32. 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].

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

iv. The Registration fees

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

3.34. 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).

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

3.35. The intellectual property 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].

3.36. 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

[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.

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) 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].

3.37. 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 period of two years.

3.38. 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

3.39. 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].

3.40. 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.

3.41. 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.

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[46] Section 40(1) of the PIDTA.
[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 >.

3.42. 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 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.

3.43. Notably, Section 21(4)(b) of the PIDTA in relation to rights conferred by a patent, provides that "[a]ny 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 or imported into Mauritius" On the other hand, Section 40(1)of the PIDTA, in relation to trademarks, provides that "[a]ny 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 require the agreement of the owner." This is further supplemented by Section 40(5) of the PIDTA to the effect 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 or with his consent".

3.44. 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].

3.45. 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 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

3.46. 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

3.47. 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].

3.48. 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

[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.

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

3.49. 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.

3.50. The Pharmacy Act also prescribes three mandatory criteria to be met by the applicant, failing which the licence 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].

3.51. 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].

3.52. 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

3.53. 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

3.54. 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

[56] Section 35(2) of the Pharmacy Act.
[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

duly issued licence; (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).

3.55. 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

3.56. 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.

3.57. All retail pharmacies require a licence obtained from the Board to operate in Mauritius. In some countries[66], doctors and manufacturers are not allowed to own a pharmacy due to a conflict of interest as prescribers. In Mauritius, restriction on the ownership of a pharmacy[67] is reflected in section 40(2) of the Pharmacy Act which stipulates that no authorised person, which is defined as being a medical practitioner, a dental surgeon or a veterinary surgeon in the exercise of his profession [68] shall have any share, participation or other financial interest in the manufacture or sale, whether by wholesale or retail, of pharmaceutical products. As such, any individual or legal entity other than the 'authorised person' may, in principle, own pharmacies in Mauritius.

3.58. 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[69].

3.59. 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

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[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'.

[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] Section 2 of the Pharmacy Act defines an authorised person as being a medical practitioner, a dental surgeon, or a veterinary surgeon in the exercise of his profession.

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

c. the recommendations of the TTC[70].

3.60. In September 2017, the Ministry of Health published updated guidelines for opening of a retail pharmacy[71]. 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.

3.61. 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.

3.62. 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.

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

3.64. 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[72]. Also, the pharmacy should be separate from any other business by a concrete partition.

3.65. 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.

3.66. 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[73].

3.67. 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.

[70] Section 18(4) of the Pharmacy Act.

[71] Ministry of Health and Quality of Life Guidelines 'Guidelines for opening of pharmacies (Retail)' (11.09.17).

[72] 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.

[73] 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

3.68. A mark-up system regarding pharmaceutical products was first introduced under Section 5 of the Supplies Control Act 1974[74] by the Medicines (Maximum Mark-up) Regulations 1977[75] and then replaced by the Medicines (Maximum Mark-up) Regulations 1981[76]. 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.

3.69. 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.

3.70. 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.

3.71. 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.

3.72. 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.

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

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

3.74. 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[77]	18th June 2004 to date	Pharmaceutical products and simple drugs	35	2

Source: Compiled

3.75. Table 7 illustrates the price structure of a pharmaceutical product using a hypothetical manufacturer's selling price (MSP, inclusive of insurance and freight) 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 (CIF)		**100**.00		**100**.00
Customs Duty	5.0	5.00	0	0.00
Special Allowance	5.0	5.00	2.0	2.00
Landed Cost		**110**.00		**102**.00
Wholesale Mark-Up	14.0	15.40	11.0	11.22
Wholesale Price		**125.40**		**113.22**
Retail Mark-Up	27.0	33.85	21.6	24.48
Retail Price		**159.25**		**137.70**

Source: Price Fixing Unit

3.76. 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

[77] 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 Minister.

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).[78] 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.[79]

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 other drugs than those meant to control blood pressure. In other words, products need to have same therapeutic value to be considered as interchangeable.

[78] 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.

[79] DOJ-FTC Guidelines on Horizontal Mergers.

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 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.[80]

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 1, 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 focus at the wholesale and retail levels.

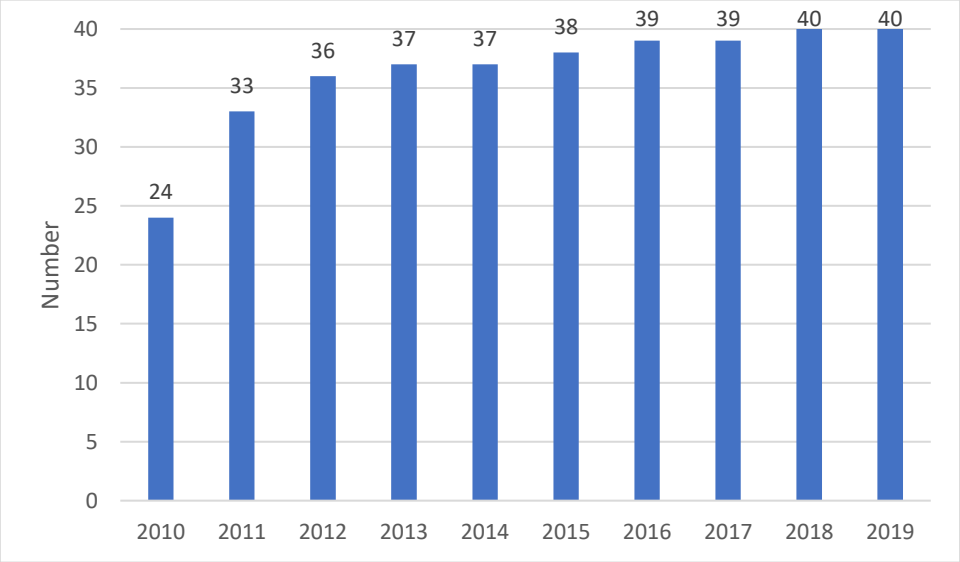
[80] Competition and Regulation Issues in the Pharmaceutical Society 2000, OECD Policy Roundtables, DAFFE/ CLP (2000)29, 6 February 2001, para 4.6, page 45: https://www.oecd.org/competition/sectors/1920540.pdf

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. With regards to potential entry in the market, the following factors have to be taken into consideration: 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[81], 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.

[81] MSJ Ltd (Unicorn) has submitted that its market share is lower than the 18-20% having regard to its turnover compared to other wholesale pharmacies. It should be highlighted the figures have been computed based on imports data on pharmaceutical products, as categorised by their HS codes. Thus, this excludes other potential products, such as cosmetics, supplements, etc, that wholesale pharmacies may also have in their trading portfolio.

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 10 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[82].

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.

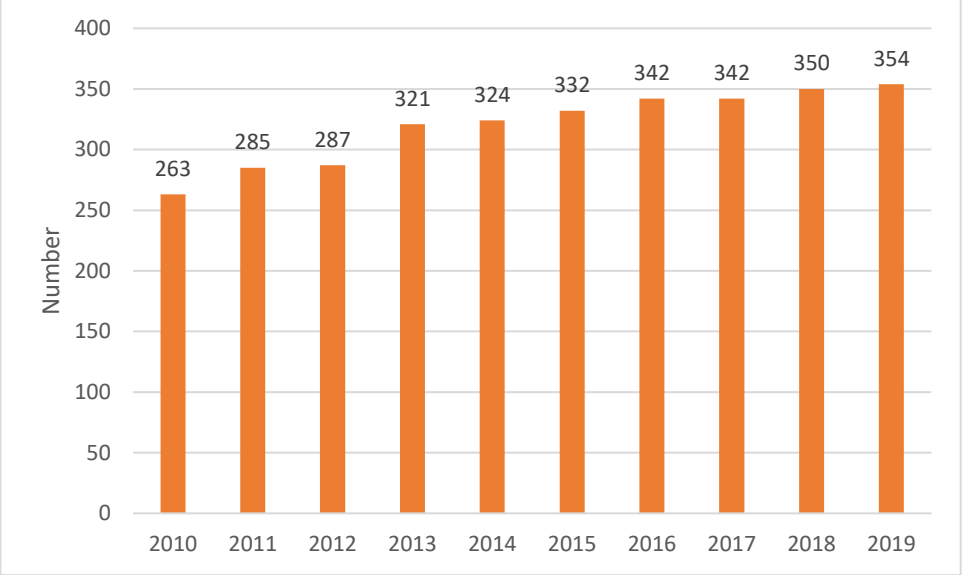
b) The retail pharmacy market

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.

[82] Based on information gathered from MRA.

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 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.

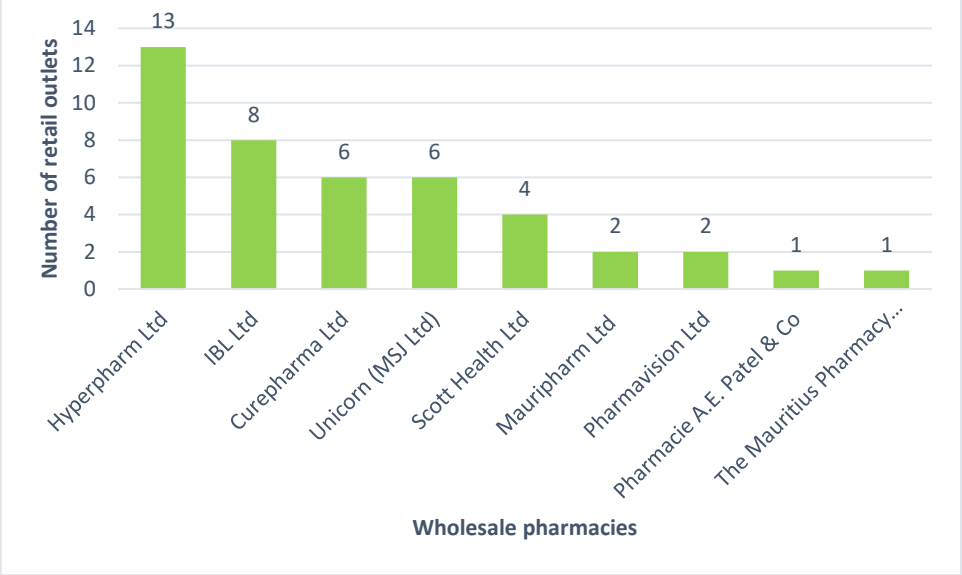
c) Vertical linkages

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 outlets owned by wholesale pharmacies



Source: Compiled from companies' websites

4.31. Some concerns have been expressed surrounding the supply of pharmaceutical products to retail pharmacies. It has been submitted that certain wholesale pharmacies tend to restrict supply of products to their own retail outlets. Such practice could potentially lead to foreclosure of access to key products to other retail pharmacies.

4.32. A cursory 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. However, the retail outlets operated by wholesale pharmacies are located in shopping malls and high converging areas. Such outlets are likely to generate significant sales compared to those located in low converging areas. Nevertheless, there does not seem to be an incentive for integrated wholesale pharmacies to restrict supply of key products to other retail pharmacies.

4.33. Certain averments were also made during the consultative process to the effect that some integrated wholesale pharmacies are currently engaging in unfair competition and unethical practices so as to gain bigger market share. These submissions are summarised below.

- Some integrated wholesale pharmacies, which are part of larger group of companies, are using their financial strength to incentivise customers to buy pharmaceutical products from their retail outlets. To this effect, they are offering loyalty cards to offer discounts on pharmaceutical products, including prescription drugs. This is putting the smaller retail pharmacies at a competitive disadvantage, as they are not able to offer same.
- Integrated pharmacies are able to negotiate better terms with manufacturers in terms of bonuses, discounts and credit facilities based on volume of pharmaceutical products sold through their wholesale and retail outlets. This enables integrated pharmacies to offer up to 12.5% discounts schemes to major customers by using funds from those bonus and discount schemes. Also, these wholesale pharmacies are also appointing marketing teams to influence prescribers to channel prescriptions to their retail outlets.
- Another concern raised is that retail pharmacies in commercial centres tend to be concentrated in the hands of two integrated wholesale pharmacies. These wholesale

pharmacies have strong bargaining power to impose trading conditions on retail pharmacies.

4.34. Nonetheless, the Executive Director has taken note of these averments and, should such claims disclose any competition concerns, he shall act in accordance with the provisions of the Competition Act 2007. In this regard, the Executive Director invites any individual or entity aggrieved by such alleged practices or holding information to this effect to come forward and make a formal complaint to the Competition Commission.

B. Regulatory Framework

a) Registration and Commercialisation Framework

4.35. 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

4.36. 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.

4.37. 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.

4.38. 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.

4.39. 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.

4.40. 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.[83] 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.

4.41. 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[84], thereby ensuring their independence.

4.42. 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.

4.43. 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.

4.44. During the consultation process, stakeholders submitted that the mechanism used for the approval or rejection of an application for licensing of pharmaceutical product is not clear and transparent enough to remove any perception of favouritism. To address this concern the following has been proposed to supplement the recommendation made:

i. A Board Charter which would include obligations for members of the Pharmacy Board to disclose any 'Conflict of Interest' or 'Related Party Transaction' and abstain from the decision-making process where they are conflicted or related.

ii. A list of the registration of products of members of the Board may be kept to show the extent of conflict of interest.

iii. A 'Board Governance' procedure with the necessary structures to ensure adherence to the National Code of Good Governance.

iv. A 'Board Evaluation' that would ensure the effectiveness, transparency, and accountability of members of the Pharmacy Board with regard to board governance.

v. Amending rules governing the internal functioning of the Pharmacy board to reflect and clarify that members will not be able to vote on matters where there is actual or potential conflict.

vi. The retail pharmacists would have an advisory non-voting function.

vii. The Pharmacy Board needs to be properly funded with a dedicated secretariat.

4.45. While it has been highlighted that the composition of the Board could potentially undermine the competition process owing to actual or perceived conflict the Competition Commission may not be the appropriate regulatory entity to assess the effectiveness of the above proposals to address the issue. The Executive Director believes that these proposals can be taken into consideration in

[83] Information provided by the Pharmacy Board; email dated 10th June 2020.
[84] Information provided by the Registrar of the Pharmacy Board; email dated 11th June 2020.

the decision-making process by policy makers when amending the regulatory framework of the pharmaceutical sector.

ii. Transparency Issue Regarding Operation of the Board

4.46. 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.

4.47. 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[85]	2017[86]	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

4.48. 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

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

Free Sale Certificate, information on marketing experience in other countries, Registration Certificate from country of origin (India), certificates to establish safety in patients and stability test, among others.

4.49. 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, as highlighted by consumer protection organisations and other stakeholders, 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.

4.50. 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.

4.51. Another anomaly noted from Table 12 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.

4.52. Such a state of affairs further reinforces the existing information asymmetry (different level of information available to different players in the market) 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. These issues should be addressed expeditiously.

4.53. In this regard, the following proposals have been made by various stakeholders:

i. The publication of an official guideline with clear timelines for approval of requests. It will also include a check list informing applicant all the documents required to be submitted at the time of application.

ii. Acknowledgement of receipt of registration dossiers and updates on status of application.

iii. Fast-tracking the online registration process of pharmaceutical products to ensure transparency in the application process and allow importers to monitor the status of their application. The reasons for rejection of applications should be given to importers and that there is right of appeal so as to ensure transparency in the process.

iv. The Ministry of Health and Wellness published reasons for not approving pharmaceutical products registrations on its website.

v. The abolishing the additional permit for Therapeutic Substances as there is unnecessary "Duality" of Control and the strengthening of "Red Tapes" now that this formal registration process is in place.

4.54. While the Competition Commission may not be the appropriate regulatory entity to assess the effectiveness of these proposals, the Executive Director believes policy makers could have regard to those proposals when amending the regulatory framework of the pharmaceutical sector.

iii. Unavailability of the List of Registered Pharmaceutical Products

4.55. 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.

4.56. 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.

4.57. 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.

4.58. 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.

4.59. 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[87] 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[88] 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.

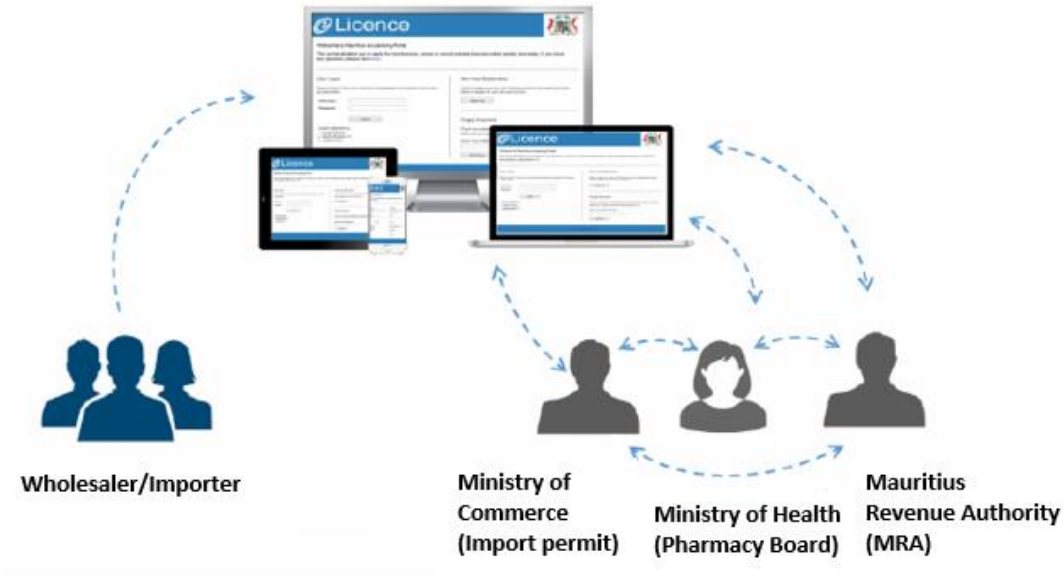
[87] See Medicines Control Authority of Zimbabwe, Regulations and Guidelines. Available at https://www.mcaz.co.zw/index.php/downloads/category/9-regulations-guidelines

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

4.60. 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.

4.61. 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.

Figure 7: National Single Window



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

4.62. 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.

4.63. The Department of Pharmacy of the Ministry of Health has submitted that the project is underway, 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 assymmetry 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

4.64. 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 BFUE standards, in particular to standards conforming to Indian Pharmacopoeia, was irrational. It was submitted that, should the Board restrict registration of pharmaceutical products to BFUE 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*'[89].

4.65. 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 BFUE 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[90].

4.66. That being said, there has been recent developments regarding this particular issue. Most notably, it was announced in the budget speech 2020/21[91] 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[92] has already been enacted and this is likely to resolve the issue tied to the import and registration of pharmaceutical products of Indian origin.

v. Registration fees

4.67. 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[93].

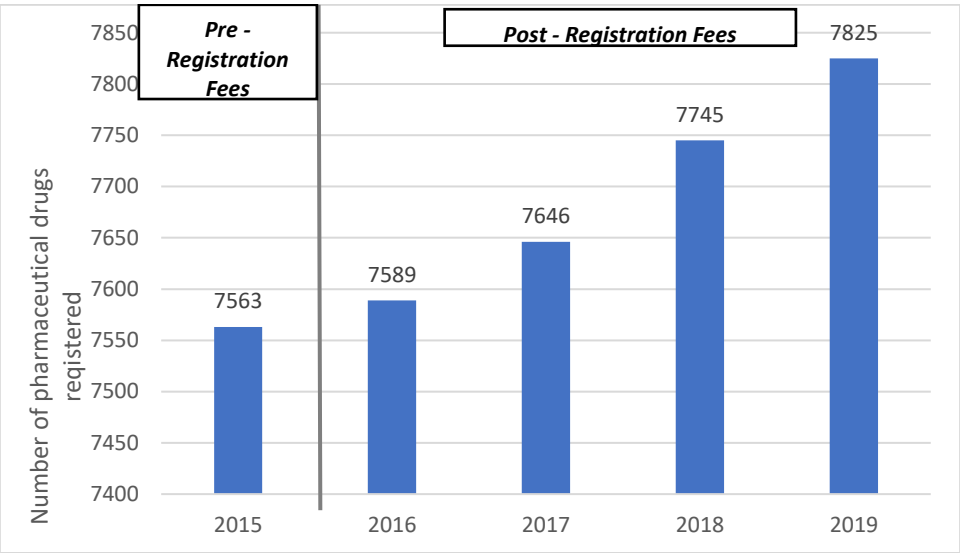
4.68. Actual figures do not support the claim of the stakeholders that the increase in registration fees led to foreclosure of small wholesale pharmacies. In fact, the number of wholesale pharmacies has not decreased in any way whatsoever but in fact increased from 39 in 2016 to 40 in 2019,

[89] Submission from the Pharmaceutical Association of Mauritius, email dated 07.10.2014.
[90] Submission from the Pharmaceutical Association of Mauritius, email dated 07.10.2014.
[91] See Annex to Budget Speech, 2020-2021. Available at: http://budget.mof.govmu.org/budget2020-21/2020_21budgetannex.pdf
[92] 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
[93] 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 >;

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.

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

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



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

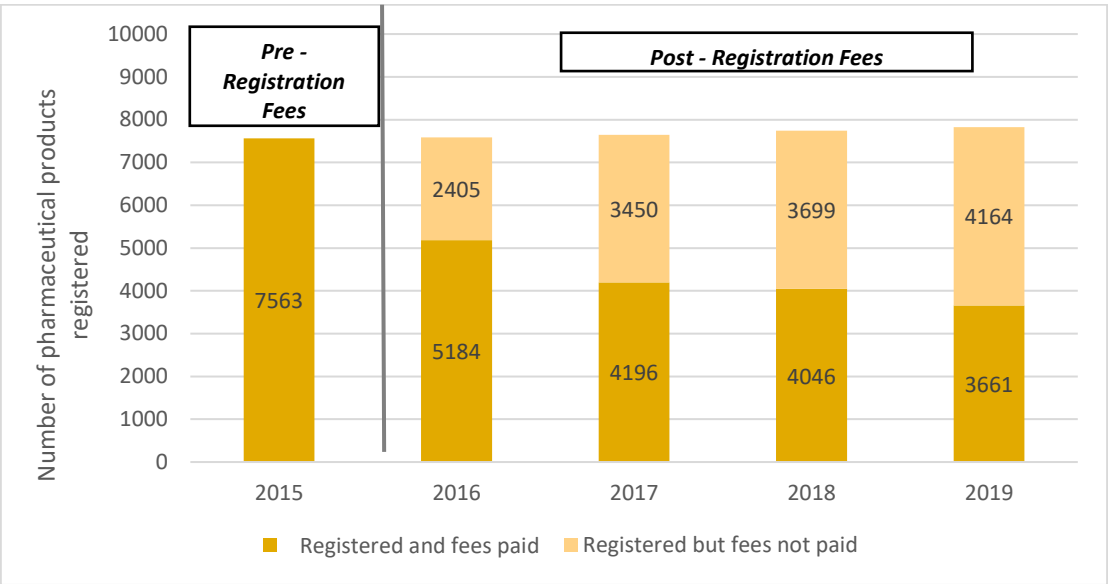
4.70. It should be mentioned that the Department of Pharmacy has indicated that data compilation on registered pharmaceutical products started formally in 2016. The numbers for the year 2015 have been compiled on a retroactive basis and may thus not provide the most reliable depiction of the number of 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.

4.71. 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.

4.72. 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%.

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

Figure 9: Registration/Renewal fees paid for registered products, 2016-2019



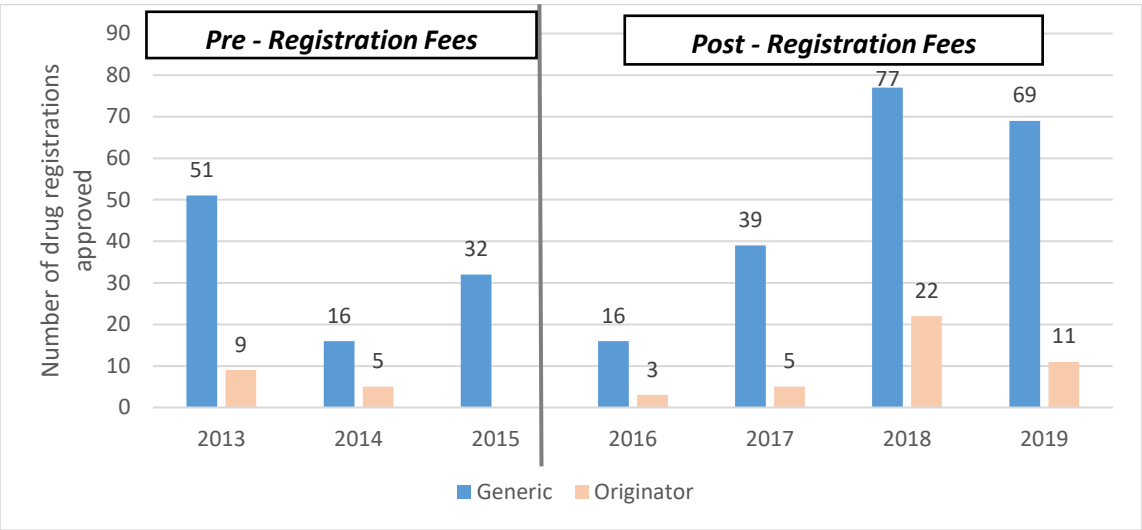
Source: Compiled from submissions of Department of Pharmaceutical Services, 2020

4.74. 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 in some instances.

4.75. 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.

4.76. 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

4.77. 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

4.78. 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).

4.79. The introduction of a geographic dimension concerning the licensing of retail pharmacies received a negative response. It was 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[94]. With the new criteria, around 650 pharmacies would be allowed to operate on the market, which would further increase the pharmacy density.

4.80. During the consultative process, several stakeholders have echoed similar concerns and also highlighted certain issues of general nature regarding the perceived adverse effects that these requirements. These submissions are summarised below:

- The Pharmaceutical Association of Mauritius (PAM) submitted that the existing pricing regulations are already overburdening the finances of both the retail and whole pharmacies, where operating margins range between 1 % - 5%, which were significantly lower than unregulated SMEs. The PAM came up with these operating margins based on an analysis of 2018-19 financial figures for a sample of 45 independent retail pharmacies and the top 5 wholesale pharmacies. According to the latter, the imposition of any regulations which would further reduce the operating margins and create new social

[94] 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 >

problems in terms of loss of jobs and a significant increase in malpractices, including the sale of illicit or dangerous drugs.

- It was submitted that informal data gathered from large pharmacies situated in malls and in urban areas with large footfalls show that cosmetics and health supplements account for up to 47% of total sales. The exemption for malls and smart cities may thus have a discriminatory and unfair dimension in this regard coupled with the fact that it would be only within the reach of bigger market players.
- A complete overhaul of the licensing framework was said to be required in order to better regulate and protect the thriving pharmaceutical sector of Mauritius.
- Other proposals were to the effect that:
    - The Pharmacy Board should treat licence requests from pharmacists operating their own retail outlets on a priority basis as many young unemployed pharmacists would like to start their business.
    - The Pharmacy Act should be amended to allow for provision of Internet Pharmacies.

4.81. 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.

4.82. '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).

4.83. 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 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.

4.84. 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.

4.85. 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

4.86. 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[95], during the consultative process, some stakeholders have denounced the lack of effective monitoring of marketing practices by the responsible authority. These submissions are summarised below:

- It is common practice for wholesale distributors to employ representatives to discuss product claims and clinical evidence with physicians and provide them with free samples. Such practice may have an influence on the doctor's choice while prescribing medicines. Some medical practitioners benefit from a number of advantages, in the forms of monetary gifts or otherwise, to promote particular drugs. In some cases, such practice may be tantamount to corruption.
- Certain stakeholders also suspect that the final prices of the pharmaceutical products are somehow inflated at source to cover for such promotional activities.
- Some wholesale pharmacies use monetary and non-monetary incentives to promote their products to the detriment of other suppliers. For instance, they have supply agreements with private clinics for stocking their products and at the same time these wholesale pharmacies incentivise medical practitioners at those private clinics prescribe their products only.
- There are many medical practitioners who indirectly flout regulations regarding ownership of pharmacies by registering the business owning the pharmacy under the name of their spouse, children, or in-laws. Their prescription choice is often biased towards products sold by those pharmacies at the expense of patients.
- Firm requests were made to have the activities of medical representatives and medical practitioners regulated from an ethical perspective, as is the case in many European countries. In France, for example, the involvement of laboratories in the information of doctors, or their continuous training, is subject to a Code of Ethics.

4.87. It should be highlighted that such practices are strictly prohibited by the Pharmacy Act 1983. Most notably, Section 40 of the Pharmacy Act 1983 stipulates that "*no manufacturer, licensee of a wholesale pharmacy or pharmacist shall enter into any arrangement with an authorised person (medical practitioner, a dental surgeon, or a veterinary surgeon) under which the authorised person is to receive any gain or benefit in return for the custom he brings to the manufacture, licensee of a wholesale pharmacy or pharmacist.*" Additionally, "*no authorised person shall have any share, participation or other financial interest in the manufacture or sale, whether by wholesale or retail, of pharmaceutical products.*"

4.88. 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 the process of rivalry. This is because choice of prescription drugs is determined by physicians and not users. As such, doctors' preference for a

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

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

4.89. The Pharmacy Act also imposes limitation on direct-to-consumer pharmaceutical advertising[96]. 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.

4.90. 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 responsible usage of such pharmaceutical products while diminishing 'self-medication'[97] 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.

4.91. 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.

4.92. The lack of a flexible regulatory framework concerning this particular type of advertising in the non-prescription segment may lead to a situation which may protect relatively inefficient incumbents from competition from new entrants. Given that the choice of the customer is one of the determining factors regarding non-prescription pharmaceutical products, the said customer must have access to maximum information, in the form of advertising, infomercial or otherwise, in order to guide that choice. As such, there may be a need to revisit the advertising framework in respect of non-prescription pharmaceutical products.

4.93. During the consultation process, some stakeholders have highlighted the rationale for maintaining the restriction on advertising and marketing of pharmaceutical products is to not encourage unnecessary utilisation of the advertised products. They, however, denounced the fact that the prohibition on advertisement of pharmaceutical products to the public is being allowed on private foreign TV channels rebroadcasted in Mauritius. As such, a framework should be adopted to enforce advertising restrictions through the various channels.

4.94. It seems that these grievances may find their source to an extent from the aforementioned lack of a flexible regulatory framework concerning advertising in the non-prescription segment of pharmaceutical products. While the current regulatory makes provision to cater for such practices, stakeholders are proposing to outline an Ethical Guidelines of Marketing Strategies

[96] 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'.

[97] 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.

coupled with Code of Practice for the Pharmaceutical Industry which further enforces the 'Informative role' of medical representations.

4.95. In this regard, a Draft Code of Practice for Pharmacists has been publicly presented by the Pharmacy Council for views and suggestions on the matter. At this point in time, the consultation process is understood to be still ongoing and further developments awaits.

C. The Pricing of Pharmaceutical Products

4.96. 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.

4.97. 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.

4.98. To assess whether prices of pharmaceutical products in Mauritius are competitive, reference is made to the 2008 field study[98] 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.

4.99. With regard to pricing, the MIH Report based on a survey of 50 selected drugs [99] 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). [100] 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.

4.100. 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 (MPR, 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

[98] 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 >
[99] 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.
[100] 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.

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.

4.101. 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.

4.102. 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).[101]

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

Table 13: Median Price Ratio, 2008 and 2020

Selected products	Generic		Originator	
	2008[102]	2020	2008[103]	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

4.104. 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 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 MPR of Atenolol is however insignificant.

4.105. For generics, 4 out of the 6 selected drugs experienced a decrease in their MPRs. 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.

4.106. While a general improvement in the MPRs is 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.

[101] Available at https://www.msh.org/blog/2015/07/02/new-edition-of-international-drug-price-indicator-guide-available
[102] Source from MIH Report
[103] Supra note 100

4.107. Regarding the current price analysis, the views expressed during the consultative process by several stakeholders were mixed and these are summarised below:

- Consumer protection organisations endorsed this price analysis. They further submitted that the current prices of medicines sold to Mauritius do not reflect the real prices at production level because it is decided on basis of GDP of import country.
- Major wholesalers and industry players, however, submitted that the IRPs, which is applicable for the sale of pharmaceutical products to non-for-profit agencies, cannot be used as a benchmark in normal commercial operations.
- To ensure affordability of pharmaceutical products, some stakeholders suggested to have recourse to healthcare insurance, namely that:
    - Government should consider the implementation of medical insurance scheme for the civil service.
    - Private healthcare insurance scheme could resolve the rising costs of drugs.

4.108. It should be reiterated that the IRPs have been used in the current analysis for mere comparative purposes and 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.

4.109. 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. One of the means to secure competitive prices could be to consider allowing importation of genuine pharmaceutical products from multiple sources by wholesale pharmacies.

4.110. As identified in the MIH Report, the mark-ups and add-on costs, notably in the form of freights, insurance, and local charges, represent a significant component of the price of pharmaceutical products.

4.111. 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

4.112. 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.[104] 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.

4.113. 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

[104] 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.

playing field among equivalent therapeutic options, favouring expensive options over cheaper alternatives to the detriment of users of pharmaceutical products.

4.114. 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 to its statutory obligations under Consumer Protection (Consumer Goods) (Maximum Mark-Up) Regulations 1998)[105], thereby undermining price competition between retail pharmacies.

4.115. 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.

4.116. 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.

4.117. During the consultative process, consumer associations have shown to be in favour of a change towards the regressive mark-up system. However, industry players (in particular PAM and retail/wholesale pharmacies) have expressed concerns on the proposed regressive mark-up system. They have asserted that such a change is not warranted, if not inappropriate in its current form at the very least. These are summarised below and discussed in-depth in the following paragraphs:

- Certain wholesaler pharmacies have questioned the basis on which the recommendations to move to a regressive mark-up system has been reached. According to them, 80% of pharmaceutical products are prescribed by medical professionals and only 20% sold over the counter. Pharmacies are thus constrained by prescribing patterns and not the price of pharmaceutical products as such.
- The imposition of any pricing regulations that further reduces the operating margins will only accelerate the creation of new competition and social problems such as:
    - the closure of existing small retail pharmacies that may result in loss of jobs with no new entrants replacing them. This may also strengthen the position of vertically integrated pharmacies.
    - the reduction in capacity to cope with stock holding costs in relation to current stocks and expired medicines.
    - the decreased incentive to import essential products such as anti-cancer drugs or hospital-only injections that are fairly expensive.
    - a significant increase in malpractices including the sale of illicit or dangerous drugs affecting the overall viability of the sector.

4.118. Wholesale pharmacies have primarily submitted that with already a low maximum mark-up of 11% which is among the lowest in the world, they are finding it insufficient to support their costs of the operations which goes beyond the simple and unique scope of selling pharmaceuticals on a wholesale basis. Retail pharmacies, particularly the smaller ones operating along areas with low

[105] 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'.

foot traffic, have echoed similar grievances. They have submitted that with the proposed regressive mark-up system, it will be almost impossible to sustain business and the system will also act as a further barrier to entry for new players.

4.119. It has been submitted that a regressive mark-up regime could work if at the same time a higher mark-up percentage than the one currently in place, is allowed on lower-priced products. Otherwise, it would come as another mechanism of margin reduction for wholesalers who are already working on low margins. Taking the example of the maximum mark up of 15% (shared between the wholesaler and retailer) recently imposed on hand sanitizers, it was averred that this led to the situation whereby some market players stopped importing the products as it was not viable for the latter to work on such low margins for relatively cheap products.

4.120. Another model proposed instead of the regressive mark-up system is the differential pricing mechanism, which according to the submission involved setting of different price ceilings for product categories in terms of nature of the drugs and their clinical importance among other things. Nevertheless, it has been highlighted that the application of the regressive mark-ups or differential pricing to pharmaceutical products would not be efficient if the sources of possible fraud such as over invoicing are not identified and tackled.

4.121. These instances of fraud have been averred to be whereby the medicine prices are manipulated through allegedly over-invoicing to inflate the landed costs on which mark-up is applied. As such, prices of medicines in Mauritius do not consequently reflect the real prices. The way in which this malpractice is carried out, according to certain stakeholders is that:

- A wholesaler pharmacy purchases a given quantity of pharmaceutical products from a manufacturer. The latter invoices the wholesale pharmacy on a lower quantity than actually purchased but at an inflated price. The regulated mark-up is then applied on the inflated base price. To compensate the wholesaler for the extra money disbursed due to the inflated price, the manufacturers send an extra quantity of pharmaceutical products in the form of free samples.
- The samples are actually sold by the wholesale pharmacy in the same manner as the actual pharmaceutical products purchased. Thus, such malpractice enables wholesale to generate higher profit margin at the expense of users paying higher price for pharmaceutical products.

4.122. Another instance concerns Indian products whereby these drugs are bought from wholesalers rather than from the original manufacturers. That would allegedly explain why certain generic drugs are so expensive in Mauritius when they should have provided a cheaper alternative.

4.123. The Executive Director wishes to highlight that the practice of over-invoicing or inflating landing costs may be an offence under Section 31 of the Consumer Protection (Price and Supplies Control) Act 1998. Consequently, as these are alleged offences that falls outside the ambit of the Competition Act 2007, the Executive Director encourages any individual or entity aggrieved by such practices or holding information to this effect to contact the Ministry of Commerce and Consumer Protection or any other relevant regulatory authorities in order to initiate proceedings in relation to such practices.

4.124. During the consultative process, certain stakeholders have proposed certain mechanisms to the curb the allegedly prevalent practice of over-invoicing as well as setting up regulatory bodies to come up with a fairer pricing system. These submissions are reproduced below:

- The now abolished Custom Duty of 5% had the effect of curbing the practice of over-invoicing, since a higher margin brought about a higher tax.
- Prices of generics should be calculated on the basis of ex-factory prices in the country of origin, which should reflect the actual maximum selling prices in that country.
- To address the issue of pricing on a more systematic level, a permanent "National Pharmaceutical Pricing Council" should be set up to assess the viability of the pricing system as well as continuously monitor and fix the prices of certain medicines while liberalising others where competition exist.
- A National Formulary could provide the best value of pharmaceutical products for chronic conditions such as diabetes and blood pressure where medicines will be used for a very long period of time.

4.125. It is proposed that a more in-depth study should be carried out in consultation with wholesalers and retailers of pharmaceutical products for using the regressive mark-up system to lower the costs of the products (as being promoted by the WHO). The Executive Director concurs with such an assertion and considers that implications of proposed changes made in the Report ought to be analysed before any implementation and such an intricate and technical analysis can only be carried out effectively to a large extent by competent experts, professionals, policy makers and regulatory authorities in this field. It should, nonetheless, be understood that competition and the ensuing tussle from the natural laws of the market will bring about the competitive foreclosure of market operators who cannot overcome and adapt to changing market conditions.

b) Fluctuations in exchange rate

4.126. Given our heavy reliance on importation for the supply of pharmaceutical products in Mauritius, fluctuations in exchange rate greatly influence prices of the products. 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, exchange rates are volatile in nature and their effects on prices tends to cancel out over time.

4.127. However, what has been observed, is that the Mauritian rupee has consistently been depreciating over time against the major currencies. 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 CIF value of pharmaceutical products only fuels the higher cost burden borne by final consumers who pay a proportionately higher price.

4.128. It was highlighted, during the consultation process, that prices of pharmaceutical products are set on the basis of the MNS (the Mauritius Network Services TradeNet Portal) rate of the week. This rate is calculated by averaging of the exchange rates of five primary commercial banks for the preceding week. During high fluctuations in exchange rate, there is a big discrepancy between the actual and the MNS rate. While this may cause at time a decrease in the profit margin of wholesalers, they can also benefit from such fluctuations.

4.129. A mechanism to stabilise the effect of exchange volatility rate in the short and medium terms has been proposed by the Pharmaceutical Association of Mauritius in the form a refund scheme to complement the two regimes set up by the Consumer Protection (Consumer Goods) (Maximum Mark-Up) Regulations 1998 for the purpose of determining the cost price of a pharmaceutical

product. This refund scheme would, in essence, compensate wholesale pharmacies for any significant appreciation in exchange rate to avoid their impact in terms of increase in prices of life-saving or other critical drugs based on national consumption level. Other forms of a similar concept put forth were Forex Stabilisation Scheme for the major currencies and Freight Rebate Scheme for Imports of Pharmaceuticals and allied products.

4.130. While the Competition Commission may be able to assess the viability of such propositions to a certain extent, the Executive Director believes that such an intricate and technical analysis can be carried out effectively to a large extent by competent professionals, policy makers and regulatory authorities in this field. Nonetheless, the Executive Director is opened to collaborate in conducting such analysis from the perspective of competition law.

c) Parallel imports

4.131. 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.[106] 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.

4.132. 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 tablets which he sold at Rs75. The plaintiff - Grays Inc. Ltd. had, for its part, been selling the said product at Rs137.50'[107].

4.133. 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 goods 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 it can be detrimental to consumer interest in the long run.

4.134. Parallel import may thus, in the right circumstances and institutional set-up, act as a complementary price control strategy aimed at bringing a reduction in the prices of branded pharmaceutical products. 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 can ultimately lead to more competitive prices.

4.135. The intellectual property rights regulatory regime is a topic which has been of common interest across the different stakeholders in regard to the analysis put forth and any sort of amendments to the law to allow for parallel imports of pharmaceutical products. While consumer protection organisations have shown enthusiasm, other stakeholders have identified certain issues. These

[106] The Ministry of Foreign Affairs, Regional Integration and International Trade has indicated that it is aware of the issues related to the national exhaustion regime. It has intimated that it is temporary and will require amendment in due course upon an in-depth assessment of its implications.

[107] 2012 SCJ 494, pg. 8.

submissions are summarised below and discussed in further details in the subsequent paragraphs:

- IP rights are excluded from the ambit of the Competition Act 2007 and the market study is thus not the right forum to discuss such matters.)
- The new Industrial Property Act 2019 which is awaiting to be promulgated also favours the National Exhaustion Regime requiring for the consent of the right holder, thereby indicating the intent of the legislator for such a framework.
- In any case, five main risks that may crop up concerning a shift of exhaustion regime, namely

  (i) health and safety risks in relation to the supply chain,

  (ii) liability issues ensuing from such health and safety risks,

  (iii)increased risk of counterfeits products on the market,

  (iv) money laundering risks, and

  (v) increased unfair competition risks.
- There is a firm request that a thorough assessment to evaluate the impact of the proposal to move from the national to international IP exhaustion regime.
- A comprehensive and systematic consultation with stakeholders should be privileged to mitigate risks before implementing parallel imports.

4.136. As pointed out, there is in fact an exclusion as per section 2 of Part A of the Schedule of the Competition Act 2007 which stipulates that "[a]ny agreement insofar as it contains provisions relating to the use, licence, or assignment of rights under or existing by virtue of laws relating to copyright, industrial design, patents, trademarks or service marks" is regarded as being excluded from the ambit of the Act.

4.137. That being said, this does not constitute a blanket exclusion and careful interpretation must be given to such a provision in the context of the present market study. As mentioned at paragraphs 4.4 and 4.5 of Guidelines CC7 – General Provisions, "[t]he Competition Commission regards these exclusions as applying to the restrictive practices listed in Part III of the Act. In case of uncertainty about whether an agreement, practice, or product fall within the exempted list or not, the Competition Commission may carry out an investigation under Part IV, using the powers specified in the Act, but will set out in its final report why it believes the matter is not excluded, if it takes action. The Competition Commission will interpret exclusions as narrowly as possible within the scope of the Act. In particular, it will not regard broad areas of activity that include some of the excluded matters as being outside its scope."

4.138. Consequently, it can be observed that the aforementioned exclusion is in relation to the conduct of investigations into restrictive business practices within the meaning pf the Act. In the present instance, the interplay of intellectual property ("IP") rights within the pharmaceutical industry is being analysed in the context of a market study, which has the aim understanding and publicising the effectiveness of competition in individual sectors of the economy in Mauritius. This is at the opposite end of the spectrum compared to an investigation conducted under section 51 of the Act.

4.139. In any case, as highlighted by paragraph 5.6 and 5.7 of Guidelines CC7 – General Provisions, "[i]n line with international best practice, the Competition Commission takes the attitude that

exploitation of IPRs by the holder to maximize the value of that intellectual property, will not be regarded as a restrictive practice. Thus, for example, an inventor with a patent is free to price it at whatever level he chooses, to assign exclusive rights, to prevent resale at prices below a specified price and so on. However, also in line with international best practice the Competition Commission does not interpret the IPR exemption to imply that any anticompetitive action or agreement is permitted if it involves IPR."

4.140. Consequently, the inclusion of the analysis of IP rights and its effects on the effectiveness of competition within the pharmaceutical sector is legitimate and in line with the provisions of the Competition Act 2007.

4.141. Regarding the various risk identified by several stakeholders, they asserted that there is a certain basis for the existing legislation on IPR, the PIDTA, to provide for the protection of the right holder against the various risks associated with parallel import as the consent of the right holder must be sought prior to importing, exporting, or dealing with such goods.

4.142. As a matter of fact, according to them, the supply chain of pharmaceutical products is presently closely monitored by the right holder given that these sensitive products that must be transported and stored under specific conditions relating to the cold chain. Any diversion from this chain may render the product ineffective or risky for consumers. It is submitted that Mauritius is in the climatic zone IV A. Importing some brands from wholesalers overseas do not necessarily guarantee stability of products under this climatic zone and could represent a potential risk to patients in case of non-adherence.

4.143. If importation of pharmaceutical product were to be sourced from entities other than the manufacturer, the same condition regarding the supply chain ought to be respected to avoid any health hand safety risks.

4.144. In this sense, traceability, liability, and quality of product are very important factors contributing to the reduction of health and safety risk. The manufacturer will accept no liability in case of any issue arising from the product as they did not authorize its export. There will also be no control on the distribution of goods across different markets and it may affect businesses in their commercial strategy, brand reputation and equity. Products may not comply with the specifications of the registered products[108] as it is not procured form the wholesaler but from wholesalers/agents abroad.

4.145. Another concern raised is the verification of the authenticity of the pharmaceutical products i.e., ability to identify the which products are counterfeit or not. With limited tools available in Mauritius, it will be difficult to ascertain whether the products are genuine or not and even if they are genuine.

4.146. It is also averred that the perception that the introduction of international exhaustion of intellectual property rights for trademarks will lead to lower price is in contradiction to numerous studies. It could in fact lead to an adverse effect on prices and supply of products on the market. There is a strong possibility that a number of international brands may no longer directly supply to Mauritius, particularly in the case of so-called 'orphan drugs' which are pharmaceutical products that are not developed by the pharmaceutical industry for economic reasons, but which respond to public health need.

[108] One of the instances put forth is that the packaging and labelling of some pharmaceutical products may be done in the language of the exporting country and not in English or French as it would be suited for the Mauritian market.

4.147. Another point raised against the international exhaustion of rights is that it may cause inefficiencies on the market and a 'free-rider' situation for parallel importers. Free-riders would benefit from a brand image and marketing built over a number of years by existing IP owners through massive investment of funds. It may also exacerbate the issues of over-invoicing, particularly in the case that such a practice is not acceptable to the original manufacturers but intermediates and wholesalers may indulge in that malpractice readily.

4.148. The following factors have been proposed to be considered when allowing the parallel imports of duly registered pharmaceutical products:

i. The registration of the brands and submission of the documents in CTD (Common Technical Document) format and payment for the mandatory fees as per the Pharmaceutical Products (fees) Regulation 2016.

ii. The issuing, at registration, of a “Free sale Certificate” of the product in the Country of Origin, i.e., a Document certifying that the same product is equally on sale in the country where it is being manufactured.

iii. The submission of certification from the wholesale/agent from abroad that that can export the products (issued by the drug regulatory authority of their country of origin/Manufacturer) and that they adhere to GDP/GSP practices.

iv. The guarantee of the traceability and liability of the pharmaceutical products.

v. The Stability/Climatic Zones and ensure that tests are done and the products are stable under these conditions.

vi. Pharmacovigilance/Product recalls

vii. Investment in creating awareness of the products to ensure that the new products are brought in the market so that Mauritius can benefit from innovative products.

viii. Heavy investment by importer/distributor in their storage and distribution capabilities as per WHO GDP/GSP norms to ensure that the final product is delivered under the same optimal conditions as that received from manufacturer.

ix. Significant investment by accredited importers/distributors to invest significantly in process efficiency initiatives, quality management systems and regulatory compliance framework to satisfy the stringent exigencies and norms applicable to operators within the pharmaceutical sector.

4.149. The Executive Director reiterates that the proposition made in this report regarding parallel import concern only the importation of a pharmaceutical product produced genuinely under the protection of a trademark, patent, or copyright from another market other than the set distribution channel between the manufacturer and its local representative in Mauritius. In no way should this proposition be construed to included counterfeit products.

4.150. The Executive Director concurs with the proposition thorough assessment to evaluate its impact must be carried out and believes that such an intricate and technical analysis can be carried out effectively to a large extent by competent experts, professionals, policy makers and regulatory authorities in this field. Nonetheless, the Executive Director is opened to collaborate in conducting such analysis from the perspective of competition law.

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 of 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 affect 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. Given that Mauritius relies essentially on imports, prices of pharmaceutical products are 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[109].

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[110]. 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[111]. 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[112]. The WHO Guideline[113] 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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[109] 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).

[110] 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.

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

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

[113] 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. Such a measure could, within the right legal framework and institutional set-up, contribute towards achieving affordability of pharmaceutical products in Mauritius while having regard to commercial viability of operators in this sector.

5.16. It is therefore important that regulation of chain mark-ups be 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 other than the set distribution channel between the manufacturer and its local representative 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. That being said, it is equally important that the right institutional set-up and legal framework is devised to minimise certain risks, in terms of safety, quality and traceability, associated with such a practice.

5.21. It is thus proposed that an evaluation of reviewing the current legal framework, to allow for the parallel import of pharmaceutical products, be undertaken as consumers can only stand to gain in the long run in terms of ensuring competitive prices and authenticity altogether.

Annex A: Written submissions from stakeholders with consent for publication of views

ANNEX I: CONSUMER ADVOCACY PLATFORM

CONSUMER ADVOCACY PLATFORM

Comments on the Competition Commission's Report on the Pharmaceutical Industry in Mauritius

Introductory remarks

It is a known fact that the Pharma Industry has a deep culture of corruption. This is what Dinesh Thakur, famous whistleblower on the Ranbaxy's compromises with quality, in India, stated in 2016.

The Pharmaceutical industry is not about health care, it is about business at all costs. We experienced this during the Covid crisis. Hence we should not deal with the industry with compassion, despite the recognized role of pharmacists as Health professionals.

Intellectual Property Rights

The current international exhaustion regime imposes restriction on parallel imports, and hence limits competition. This could lead to dual pricing to the detriment of customers. This statement of the Competition Commission confirms what the Consumer Advocacy Platform (CAP) has since long denounced.

Furthermore, in paragraph 3.37, the Competition Commission explains the procedures adopted by the MRA customs to identify goods suspected of infringing IP rights for which an application for customs action has been filed. Customs leave it to right holders to identify whether a product is genuine or not. This is a clear illustration of how trade mark holders are allowed to act as judge and party.

Restriction on parallel import, as stated by the Commission, reduces intra-brand competition and forecloses potential competitors from the market. Trademark registration of pharmaceutical brands in relation to import is the most prominent form of IP protection .

According to our sources, the Pharmacy Board, whose members can be judge and party at the same time, often rely on the Intellectual Property Act, to support controversial decisions on the acces of medicines to the market. It needs to be recalled that, since the implementation of the Fair Trading Act, there is no such thing as sole representative, unless the manufacturer decides to deal exclusively with its appointed agent. In the medicine sector, as in the case of many other goods, trade-marked items can be available at much lower prices through large conglomerates purchasing in bulk. They, in turn, sell the same trade-marked goods at lower prices. This is how parallel importers have been able to offer for sale trade-marked medicines cheaper, alongside generic medicines, also known to be cheap.

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CONSUMER ADVOCACY PLATFORM

The Pharmacy Board, has, in the past, erred, according to CAP, in justifying its decision to allow or ban the import of products from parallel import because of the presence of such medicines on the Intellectual Property Rights (IPR) list of the Mauritius Revenue Authority (MRA). According to informed sources, the presence of goods on this list does not imply that the patent holder can be the exclusive importer. This would be in contradiction with the Fair Trading Act. According to an MRA source, the import of patented goods by importers other than the patent holder only enables the latter to check whether these goods are fake or not. If they are found to be authentic, the customs would have no other choice than to allow delivery of the goods.

CAP avers that the adoption of the international exhaustion regime restricts consumers' choice and is an obstacle to consumers' access to cheaper pharmaceutical products. While Government is still waiting for the report of consultant Anna Maria Pacon, on the exhaustion regime to be followed, CAP avers that Government should adopt the international regime for the import of pharmaceutical products, hence enabling parallel import.

Prices of medicines

In addition to the impact of the international exhaustion regime of the prices of medicines, it is important to underline that medicines prices, are often decided on the basis of the GDP of the import country. This was revealed by a survey conducted in the 90s by Health Action International. CAP avers that prices of medicines sold to Mauritius do not reflect the real prices at production level.

CAP also supports the Commission's views that the current price model may incentivize wholesalers and retailers to stock higher -priced drugs, eventually favouring more expensive options over cheaper alternatives to the detriment of users of pharmaceutical products. Hence, the higher the cost price of medicines the higher is the quantum of mark-up and consequently price of medicines to buyers.

CAP is in favour of a regressive mark-up system, as recommended by the Competition Commission, in line with WHO recommendations. We also agree with the need for generic medicines to be promoted through a mix of policies and strategies

Doctors' prescription behaviour

As underlined by the Commission's report, in most cases, it is the doctors who decide on the choice of medicines rather than the users themselves. Doctors tend to give higher weight to product attributes rather than price.

It is also common practice for wholesale distributors to employ representatives to to discuss product claims and clinical evidence with physicians and provide them with samples. Such

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practice may have an influence on the doctor's choice while prescribing medicines. In some cases, such practice may be tantamount to corruption.

CAP avers that the activities of medical representatives need to be regulated, as is the case in many European countries. In France, for example, the involvement of laboratories in the information of doctors, or their continuous training, is subject to a Code of Ethics

Mosadeq Sahebdin,

President,

CAP

12.10.2020

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ANNEX II: CONSUMER EYE ASSOCIATION

Consumer's Eye Association views and comments on the Market Study on the Pharmaceutical Industry in Mauritius MS/004

Consumer's Eye Association (CEA) welcomes this study which did not demonstrate issues about competition in the pharmaceutical sector. There was not an in-depth assessment of the various individual market and the Competition Commission (CCM) based its conclusion that the pharmacy market "tends to show competition in terms of the increasing number of players in the market." (page 32: 4.21). Clearly a more in-depth study is required.

The CCM based this conclusion on the fact that the WHO recommends a ratio of one pharmacy per 5000 inhabitants. As the pharmacy to population ratio is 1:3500 in Mauritius it is assumed that competition exists and therefore that there is no price differentiation between areas, although that has not been demonstrated in the report. Table 11 page 33 clearly demonstrates that 3 regions Black River, Pamplemousses and Savanne do not meet the WHO recommendations. Also, it shows that Port Louis, Plaines-Wilhems and Rivière du Rempart have higher concentrations of pharmacies with Port Louis showing a pharmacy population concentration of 1:1885. Hence it demonstrates fluctuation in the alledged competition. In the immediacy of medication's need the consumer will not bargain for prices or travel to another region and will pay the price quoted.

The report however clearly demonstrates that there is a lack of transparency, accountability all round in the pharmacy industry. Owners of Wholesale pharmacies with additional retail pharmacies should not sit on the Pharmacy Board and influence policies given that some could be importing unique products and therefore could bar others from parallel importations of similar products. CEA supports the CCM in its recommendation to amend the law to allow for parallel import of pharmaceutical products for the benefit of consumers with better prices and for greater transparency and accountability.

The membership of pharmacists who may be wholesale pharmacy business sitting on the Pharmacy Board and its Trade and Therapeutic committee is unhealthy and one that consumers mistrust. Added to the fact that the guidelines of the Pharmacy Board for registering therapeutic products are not publicly available could lead to abuse, corruptible practices and increased prices. The report clearly makes allusion to how these pharmacists may dictate on products registered and commercialised for their benefit and in quasi monopolising the market on certain products. There needs to be a more transparent and accountable process in appointing to the Pharmacy Board. CEA welcomes the CCM's recommendation for the "facilitation of access in relation to Pharmacy Board's registration process, criteria and applicable standards".

CEA is concerned on the custom of the pharmacy industry to apply the maximum 35% mark-up recommended as the basic mark-up for all pharmaceutical products regardless of the basic cost. The WHO recommendation for a regressive Mark-up system is not practiced in Mauritius. This is blatant profiteering by pharmacists. Take for example somebody with degenerative macular disorder who will eventually go blind if they do not receive intravitreal injection of appropriate pharmaceutical preparations which are extremely expensive Rs 13,000- 19,000 per injection. Patients on average receive up to 2 injections monthly for 5-6 months and reviewed 3 months later which may result in more treatment and so on for the rest of their lives. With the current system and the depreciating rupee the patient is unfairly treated and may discontinue treatment because of the price. A more regressive price policy would have taken into consideration the cost of the product and its psychological, physical and social

purpose in terms of necessity. The sick in the current system is punished for being sick with impunity with a system biased towards the greedy importers and pharmacists. CEA would have welcomed the recommendation of a regressive pricing system by the CCM instead of the organisation fudging the issue.

The report gives rise to some alarming data in that private patients bear the maximum cost of the health care expenditure 60%. They also spend 80% (RS 4 billion) on pharmaceutical products and the government Rs 1 billion. Given that 70% of the population receive their care and medication free of charge from the government health care system it is disorientating to find that the government orders only 4% and wholesale pharmacies 94.1% of the pharmaceutical products. This reinforces the fact that wholesale pharmacists' membership on the Pharmacy Board is a worrying factor that needs addressing promptly for the reasons already given. Also, there is a further issue that requires investigating in terms of the prescription culture in the private sector. This clearly is something that the Ministry of Health needs to address. CEA will definitely raise this issue with the Minister of Health when he replies to CEA's request for a meeting.

This report is highly recommended as it sheds light on an industry which impacts on the lives of every Mauritians Citizen.

Dr. E. Hugues Gregoire

President Consumer's Eye Association.

COMMENTS ON THE REPORT ON THE MARKET STUDY OF PHARMACEUTICAL INDUSTRY IN MAURITIUS (MS/004)

1.0 Introduction

I am Dr Bhimsen Abacousnac, Pharmaceutical Technologist, having completed a B.Tech from the Institute of Chemical Technology (ICT), Bombay and a PHD from Leeds University. I have always been a close observer of the Pharmaceutical Industry, both in Mauritius and around the world, particularly concerning new developments. I am retired now but still active as a lecturer and as a local and international consultant with the United Nations. Here, I will add that it is only this industry that can provide a permanent solution to the COVID-19 crisis. Let us all hope that a vaccine is found quickly.

Coming back to the report. It is an informative report and does provide a good picture of the local Pharmaceutical market. Talking of the "Pharmaceutical Industry in Mauritius" is a bit farfetched when we just have one firm manufacturing pharmaceutical products in the country. All the players mentioned in the report are distributors and hence it should be market instead of industry. One day when we have several firms operating in the pharmaceutical sector then we can refer to it as an industry. Not now at least.
Here are my other comments.

2.0 Members of the Regulatory Body

It is good that the fact was pointed that members of wholesale pharmacies having been members of the Pharmacy Board. This is a definite instance of conflict of interest, which the appointing Body, the Ministry of Health and Wellness, should have been aware of. It is unfortunate in Mauritius that we are always wise after the event. It normally takes at least six months to approve the registration of a new product in Mauritius, even if this product is already approved by an internationally recognised agency, such as, the Food and Drug Administration (USA). It can even take up to two years for certain products. More light should be shed on the registration of products of members of the Board to show the extent of any conflict of interest. A Government Agency, such as the Competition Commission can easily obtain this information. How many products have been approved for the last five years by the Pharmacy Board and who submitted the application for registration. This information can be included in a future report.

3.0 Pricing of Pharmaceutical Products

The price of medicine is controlled in Mauritius, since the Government fixes the mark-up. There was a commission of enquiry on pharmaceutical products some years back whereby views of all stakeholders were sought. One of the recommendations was to fix the mark-up for pharmaceutical products. Initially the mark-ups were fixed at 17% for wholesalers and 30 % for retail pharmacies and a special allowance of 5% was given to cover import costs. Currently the mark-ups are 11% for wholesalers and 21.6% for retailers whereas the special allowance has been reduced to 2%. Here it must be noted that some products are sold in India for Rs 50 Indian rupees and same is offered at Rs 100 in Mauritius.

The reliability of the product is important. A Salbutamol inhaler should dispense exactly 100 micro grams at one puff and a patient should receive 200 micro grams in two puffs. This is sold at Rs 89.49, retail. The amount received is crucial. It is life-saving. Can one afford to buy a cheaper product at the expense of its potency and reliability? Doctors will tell you of course "No". Asthma patients can confirm.

As an indication the price of some products in UK and Mauritius are compared in the table below.

Product	Price in UK	Same price in MRU	Price in Mauritius
Avamys Nasal Spray	£6.44	Rs 328	Rs 237.87
Seretide 50/100 Accuhaler	£18.00	Rs 918	Rs 334.00
Seretide 50/250 Accuhaler	£35.00	Rs 1785	Rs 583.35
Zinnat 250 mg x 10 tablets	£17.72	Rs 903	Rs 254.61
Ventolin Inhaler x 200 doses	£1.50	Rs 76.50	Rs 89.49
Betnovate Ointment 15 gm	£1.88	Rs 95.88	Rs 83.21
Betaloc 50 mg tablet x 30	£7.80	Rs 397.80	Rs 476.27
Betaloc 100 mg tablet x 30	£8.08	Rs 412	Rs 555.28
Crestor 5 mg x 28 tablet	£18.03	Rs 919.53	Rs 977.02
Crestor 20 mg x 28 tablet	£26.02	Rs 1327.02	Rs1381.20
Avomine x 10 tablet	£3.13	Rs 159.63	Rs 53.00

From the above table, it can be concluded that there is not much difference between the price of products in the two countries. We have to ensure that our patients get the best in terms of quality of products. Doctors use high tech equipment to enable them to carry out a perfect diagnosis. They also want the best medicine to administer to their patients. Quality has a price.

4.0 Control mechanism for pharmaceutical products V/S Parallel Import

It is important to know that before a product is marketed it goes through a whole process. The product is tested on rats, guinea pigs, monkeys and finally clinical testing is carried out on humans. If at any stage toxicity or presence of adverse reaction is found with the product, the test is discontinued and the product is discarded. Research and Development is extremely Costly. This is why new products are rare. Glaxo, Smithkline Beecham and Wellcome were three different companies and they merged in order to be able to compete. It takes years before a product is approved by a recognised body, such as the Food and Drug Administration (FDA).

If a product is imported directly from the Laboratory (manufacturer) the quality of the product is ensured. The control mechanism is well established. The product comes with a data logger.

From the time it leaves the factory till it reaches the wholesaler in Mauritius, the temperature is monitored. When the wholesaler collects the product in case there has been a deviation in the temperature beyond the acceptable range there will be a temperature alert into the red zone. On reaching the office the pharmacist can just plug in the data logger on a PC. He can obtain a print out of the graph of the temperature throughout the journey. It is a control chart. Any deviation can be immediately detected, the product is immediately kept in quarantine, the Laboratory contacted and the print out sent. Instructions are obtained from the Laboratory to destroy or sell the product. Then an investigation is undertaken to find out the root cause of the problem.

With the liberalisation of the market and allowing parallel import it is doubtful whether this strict control can be exercised. What will happen if a temperature sensitive product had a temperature incursion into a forbidden zone and the medicine is administered to a patient? Who will be responsible? Traceability is important in the case of pharmaceutical products. It will be impossible to trace the source of the product and problem. What system will be there to ensure the safety of patients?

Another issue is concerning Pharmaco Vigilance or Adverse Event. All well-known Laboratories require that wholesalers have a well-established process in place for addressing Adverse Events. Laboratories audit the system in place for storage and delivery of their products by wholesalers. They have to take corrective and preventive actions (CAPA) in case of any non-conformity. They are very strict. The pharmaceutical market is one of the very few where the power of Laboratories (suppliers) is higher than that of Customers (wholesalers). Will the control be there in the instance that there is parallel import? That's the question!

5.0 Manufacture of Pharmaceutical Products locally

In successive budgets Finance Ministers have announced that a Pharmaceutical Industry will be set up in Mauritius. However, it never materialised. There are many reasons why this is so. First of all the Pharmaceutical Industry is highly sophisticated. I was given the first choice to choose my field of specialisation, being the University Topper at BSc. You need to have a BSc to go for Chemical Technology. I chose Pharmaceutical Technology because it is highly sophisticated and with the aim of working overseas, because it is very much in demand there. The Pharmacy Act requires that someone should be a Pharmacist in order to be responsible for production of Pharmaceutical Products in Mauritius. This is an aberration. You need a soap technologist to work in a soap making factory, a textile technologist in a textile factory, food technologist in a food manufacturing company but not a pharmaceutical technologist in a pharmaceutical company. Mauritius is a country of paradox after all.

There has been Mauritius Pharmaceutical Manufacturing Ltd of Sir Kailash Ramdenee. With the change of Government it started facing problems due to lack of Government contracts and it closed down finally. Some years later Mascareign Pharmaceuticals Ltd started operation on the same site. I audited the organisation and found major non-conformities. They had to take corrective actions. There was an Indian in charge of production. Soon a batch of Paracetamol was found to be contaminated with fungus and it was given a prohibition order. It never recovered and it closed down.

Good Manufacturing Practice (GMP) is essential in the industry and standards have always existed. Concessions cannot be made. Will the internal control system be stringent enough? Will the enforcement body be able to enforce? Mauritius has beautiful laws but there is always a problem of enforcement. When people do not even care about the health of the population when it comes to business, can we ensure the quality of pharmaceutical products? Some years back Innodis Ltd was verbalised for changing the package of frozen meat. What happened after that? Today, food inspectors have confiscated frozen food at a factory or cold room in Pailles. Expired food was being repacked. It is a culture in Mauritius. Profit first. Control of the manufacture of pharmaceutical products should be very strict by the Authorities. Wonder if they can do it?

What about approval? Imported products come with a full dossier. Still approval takes at least six months. I hear that there will be a fast track for the approval of locally manufactured products. What guarantee will the consumer has?

6.0 Conclusion

Mauritians are very much concerned about two things: the education of their children and the health of their family. A study by Jawaheer and Kassean (2009) from UOM, revealed that more and more Mauritians are shifting to the private sector for healthcare in spite of the fact that they do not have medical insurance policies. They even take loans so that they can get a better service. They want to get a product which works, irrespective of its price.

The potency of the medicine is important. As an example some years back there was "dolex" - an anti-pyretic and analgesic, manufactured locally. I gave my child 5 ml and the temperature never fell. Then I bought the imported "Panadol" and I gave him 5 ml and within minutes his temperature fell. I do wonder about the potency of the local product. One month back a pharmacy offered me an eye drops for Rs 25. An eye drop is produced under sterile conditions. How can it be Rs 25? I refused to buy it. We all know the case of several patients claiming of having lost their eyesight after being administered eye drops at Moka Eye Hospital. Has the root cause of the problem been found? We cannot be wise after the event. Unfortunately, in Mauritius we often react. I always do a risk analysis before taking decisions. The risks are enormous. It is good that in the present case the opinion of the population is being sought. I have voiced out my opinion as a professional.

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Date: 30.09.2020

ANNEX IV: MAURITIUS CHAMBER OF COMMERCE AND INDUSTRY

MCCI
THE MAURITIUS CHAMBER OF COMMERCE AND INDUSTRY
170 YEARS

MCCI SUBMISSION

CCM MARKET STUDY INTO THE PHARMACEUTICAL SECTOR IN MAURITIUS

Following the market study undertaken by the Competition Commission Mauritius (CCM) on the Pharmaceutical sector, the MCCI would like to submit hereunder its comments following consultations with its Members operating in this sector.

1. Competition in the Pharmaceutical Sector

The MCCI takes note of the observations of the CCM in the market study regarding the fact that the pharmaceutical sector is already highly competitive with the number of wholesalers in Mauritius increasing by more than 65% over the last ten years. The CCM market study further states that there is, at this stage, no evidence of any market concentration at wholesale level and suggests that the only potential competition concerns could arise from the regulatory framework.

2. Current Regulatory Framework

Given the specificities of the pharmaceutical sector, the current regulatory framework for the import of pharmaceutical products in Mauritius has always been subject to strict policies and regulations defined by the Ministry of Health and Wellness and the Pharmacy Board with the primary objective of ensuring that the health and safety of the public in general is guaranteed and safeguarded.

The current regulatory framework has always ensured that all importers of pharmaceutical products in Mauritius are subject to the following:

(i) Thorough registration and validation process before products are put on sale on the local market; and

(ii) Strict procedures regarding traceability of products from the manufacturer up to the final consumers with pre-defined protocols for rapid product recall in case of problems reported with specific products or batch numbers.

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Over the years, the local importers have always fully complied to the local regulations and they have endeavoured to:

(i) Build strong commercial relations with international suppliers to ensure regularity of supply of pharmaceutical products on the market at all times;

(ii) Guarantee the supply of safe and quality of the pharmaceutical products on the local market and to consumers;

(iii) Adhere to stringent compliance protocols and requirements of Good Distribution Practices throughout the supply chain to ensure that optimal storage/conservation conditions are applied for all pharmaceutical products;

(iv) Ensure that only products destined for our market in terms of climate conditions are imported so as to ensure pharmaceutical products dispensed to final consumers are safe; and

(v) Invest significant financial and human capital resources on a continuous basis to ensure that the above aspects are undertaken most efficiently.

3. Pharmacy Board

The report highlights a number of areas of concern regarding the Pharmacy Board on the possibility of conflict of interest on the Board and the lack of transparency in procedures for approval of pharmaceutical products.

The MCCI would like to make the following proposals in order to address the concerns raised:

a. Board Procedures

According to The Pharmacy Act 1983, the Board shall be comprised as follows:

There is established for the purposes of this Act a Pharmacy Board which shall consist of –

(a) the Chief Medical Officer, Chairman;

(b) the Chief Government Pharmacist;

(c) 5 pharmacists appointed by the Minister;

(d) a law officer designated by the Attorney-General.

It is common practice and recommended that professionals in the sector be appointed on the Board given that they have the required expertise in the matter.

In order to address the concerns raised by the CCM, it is proposed that the Pharmacy Board considers the adoption of the following best practices:

- 'Board Charter' which would include obligations for members of the Pharmacy Board to disclose any 'Conflict of Interest' or 'Related Party Transaction' and abstain from the decision-making process where they are conflicted or related.

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- 'Board Governance' procedures with the necessary structures to ensure adherence to the National Code of Good Governance

- 'Board Evaluation' that would ensure the effectiveness, transparency and accountability of members of the Pharmacy Board with regard to board governance.

b. Registration of pharmaceutical products

The CCM market study also highlights the lack of clearly defined procedures and guidance on the registration of pharmaceutical products.

The MCCI would like to make the following proposals to address the concerns raised:

(i) The publication of official guidelines by the Ministry of Health and Wellness for registration of pharmaceutical products with clear timelines for approval of requests.

(ii) The publication of the list of pharmaceutical products registered in Mauritius.

(iii) Acknowledgement of receipt of registration dossiers and updates on status of application.

(iv) Fast-tracking the online registration process of pharmaceutical products to ensure transparency in the application process and allow importers to monitor the status of their application. It is also important that the reasons for rejection of applications be given to importers and that there is a right of appeal so as to ensure transparency in the process.

4. Pricing Policy

The CCM market study mentions that the local prices are higher when benchmarked against 'International Reference Pricing'. The CCM also suggests a review of the maximum mark-up system.

The MCCI would like to bring forward the following elements:

a. In its market study, the CCM uses as benchmark the 'International Reference Pricing' which refers to the 'recent procurement prices by for-profit and not-for-profit suppliers to international not-for-profit agencies for generic products' (paragraph 4.88)

b. The reference price used by the CCM is a price applicable for the sale of pharmaceutical products to 'non-for-profit agencies' and therefore cannot be used as benchmark for the sale of pharmaceutical products in normal commercial operations. There will be a disparity as the pricing methods applied are fundamentally different in both cases.

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c. Given the large number of importers and wholesalers in Mauritius, there is a wide range of pharmaceutical products and generic alternatives available on the market from different suppliers, country of origin and with different price ranges. The prescriber has the liberty to choose the product most affordable to his patient in the case of prescription drugs and likewise the consumer has the possibility to choose the most affordable quality product in consultation with his healthcare practitioner.

d. There are also a number of external factors to be taken into consideration such as costs of freight and fluctuations in exchange rates that have to be included in the price computation and that have a direct impact on prices in the local market.

e. Importers and wholesalers have highlighted that the maximum mark-up being applied for wholesalers (11%) in Mauritius is among the lowest in the world. It has to be noted the definition of wholesale mark up as defined in other countries is the mark up applicable to an entity whose only function is to wholesale products to retail clients. In Mauritius, the wholesaler has a much wider role being involved in the import, distribution and wholesaling of pharmaceutical products. In addition, they are involved in creating awareness/ marketing/ brand building and have a regulatory function (registration of products/ renewal and variations management/ pharmacovigilance, etc.). Considering all these functions, they are maintaining their operations even with a restrictive mark up to bring added value to the life of Mauritian patients.

f. Moreover, it has been amply demonstrated in the past that price control and reduced margins have had a contrary effect by significantly reducing competition and acting as a barrier to entry for new players in the market.

5. 'Intellectual Property Rights' Legislation

The MCCI would like to highlight the following elements with regard to the proposals made in the CCM market study on amendments to the current Intellectual Property Rights Legislation:

- The report only considers the price aspect of parallel imports and it is essential that other critical factors be taken into consideration since the treatment of patients and the quality, safety and efficacy of medication cannot be compromised.

- The report also mentions that genuine sources of supply, therapeutic equivalence and authenticity are critical elements in evaluating the matter of parallel imports of pharmaceutical products in Mauritius.

For the MCCI, it is therefore crucial that a proper assessment be conducted to evaluate the impact of the proposal to move from 'national' to 'international exhaustion of rights' so that an informed decision be taken given the impact, not only on the pharmaceutical sector, but on other industries and other sectors of the economy as well.

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Pharmaceutical products, unlike other commodities, relate to the health of the nation and hence the concept of quality and traceability is critical for optimal control and treatment of patients affected with different pathologies. Hence, the legal framework should ensure that the aspects of quality, criticality and traceability of products can be enforced.

The following points need to be emphasized:

a. The perception that the introduction of international exhaustion of Intellectual Property Rights for trademarks will lead to lower prices, is in contradiction to numerous studies, which have shown that in the long run there will be no net real benefits accruing to consumers. On the contrary, as a small economy, this could lead to an adverse effect on prices and supply of products on the market.

b. There is a strong possibility that a number of international brands may no longer directly supply the Mauritian market given the small size of our local market. A number of existing exclusive right holders have indicated that their brand owners may drop the supply or distribution of goods in Mauritius. In case of such a situation arising, Mauritian patients may be deprived of innovator drugs, critical drugs and drugs for rare diseases (the 'so called orphan drugs') which will reflect negatively on the standard of healthcare in Mauritius in the long term.

c. International exhaustion of rights will cause inefficiencies on the market and a 'free rider' situation for parallel importers who would benefit from a brand image and marketing built over a number of years by existing IP owners through massive investment of funds. It is a fact that products subject to grey marketing are of high status with an established brand name, image and sales volumes. Slow-moving items are not targeted for parallel imports since they would not make quick profits.

d. With parallel imports, there will be no control on the distribution of goods across different markets and it will affect businesses in their commercial strategy, brand reputation and equity.

e. Parallel imports will further increase the risk of counterfeit products getting on Mauritian market, and thus threatening public safety.

f. Parallel imports may be labeled in foreign languages that are unknown to the local consumer.

g. Parallel importers do not procure the products from the manufacturer but from wholesalers / agents abroad. Though bearing the same name, parallel imported products, may not always comply with specifications of the registered product such as pack size, Country of Manufacture, Packaging and Labelling, etc. Such variations would normally be subject to notification to the Pharmacy Board as clearly explained above under section 2 by the

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approved distributor. This raises strong concern on quality control, supply chain and the lack of traceability. These are particularly critical for the pharmaceutical sector where consumer and patient safety is vital.

h. To allow parallel imports of duly registered pharmaceutical products in Mauritius, the following factors should be considered, bearing in mind the very nature of the products:

- The parallel importer should register the brands and should submit registration documents in CTD (Common Technical Document) format and pay the mandatory fees as per the Pharmaceutical Products(fees) Regulations 2016.

- The wholesaler/agent from abroad should submit certifications that they can export the products (issued by the drug regulatory authority of their country of origin/manufacturer) and that they adhere to GDP/ GSP practices.

- Traceability and liability should be guaranteed. If a patient suffers any adverse effects, the local parallel importer or the overseas wholesaler should be liable (the overseas wholesaler- for inherent defect in the product and the local importer- for defect due to improper storage/distribution) if proven to be the case. For manufacturers and their accredited distributors in Mauritius, these elements are already guaranteed.

- Stability/Climatic zones- Mauritius is in the climatic zone IV A and products which are sent by manufacturers ensure that tests are done, and products are stable under these conditions. Importing the same brands from wholesalers overseas do not necessarily guarantee stability of products under this climatic zone and could represent a potential risk to patients in case of non-adherence. Hence stability under the prevailing conditions in Mauritius would need to be shown.

- Pharmacovigilance/ Product recalls- The parallel importer would need to show adherence to these procedures as these are important elements in the pharmaceutical supply chain process to ensure the safety of patients.

- The manufacturer and their accredited local wholesaler/ distributor invest in creating awareness of the products to ensure that new products are brought in the market (after registration) so that Mauritius can benefit from innovative products. Furthermore, Healthcare Professionals are kept abreast in terms of continuous education programs and clinical studies so that they take cognizance of new protocols for treatment.

- Importer/ distributor also invests heavily in their storage and distribution capabilities as per WHO GDP/GSP norms to ensure that the final product is delivered under the same optimal conditions as that received from manufacturer. Manufacturers regularly audit premises of their accredited distributors to ensure adherence to these norms to ensure safety of patients.

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- Accredited importers/distributors also invest significantly in process efficiency initiatives, quality management systems and regulatory compliance framework to satisfy the stringent exigencies and norms applicable to operators within the pharmaceutical sector.

- Finally, parallel imports will not help the country in building a reputation of health hub from a global perspective.

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ANNEX V: MINISTRY OF FOREIGN AFFAIRS, REGIONAL INTEGRATION, AND INTERNATIONAL TRADE

MINISTRY OF FOREIGN AFFAIRS, REGIONAL INTEGRATION AND INTERNATIONAL TRADE

16 October 2020

Dear Sir,

Re: Consultation process for the Market Study of the Pharmaceutical Sector in Mauritius

Please refer to your letter dated 11 September 2020 regarding the above subject and find below the views of the Ministry thereon:

- It is observed that Section (c) of the Report dealing with IP falls directly under the purview of this Ministry.
- The Patents, Industrial Designs and Trademarks Act 2002 cater for a number of remedies to prevent abuse of the exclusive rights granted to patent owners. These remedies are incorporated in the following sections:

a)	Patentability Criteria	-	Section 12
b)	Exhaustion of rights (International)	-	Section 21
c)	Duration (no extension)	-	Section 22
d)	Exploitation by Government or person thereby authorized	-	Section 23
e)	Non-Voluntary Licence	-	Section 24

- The concept of national exhaustion has been maintained in both the existing Patent, Industrial Design and Trademark Act and the new Industrial Property Act which has yet to be proclaimed. The concept prohibits parallel imports of any genuine trademark labelled goods, unless authorization is obtained from the right holder in Mauritius, which applies equally for pharmaceutical products.

- The national exhaustion regime is temporary and will require amendment in due course. Given the perception that international exhaustion may lead to an increase in the imports of counterfeit goods, it has to be ensured that enforcement officers at the border are adequately trained to cope with such situation.

- The proposal made at paragraph 3.2 of the report for the Legislation to be amended to allow parallel import of pharmaceutical products, more consultations with relevant stakeholders are required.

- In parallel, the Competition Act should also be amended in particular part A (2) relating to agreements or products excluded from the scope of the Act. Intellectual Property Rights are excluded from the scope of the Competition Act which might give rise to an abuse of IP right holders to the detriment of the consumers.

...Contd/

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- Issues relating to transparency and conflict of interest should be addressed expeditiously. Furthermore, the pricing mechanism linked to the value of products, as well as registration fees may also have to be revisited to ensure principle of reasonableness.

Yours faithfully

D. Takoory (Mrs)
For Secretary for Foreign Affairs

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ANNEX VI: PHARMACEUTICAL ASSOCIATION OF MAURITIUS

Response to the Consultation Report - Market Study on the Pharmaceutical industry in Mauritius (MS/004)

29 October 2020

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29 October 2020

The Executive Director
The Competition Commission (the "Commission")
10th Floor, Hennessy Court
Pope Hennessy Street
Port Louis
Mauritius

To the kind attention of Mr. Deshmuk Kowlessur

Dear Sir,

Consultation Report – Market Study on the pharmaceutical industry in Mauritius (Reference: MS/004)

The Pharmaceutical Association of Mauritius ("PAM") values the opportunity to comment on the *Consultation Report - Market Study on the pharmaceutical industry in Mauritius (Reference: MS/004)* (the "Market Study") and appreciates the extension to the original deadline set out in the public consultation process.

As at date, PAM's membership comprises of pharmacists across the profession including wholesale, hospital, retail and academia. Given our broad representation across the supply chain, knowledge of the industry specifics and our unique proximity to the end drug user, PAM remains one of the most important stakeholder groups on critical issues relating to pricing, availability and affordability of drugs in Mauritius.

We have carefully reviewed the Market Study and whilst we agree with some of the recommendations made by the Commission, we are of a different opinion with the Commission's views on (a) the application of a regressive mark-up system and (b) the introduction of parallel imports as a mechanism to drive down prices of drugs. In addition, we wish to use this opportunity to draw the attention of the Commission on key competition issues which have been overlooked in the Market Study and which currently impact on the sustainability of the retail pharmacy model in Mauritius.

In our humble opinion, the Commission did not address several risks and critical points linked to the aforenamed items sufficiently in the Market Study. Through our submissions, we hope that the Commission would consider all the facts before issuing any recommendation or conclusions on the aforementioned subject matters which would undoubtedly have unintended negative consequences on the wholesale and retail segment of the pharmaceutical industry but more importantly on patients as a whole.

We set out in this document (the "Report") our viewpoints on the abovementioned points. Please note that we have appointed an independent consulting firm to assist us on all financial or economic analyses. Insofar as any opinion or observation expressed in this Report relate to financial or economic analyses, we have relied entirely on the independent consultant's report.

Further to the study carried out by the consulting firm, we wish to reiterate that pharmacies are operating at a net margin of 1 to 5%. The sector is already burdened by the current low profit margin and any subsequent reduction in the current drug margin will lead to the collapse of the pharmaceutical sector.

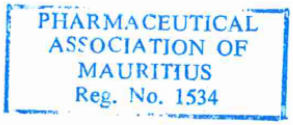
PAM views with much concern the proliferation of wholesale owned retail pharmacies. This leads to the further concentration on the market and in the long run we could be faced with monopoly issues by wholesales which are vertically integrated. We would suggest that that the authorities consider giving licences to operate a pharmacies to Pharmacists only or to companies with 51% shareholding to Pharmacists.

We wish to reiterate to the Commission that PAM remains at their disposal for any follow-up comments to the viewpoints expressed herein and we look forward to engaging with the Commission on a constructive dialogue in order to address the rising costs of drugs on the island.

Should you have any queries please do not hesitate to contact me at yaminimoothoosamy@gmail.com.

Yours sincerely,

Yamini Kasturi Moothoosamy Murugesan
President
Pharmaceutical Association of Mauritius



Abbreviations used in this Report

BIG 4	IBL, Unicorn, Pharmacie Nouvelle and Scott Health
Billadam's Pharmacy	Shahross and company ltd
Bn	Billion
CAGR	Compound annual growth rate
CBRIS	The Companies and Businesses Registration Integrated System
CHF	Swiss franc
CIF	Cost insurance and freight
Commission	Competition Commission of Mauritius
CSG	Contribution Sociale Généralisée
ForMe Pharmacy	Vertically integrated retail pharmacy of Scott Health
FSC	Financial Services Commission
GBP	British Pound
GDP/GSP	Good Distribution Practice and Good Storage Practice
GP	Gross Profit
HAI	Health Action International
HyperPharm	HyperPharm Ltd
IBL	Ireland Blyth Limited
IFC	International Financial Centre
IP	Intellectual property
K	Thousand
Love Life	Forms part of AL-FAH Distributors Ltd and trading under the business name of Love Life for its retail pharmacy
Market Study	Pharmaceutical industry in Mauritius MS/004 issued by the Competition Commission
MedActiv	Vertically integrated retail pharmacy of IBL
MSJ UNICORN	Unicorn is also known as MSJ Ltd
MSP	Manufacturing selling price
MUR	Mauritian Rupee
PAM	Pharmaceutical Association Mauritius
PAT	Profit after tax
PBT	Profit before tax
Pharmacie Nouvelle	Pharmacie Nouvelle Ltd
Planet Health Pharmacy	Vertically integrated retail pharmacy of HyperPharm Ltd

PPM	Pharmacy to Population
PRGF	Portable Retirement Gratuity Fund
Report	Report responding to the market study issued by Competition Commission
Sample	Sample of 45 retail independent retail companies used in our analysis
Scott Health	Scott Health Limited
Ste A.E Patel	A. E. Patel & Co.
The Board	The Pharmacy board of Mauritius
UK	United Kingdom
Unilink Pharmacy	Vertically integrated retail pharmacy of Unicorn
USA	United States of America
USD	American Dollars
VAT	Value-added-tax
WHO	World Health Organization
y-o-y	Year over year

Contents

1. Introduction

1.1 On 11 September 2020, the Commission issued the Market Study as part of a public consultation process.

1.2 Whilst the Market Study provides the Commission's views as well as its conclusions on several matters (administrative, technical, financial and others) relating to the local pharmaceutical industry; this Report only focuses on the following points/assertions referred to in the Market Study, namely that:

1.2.1 the current competition level across the pharmaceutical supply chain in Mauritius is healthy;

1.2.2 the current pricing regulation of medicines in Mauritius 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. Consequently, 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;

1.2.3 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;

1.2.4 to address the pricing issues, a regressive mark-up system, as recommended by the WHO, can be considered; and

1.2.5 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.

2. Executive summary

The need for rigorous mark-up studies by WHO

2.1.1 The Commission has not presented any empirical evidence to confirm that the application of a regressive mark-up system would shift consumer spending towards cheaper therapeutic alternatives. In its policy review, the WHO/HAI 's latest guideline on pharmaceutical pricing policies clearly states that there is no evidence on the impact of mark-up regulation on medicine prices and recommended systematic pre- and post-implementation studies to be carried out as a minimum before proceeding with changes in mark-up regulations.

2.1.2 The implementation of new mark-up regulations can have unintended impacts or consequences contrary to what the policymakers initially plan to achieve. Unless rigorous analyses and evidence are put forward to all stakeholders, it would be unwise to proceed with the amendment of the existing mark-up regulations when the subject of the matter is a significant overhaul of pricing regulations which have wide stakeholder implications.

The profitability and commercial viability of the pharmaceutical industry based on the flat mark-up scheme

2.1.3 The existing pricing regulations were already overburdening the finances of both the wholesale and retail pharmacies in 2019, where operating margins range between 1% to 5% - significantly lower than unregulated SMEs.

2.1.4 The introduction of CSG and PRGF in 2020 have further deteriorated operating margins and render operations challenging to sustain. The introduction of PGRF in 2022 will further burden the sector.

2.1.5 The fragile nature of the retail pharmacy operating model due to regulation of mark-up is one of the catalysts for certain unscrupulous practices such as illegal trade of psychotropic substances, and the application of the regressive mark-up system will only worsen the current crisis as business owners make ends meet.

2.1.6 The imposition of any pricing regulations which would reduce operating margins further will only accelerate the creation of new social problems in (a) existing small retail pharmacies closing down with loss of jobs and with no new entrants replacing them due to the prevailing low margins (b) a significant increase in malpractices including the sale of illicit or dangerous drugs affecting the overall viability of the sector.

2.1.7 A reckless application of additional pricing regulations would only be counter-productive as clearly stated by the WHO in its guidance on shifting to new pricing regulations.

Addressing the currency volatility issue more efficiently

2.1.8 The depreciating currency situation of the Mauritian Rupee ("MUR") is not new and affects businesses across the economy and not just the pharmaceutical industry. The control of currency volatility remains very much at the hand of government policies, central bank intervention and global market forces which neither the wholesaler nor retailer within the pharmaceutical industry has any control of. Consequently, it would be unfair for the pharmaceutical industry to bear the brunt of uncontrolled market forces.

2.1.9 The imposition of any pricing regulations (whether regressive mark-up scheme or any other) does not in any way address the currency volatility issue. In the case of a regressive mark-up system if, say, the MUR depreciates further by 10% over the next five years, then the retail value of drugs still increases by 10% in the hands of the end consumer;

2.1.10 The impact of any currency volatility should be measured in terms of the weight it has on an individual's out-of-pocket expenditure on healthcare (representing only 3% to 4% of the local household budget) which comes down to a maximum nominal amount of MUR800 per person on a monthly basis. In any event, the use of a properly implemented and efficient public healthcare system shall absorb currency volatility issues.

2.1.11 Given that the currency volatility appears to be the primary driver of rising retail prices of drugs (and not the export price of drugs itself), we would recommend that the Ministry of Finance evaluates other mechanisms which could more efficiently address the rising depreciation of the MUR either in the short or medium term.

2.1.12 Such mechanism could be in the form of a refund scheme to the wholesaler for any purchases made at an exchange rate which appreciated more than x% of previous' year's exchange rate costs for life-saving drugs or other critical drugs based on national consumption levels. We have provided a simplistic illustration below, and we would be pleased to actively engage with the various stakeholders on how such a mechanism could operate.

		Exchange rate movement		
	CIF value	2019	2020	2021
Currency movement - USD y-o-y movement - %		35.6	40.2 13.0%	42.2 5.0%
	USD	**MUR**	**MUR**	**MUR**
MSP	10	356	402	422
Special Allowance provided		2%	2%	2%
Landed cost	-	362.9	410.0	430.5
Wholesale and retail mark-up	-	35%	35%	35%
Retail price without reimbursement	-	489.9	553.6	581.2
Variance with last year's price				27.7
Refund to wholesaler due to exchange rate volatility	-	-	-	(27.7)
Final selling price retail with reimbursement	-	-	-	553.6

The rise of health insurance penetration

2.1.13 From 2008 to 2018, accident and health claims totalling MUR7Bn have been settled by insurance companies in Mauritius. Whilst these numbers need to be taken into perspective (as they include claims for doctors' fees, surgery and others), the private healthcare insurance scheme naturally resolves the rising costs of drugs for those who have access to same.

2.1.14 With the introduction of the Government Medical Insurance Scheme, as recently announced, we would expect a significant boost to the health insurance penetration ratio, which would help cushion increases in drug prices.

2.1.15 For individuals falling within the low-income groups or are vulnerable, the dispensing of drugs within the public healthcare system remains an option and hence, neutralises the risks of rising costs of medications at their level.

The competition level within the pharmaceutical industry in Mauritius

2.1.16 The use of the Pharmacy to Population ("PPM") ratio is incorrect in estimating the relative level of competition within retail pharmacies as it assumes that the end-user always purchases drugs within his or her residence. Given the significant mobility of workers across the island, the PPM ratio does not provide optimal results. This methodology also does not capture how commercial malls significantly skew the PPM ratio, which may create unfair level playing fields.

2.1.17 Based on our analyses, retail pharmacies in commercial malls tend to be concentrated in the hands of two vertically integrated pharmacies, namely: IBL and Scott Health and given that these groups are relatively large, they could influence their position to win tenancies on major future malls or real estate developments.

2.1.18 It is difficult to ascertain to what extent vertically integrated players have an economic incentive to favour their retail outlets to the detriment of other retail pharmacies. PAM should consider whether a separate study should be carried out concerning the use of discount cards by large, vertically integrated retailers at the expense of smaller retailer outlets.

2.1.19 The fragile nature of the retail business model is compounded by the complex, competitive interaction between independently owned pharmacies and vertically integrated pharmacies both competing within the same regions in some cases but with significantly more firepower at the hands of vertically integrated pharmacies.

2.1.20 The application of the regressive mark-up system is likely to shift the bargaining power to pharmacies that can drive volumes, and these would typically be vertically integrated pharmacies in malls or other large real estate developments such as smart cities. Consequently, It is critical that the Commission reviews how the commercial tenancy negotiations for future commercial mall projects or smart cities are conducted and whether they operate are in a fair and considerate manner and free from any influence so that retailers which are not part of large conglomerates have equitable access to.

Mitigating the risks associated with parallel imports could be challenging to achieve

2.1.21 Based on the review of authoritative literature1, the risks relating to the parallel import of drugs can be classified into three categories:

2.1.21.1 Health and safety risks – namely traceability, optimal product stability and strict adherence to pharmacovigilance;

2.1.21.2 Money laundering risks given the prevalent use of parallel import for money laundering purposes; and

2.1.21.3 Increased unfair competition risks as parallel importers do not adhere to strict health and safety norms, training, quality assurance compared to existing wholesalers which have invested heavily in this regard.

2.1.22 In 2007, Mauritius was severely reprimanded by the international community as being responsible for facilitating financial flows on Operation Singapore2. It involved counterfeiting of three prescription-only medicines – Plavix (clopidogrel), Casodex (bicalutamide) and Zyprexa (olanzapine), used for the treatment of psychosis, heart disease and prostate cancer, respectively in the UK.

2.1.23 This operation involved the import of medicines from Asia, which landed in Belgium and were transported overland and arrived in Britain. In Britain, these medicinal products were assembled and then re-introduced in the legal supply chain. It involved a multitude of players, and some of them were aware of the illegal activity. However, other players were hired for specific market activity, such as printing packaging material and were unaware of the counterfeiting process.

2.1.24 At a crucial cross-road where the Mauritius International Financial Center ("IFC") is struggling to strike its name from the list of High-Risk Third Countries (the "EU Blacklist") and the global business industry at stake, we urge the Commission to carefully evaluate the systemic repercussions of parallel imports of medicines on the financial services as part of its review..

2.1.25 Mauritius cannot afford to implement parallel imports without a comprehensive and systematic consultation with stakeholders to mitigate risks. Should the authorities take this issue lightly, the repercussions could be life-threatening as well as damaging to our financial services industry.

2.1.26 Unless, parallel importers are imposed foolproof financial, technical and operational health and safety conditions prior to them being able to operate as well as contributing a significant share to the investments already made by existing wholesalers, the introduction of parallel imports will create a disequilibrium in the competitive landscape which may not be reversible.

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[1] Combatting Falsification and Counterfeiting Of Medicinal Products in the European Union: A Legal Analysis, PhD Series, No. 1.2018, Provided in Cooperation with: Copenhagen Business School (CBS)

[2] https://www.lexpress.mu/article/maurice-bien-servi-de-plaque-tournante-pour-un-vaste-trafic-de-faux-m%C3%A9dicaments

3. The profitability and commercial viability of the pharmaceutical industry based on the flat mark-up scheme

3.1 Observations from the Market Study

3.1.1 None.

3.2 General observations and analyses

3.2.1 For a more balanced view, the Market Study should have captured the impact of the existing pricing regulations on the wholesalers and retailers operating within the pharmaceutical industry. Unfortunately, no such analyses were carried out by the Commission, and without proper context, the Market Study could infer that patients are paying for higher costs of medicines at the expense of pharmacies generating abnormal commercial profits.

3.2.2 We have analysed the profitability and other key financial metrics of a sample of 45 retail independent retail companies (with a combined turnover of MUR1Bn) (herein referred to as the "Sample") and the top 5 wholesale pharmaceutical companies in Mauritius for 2018 or 2019 (latest submissions of financial statements to the Registrar of Companies have been applied). Please refer to Appendix 1 for the detailed listing.

3.2.3 We consider that our Sample is a full reflection of the pharmaceutical industry for the following reasons :

3.2.3.1 A selection of small, medium and large retail pharmacies with a turnover level ranging from MUR5m to MUR100m has been made at random; and

3.2.3.2 The geographical location of the sample pharmacies is balanced across urban and rural areas to capture potential differences in purchasing power.

3.2.4 Insofar as the wholesale business is concerned3, the gross profit margins ranged between 14% and 23.5% for the five largest wholesalers operating in Mauritius and a net profit margin ranging between 2.5% and 4.3% – refer to the table on next page

Analysis of profitability of wholesalers[4]

No	Wholesaler	Turnover	GP Margin	PBT Margin	PAT Margin
		MUR(m)	**%**	**%**	**%**
1	Port-Louis - 1	1154.1	14.0%	5.2%	4.3%
2	Pailles - 1	2204.1	17.1%	3.1%	2.5%
3	Riche Terre - 1	1484.8	23.5%	4.8%	4.1%
4	Curepipe - 2	32.9	12.9%	0.3%	0.3%
5	Curepipe - 1	279.6	12.6%	2.0%	1.6%
Median value		**1154.1**	**14.0%**	**3.1%**	**2.5%**

3.2.5 Note that the gross profit margins of Pharmacie Nouvelle and Scott Health are skewed and exceed the wholesale mark-up of 11% as a significant volume of their turnover relate to non-pharmaceutical products such as consumer goods, cosmetics and others which are not captured by the flat mark-up scheme. Hence, the

[3] HealthActiv Ltd's financial statements could not be accessed as part of our analysis.

[4] Source : Data extracted from CBRIS

aforenamed two companies' sales of non-pharmaceutical product base are cross-subsidising their operations.

3.2.6 Our review of the retail operators' businesses reflected the following:

3.2.6.1 A median GP margin of 22.6% (which is very much in line with the existing mark-up applicable to retailers of 21.6%);

3.2.6.2 A median PBT margin of 1.3% (with at 11 retailers operating at a negative PBT margin which is alarming);

3.2.6.3 A median PAT margin of 1%;

3.2.6.4 A median gearing ratio of 37% (with 19 retailers operating at gearing levels exceeding 50%); and

3.2.6.5 A median inventory days[5] of 46 days (with 17 retailers having unsold stock exceeding 60 days)

3.2.7 Detailed charts reflecting the financial metrics discussed in 3.2.6.1, 3.2.6.2, 3.2.6.3, 3.2.6.4, and 3.2.6.5 are shown in Appendices 2, 3,4,5 and 6, respectively.

3.2.8 The relatively high gearing level of certain retail pharmacies within the Sample is fully explained by the fact that existing margins on pharmaceutical products are already low and with cash tied in inventory, several retailers are bound to engage into significant short term debt to finance their working capital.

3.2.9 Furthermore, in line with the gradual shift towards cashless operations, the cost of running small retail pharmacies will suffer a higher burden as most retail outlets are being charged bank charges ranging between 2.5% to 3.5%. The Commission did not take into consideration the net operating cost of retail companies in the Market Study and we believe that retail pharmacies should be exempted from such costs. Currently, petrol stations are benefitting from preferential charges as they run on a low profit margin and we urge the Commission that due consideration is given to retail pharmacies as well. Additionally, all retail and wholesale pharmacies are invariably left with expired products which need to be destroyed.

3.2.10 As indicated in 3.2.2, the above profitability analyses have been based on financial statements covering the year 2018 or 2019. Consequently, we expect further margins deterioration of retail pharmacies in 2020 (excluding any COVID-19 impact) due to the introduction of :

3.2.10.1 the Contribution Sociale Généralisée ("CSG") in September 2020 in replacement of the National Pension Fund contribution system at the rates of 3% to 6% depending on earnings level;

3.2.10.2 Portable Retirement Gratuity Fund ("PRGF") contributions at the rate of 2.1% to 4.5% depending on earnings level; and

3.2.10.3 Annual wage inflation and other operating costs such as utilities, credit cards costs which further burdens the whole pharmacy sector given the existing mark-up regulations.

[5] Measures how quickly a business can turn its inventory into cash

3.3 Impact of the application of a regressive mark-up system

3.3.1 The Market Study is silent on the quantum of regressive mark-up percentages proposed except by stating that "*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.*"[6]

3.3.2 Irrespective of the mark-up percentage, it is evident from our analyses that the application of any further pricing regulations on the pharmaceutical industry will further reduce gross profit margins of the wholesale and retail pharmacies and render those businesses unsustainable to operate.

3.3.3 This would have serious negative repercussions for patients and the broader economy as:

3.3.3.1 Existing retail pharmacies which are already struggling to operate under the existing pricing regulations may be forced to wind down their activities and given the perceived low margins within the industry, and new entrants are unlikely to enter - consequently, creating a lack of drug dispensing units across the island;

3.3.3.2 A regressive mark-up system would also create a favourable terrain to encourage the emergence of vertically integrated players to increase their dominance on the retail business side and in the long run, the level competition on the retail side will drop significantly at the detriment of consumers at large; and

3.3.3.3 It forces existing pharmacy owners to engage into malpractices such as overselling of cough syrups, illegal trade of psychotropic substances and others only as a matter of survival and making ends meet. It is worth noting that these malpractices are nothing new as evidenced by the observations made in the Commission on Enquiry of Drug Trafficking Report led by former judge Paul Lam Shang Leen.

3.4 Conclusion

3.4.1 The existing pricing regulations are already overburdening the finances of both the wholesale and retail pharmacies.

3.4.2 The introduction of CSG and PRGF as well as other hike in operating costs have further deteriorated operating margins and rendering operations challenging to sustain.

3.4.3 In view of the gradual shift in consumer behaviour towards cashless payments, retail pharmacies should be exempted from bank charges or credit card processing fees in line with preferential treatment being allocated to petrol stations.

3.4.4 A reckless application of additional pricing regulations would only be counter-productive to the public and there is a high risk that it accelerates the creation of new social problems in (a) existing small retail pharmacies closing down with no new entrants replacing them due to the prevailing low margins (b) a significant increase in malpractices including the sale of illicit or dangerous drugs.

3.4.5 As a matter of fact, there is a need to review existing pricing regulations by revising the mark up upwards to alleviate the financial burden currently being borne by retail pharmacies and not the reverse. It must be emphasised that pharmacies are professional businesses and need to offer decent salaries to graduate pharmacists and trained staff members which is hardly the case currently.

[6] Refer to paragraph 4.104 of the Market Study

4. Factors influencing high cost burden of drugs as per the Market Study

4.1 Observations from the Market Study

4.1.1 The Market Study singles out two main reasons which explains the high cost burden imposed on end users of pharmaceutical products, namely:

4.1.1.1 The existing flat mark-up scheme which in the view of the Commission 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[7]; and

4.1.1.2 The consistent depreciation of the MUR against major trading currencies which adds to high retail prices distributed in Mauritius.[8]

4.2 General observations and analyses

4.2.1 With regard to the point raised in 4.1.1.1, we are not on the same wavelength with the rationale applied by the Commission. As indicated by the Commission itself in paragraph 4.7 of the Market Study, prescription patterns are influenced by doctors, and the latter tend to give higher weight to product attributes rather than price.

4.2.2 It must be noted that 80% of pharmaceutical products imported in Mauritius are prescription-only products and that doctors are the ultimate decision-makers regarding what to prescribe to patients at their professional discretion. Several factors are involved in the prescribing habits of doctors, including quality, safety, affordability and patients 'choices. Consequently, the Commission has made a wrong assumption in pointing out that the current pricing regulations favour expensive products over cheaper therapeutic equivalents.

4.2.3 With regard to the point raised on 4.1.1.2, we agree with the Commission's views that the depreciating currency situation of the MUR has had an adverse impact on retail prices of pharmaceutical products.

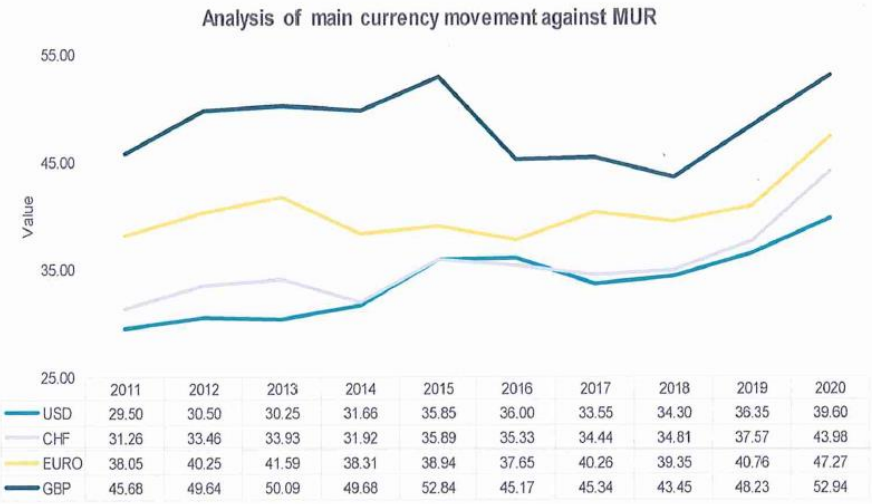
4.2.4 For example, we have analysed the CIF, wholesale and retail prices of three commonly used drugs in the market (Zetitor, Ketoplus, Tacroz Forte) for the year 2008 and 2020. Based on our review, the unit CIF prices of all three drugs have remained constant over the years – Zetitor has witnessed a marginal decrease. However, both the wholesale and retail prices for "Ketoplus" and "Tacroz Forte" have increased by more than 60% over the period in line with the depreciation of the MUR over the same period. This clearly shows that the currency volatility remains the predominant driver of the increase in drug prices and not the manufacturer's costs.

[7] Refer to paragraph 4.101 of the Market Study
[8] Refer to paragraph 4. 105 of the Market Study

Item	Unit CIF Price	Wholesale Price - MUR	Retail Price - MUR	USD exchange rate
	USD	11%	21.6%	
2008				1USD = 24.10 MUR
Zetitor Tab 1*30	10.00	265	293	
Ketoplus 120ml	3.30	87	97	
Tacroz Forte	6.00	159	176	
2020				1USD = 40.20 MUR
Zetitor Tab 1*30	9.75	431	477	
Ketoplus 120ml	3.30	146	161	
Tacroz Forte	6.00	265	293	

4.2.5 In the Market Study, the Commission uses the IRP ("International Reference Pricing") as a benchmark which refers to the "recent procurement prices offered by for-profit and not-for-profit suppliers to international not-for-profit agencies for generic products'-refer to section 4.88 in the Market Study. This is the reference price to sale to 'non-profit agencies' and hence cannot be applied in normal commercial operations.

4.2.6 Based on our analyses, all major trading currencies have appreciated against the MUR with a range of 20% to 35% over the last ten years.



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
USD	29.50	30.50	30.25	31.66	35.85	36.00	33.55	34.30	36.35	39.60
CHF	31.26	33.46	33.93	31.92	35.89	35.33	34.44	34.81	37.57	43.98
EURO	38.05	40.25	41.59	38.31	38.94	37.65	40.26	39.35	40.76	47.27
GBP	45.68	49.64	50.09	49.68	52.84	45.17	45.34	43.45	48.23	52.94

Source: Data extracted from websites (investing.org and exchangerate.uk.org), average exchange rates have been used

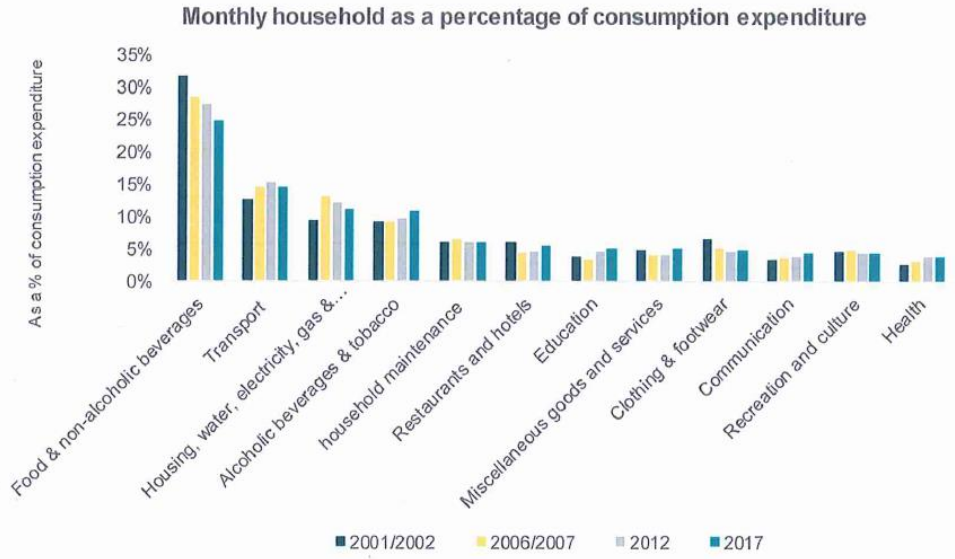
4.2.7 However, we consider that the weight of the currency volatility issue in the Market Study in justifying a significant overhaul of the current pricing regulations is disproportionate for the following reasons:

4.2.7.1 The depreciating currency situation of the MUR is not new and affects businesses across the economy and not just the pharmaceutical industry. The control of

currency volatility remains very much at the hand of government policies, central bank intervention and global market forces which neither the wholesaler nor retailer within the pharmaceutical industry has any control of. Consequently, it would be unfair for the pharmaceutical industry to bear the brunt of uncontrolled market forces;

4.2.7.2 The imposition of any pricing regulations (whether regressive mark-up scheme or any other) does not in any way address the currency volatility issue. In the case of a regressive mark-up system if, say, the MUR depreciates further by 10% over the next five years, then the retail value of drugs will still increase by 10% in the hands of the end consumer;

4.2.7.3 The impact of any currency volatility should be measured in terms of the weight it has on an individual's out-of-pocket expenditure on healthcare rather than analysed on a macro-level. We have analysed the household expenditure statistics published for the years 2001/2002, 2006/2007, 2012 and 2017. Health out-of-pocket expenditure for the average household in Mauritius has remained within a constant range of 3% to 4% of expenditure across the aforementioned period (which comes down to a nominal amount MUR800 per month). We must bear in mind that cost of medicines is just a fraction of the health care costs



Source: Data extracted from Statistics Mauritius

4.3 Impact of the application of a regressive mark-up system

4.3.1 The Commission has not presented any empirical evidence to confirm that the application of a regressive mark-up system would actually shift consumer spending towards cheaper therapeutic alternatives. The following extract from WHO[9]'s latest guideline on pharmaceutical pricing policies clearly summaries the importance of objectively assessing empirical evidence prior to the implementation of any change in pricing regulation:

"The WHO/HAI policy review noted that regulation of distribution mark-ups can have unintended impacts or consequences. Incentives and disincentives within a supply chain must be mapped and potential unexpected effects considered before controls are imposed. The review also suggested that mark-ups that include a regressive component (i.e. a lower mark-up for higher-priced products) with or without fixed fees, as is done in countries such as Tunisia, Syria, and Lebanon, probably lead to better

[9] WHO Guideline on Country Pharmaceutical Pricing Polices (2015)

outcomes than fixed percentage mark-ups through their influence on financial incentives. However, fixed fee mark-ups can dramatically increase the price of otherwise low-cost medicines.

It is clear that mark-up controls are used in many countries, irrespective of income (see Annex E), although notable exceptions are the USA and the UK. However, there is no evidence comparing the use of mark-ups to other pricing policies with respect to comparative price or availability of and access to medicines. Nor is there evidence on the impact of mark-up regulation on medicine prices. The panel noted that systematic pre- and post-implementation studies, such as the case -study of Jordan noted above, would be very helpful as a minimum to document mark-up policy effects."

4.3.2 The regressive mark-up system may temporarily absorb currency volatility but any further depreciation of the MUR over time would impact on the CIF value of pharmaceutical drugs in the future and increase the costs to the end consumer once again. In view of our earlier comments in section 2.1.13, it would not be sustainable to keep on reducing mark-up percentages over time.

In other jurisdictions where there is a controlled mark-up system on the pharmaceutical industry, there are compensatory mechanisms given by the government in terms of dispensing or distribution fees to support the industry and this is not the case in Mauritius.

4.4 Conclusions

4.4.1 Without detailed systematic studies, there is no empirical evidence suggesting that the application of a regressive mark-up system would address the rising costs of medicines.

4.4.2 Given that the currency volatility appears to be the primary driver of rising retail prices of drugs (and not the export price of drugs itself), we would recommend that the Ministry of Finance evaluates other mechanisms which could more efficiently address the rising depreciation of the MUR either in the short or medium term.

4.4.3 This could be in the form of a refund scheme to the wholesaler for any purchases made at an exchange rate which appreciated more than x% of previous' year's exchange rate costs for life-saving drugs or other critical drugs based on national consumption levels. We have provided a simplistic illustration below, and we would be pleased to actively engage with the various stakeholders on how such a mechanism could operate.

		Exchange rate movement		
	CIF value	2019	2020	2021
Currency movement - USD y-o-y movement - %		35.6	40.2 13.0%	42.2 5.0%
	USD	**MUR**	**MUR**	**MUR**
MSP	10	356	402	422
Special Allowance provided		2%	2%	2%
Landed cost	-	362.9	410.0	430.5
Wholesale and retail mark-up	-	35%	35%	35%
Retail price without reimbursement	-	489.9	553.6	581.2
Variance with last year's price				27.7
Refund to wholesaler due to exchange rate volatility	-	-	-	(27.7)
Final selling price retail with reimbursement	-	-	-	553.6

5. The affordability of private healthcare in Mauritius

5.1 Observations from the Market Study

5.1.1 None.

5.2 General observations and analyses

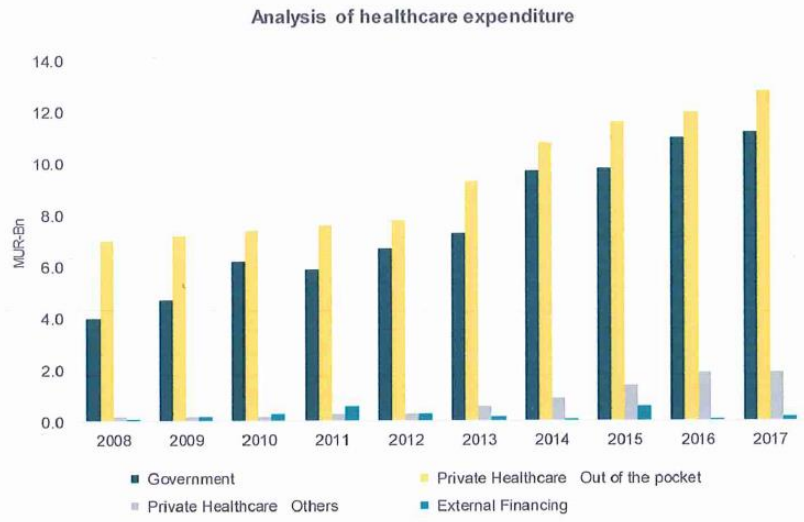
5.2.1 The Market Study does not address the demand side of private healthcare in Mauritius. We consider that, to bring balance and objectivity to the points raised by the Commission on the rising costs of pharmaceutical products, there is a need to put things under perspective.

5.2.2 Without appropriate context, the Market Study appears to infer that the rising cost of drugs is of national concern across all income groups and that patients within the lower-income or vulnerable groups are being left behind.

5.2.3 As the Commission rightly pointed out in the Market Study, healthcare expenditure has increased by 130% between 2008 to 2017 to reach a total of MUR26.1Bn.

5.2.4 Public health expenditure has risen by 183% during the aforementioned period compared to private health expenditure which has increased by 83% only. Out-of-pocket spending averages 50% throughout the time period.

5.2.5 Consequently, insofar as lower-income or vulnerable groups are concerned, drugs are prescribed free of charge under the current public healthcare system, and they would have been shielded from the rising costs of drugs.



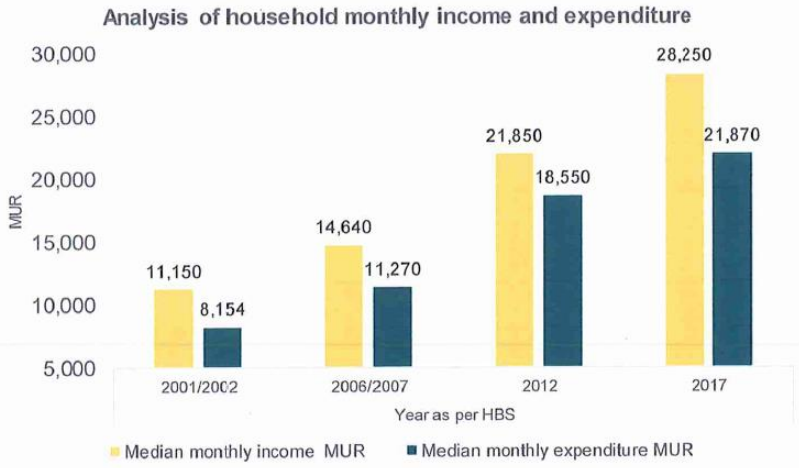
Source: Data from competition commission report "Pharmaceutical Industry in Mauritius - MS/004"

5.2.6 The significant increase in out-of-pocket expenditure for private healthcare is explained by two main factors:

5.2.6.1 A significant increase in median income level over the recent years at a growth rate exceeding depreciation of the MUR and inflation costs; and

5.2.6.2 A significant increase in the penetration of healthcare insurance.

5.2.7 With regard to our comments in 5.2.6.1, in 2001, the median monthly income level in Mauritius was around MUR11K compared to MUR28K in 2017. Whilst the median income level has doubled over time; the monthly household expenditure has also followed a similar pattern.



Source: Data extracted from the world bank

5.2.8 However, as indicated earlier in our Report, the weight of healthcare in the overall household expenditure budget has remained relatively fixed over time at 3% to 4% - which given current earnings level should absorb any increase in drug prices.

5.2.9 In order to demonstrate this assertion, we have extracted turnover figures as well as the number of receipts issued for three retail pharmacies across the island (with a combined turnover of MUR100m on a 12-month basis) during the period running from (a) January 2019 to September 2019 and (b) January 2020 to September 2020.

5.2.10 The implied patient spend (being turnover figures divided by the number of receipts issued) was on average MUR424 in 2019 and MUR516 in 2020. The increase in price in 2020 is justified to additional healthcare spend during the COVID-19 pandemic. Note these numbers include VAT and contain a mix of pharmaceutical and non-pharmaceutical products as well.

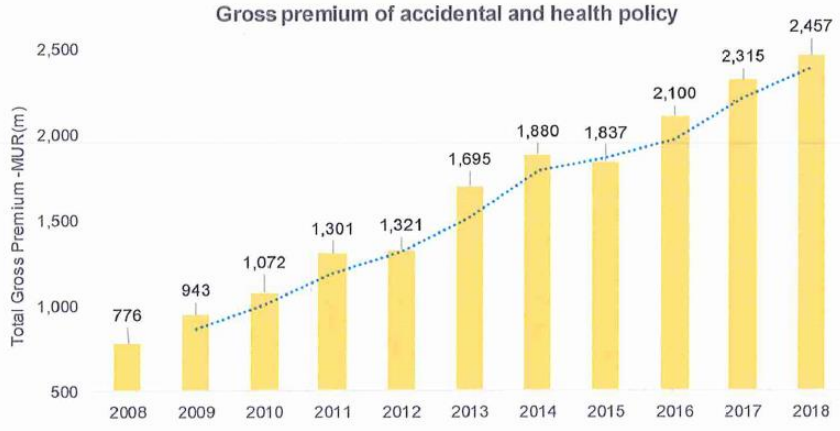
Location	Average spend per customer - MUR	
	January 2019 - September 2019	January 2020 - September 2020
	Pre COVID-19	Post COVID-19
Rose Hill	256	344
Tamarin	465	557
Barachois	551	649
Average value - MUR	**424**	**516**

5.2.11 Considering that the minimum monthly wage of around MUR10K is applicable in Mauritius, we believe that the average out-of-pocket spend of MUR500 does not have a disproportionate bearing on the end-user. In the same manner, we consider that the introduction of sweeping pricing regulation reforms remains entirely disproportionate to the economic burdens of end-users.

5.2.12 With regard to our comments in 5.2.6.2, we consider that the Commission should have considered the role of private healthcare insurance in absorbing the rising costs of drugs to the end-user.

5.2.13 Healthcare insurance is not mandatory in Mauritius and is regarded more as a "perk" by employees. If an employer does not operate a private healthcare insurance scheme, voluntary registration is not an option for young professionals, given the additional costs.

5.2.14 Whilst healthcare insurance penetration remains low in Mauritius with gross premiums peaking at MUR2.5Bn in 2018 (covering maximum 100K people only out of a total workforce of 575K) as shown in Figure below, year-on-year gross premiums have increased at a CAGR of 12% between 2008 and 2018 which suggests an uptick in new healthcare insurance subscriptions.



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Source: Data extracted from FSC

5.2.15 In addition, all registered insurers have settled claims totalling MUR7Bn towards accident and health claims from 2008 to 2018. Whilst these numbers need to be taken into perspective (as they include claims for doctors' fees, surgery and others), the private healthcare insurance scheme naturally resolves the rising costs of drugs for those who have access to same.

5.2.16 With the introduction of the Government Medical Insurance Scheme, as recently announced, we would expect a significant boost to the health insurance penetration ratio, which would help cushion increases in drug prices.

5.3 Impact of the application of a regressive mark-up system

5.3.1 Mauritius, as a high-income country under the new World Bank classification, would not appear to benefit from the application of a regressive mark-up system as the marginal benefit to the average patient spend is immaterial considering (a) the already low patient spend as demonstrated earlier (b) current earnings level and (c) rising health insurance penetration.

5.4 Conclusion

5.4.1 The public healthcare system would absorb the rising cost of drugs for the low income or vulnerable group of patients.

5.4.2 Whilst we admit more needs to be done to increase the healthcare insurance coverage, there is enough traction year-on-year to suggest that eventually, a significant majority of employees over time will receive coverage and indirectly shield themselves of rising drug prices. Incentives could be given by the government to motivate private organisations to subscribe their employees to private healthcare insurance schemes

6. The competition level within the pharmaceutical industry in Mauritius

6.1 Observations from the Market Study

6.1.1 The number of wholesales companies increased by 16 from 2010 to 2019 while retail companies have risen 91 over the same period.

6.1.2 The wholesale pharmacy market tends to show competition in terms of the increasing number of players in the market and volume of products supplied.

6.1.3 There is an adequate number of retail pharmacies scattered all over the island and which somehow does not raise concentration issue as such.

6.1.4 The Commission further stated that 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 retail outlets to the detriment of other retail pharmacies.

6.2 General observations and analyses

6.2.1 With regards to the comments made in 6.1.2, the number of wholesale pharmacies in Mauritius is estimated to be around 40 with IBL, Unicorn, Pharmacie Nouvelle and Scott Health (collectively referred to herein as the "Big 4") controlling c.60% of the market share. The remaining 40% of the wholesale market is left in the hands of 36 other different economic operators.

Wholesale pharmacies	Median value of market share (based on Market Study estimates)		
	2017	2018	2019
IBL	25%	24%	20%
MSJ Ltd (Unicorn)	17%	19%	19%
Pharmacie Nouvelle	12%	12%	11%
Scott Health	11%	9%	12%
Anichem Pharmacy	6%	6%	6%
Ste A.E Patel % Co	5%	5%	5%
Other wholesale pharmacies	24%	25%	27%
Total	**100%**	**100%**	**100%**

Source: Data from competition commission report "Pharmaceutical Industry in Mauritius - MS/004

6.2.2 It is evident that there is a significant level of concentration of the wholesale market within the Big 4, but this is justifiable given that most of them are backed by conglomerates (except for Unicorn) with reasonably balance sheets. As a result of their financial strength, they can retain a market leadership role, make the necessary capital and/or operating investments as and when required.

6.2.3 However, we need to put things in context. The definition of a "wholesaler" as defined in other jurisdictions is an entity whose only function is to wholesale products to retail clients. In Mauritius, using the term 'wholesaler' is a misnomer, as they are involved not only in wholesaling products but have other functions such as education of healthcare practitioners, creating awareness on diseases, the introduction of new innovative products, regulatory including registration of products or renewal and adherence and compliance to rigorous quality management systems including WHO GSP/GDP norms. Considering that they do all these functions, wholesalers have managed to maintain their operations despite a low restrictive mark-up.

6.2.4 Wholesalers have a mix of healthcare products including pharmaceuticals, health supplements, cosmetics, medical devices, medical equipment and consumables, etc. Hence the extrapolation of market share based on their total turnover, in which pharmaceuticals only represent a part, is therefore not the appropriate method. The market is sufficiently ventilated and mature to allow competition with both originator and generic products available at the different price range and imported by various wholesalers.

6.2.5 We disagree with the Commission's view that the barriers to entry within the wholesale market are not too high. In our opinion, access to capital remains a barrier to entry at present-day levels.

6.2.6 With regards to the comments made in 6.1.3, we disagree with the conclusion of the Commission for the following reasons:

6.2.6.1 Applying the Pharmacy to Population ("PPM") ratio is incorrect in estimating the relative level of competition within retail pharmacies as it assumes that the end user always purchases drugs within his or her residence. Given the significant mobility of workers across the island, the PPM ratio does not provide optimal results. This methodology also does not capture how commercial malls significantly skews the PPM ratio, which may create unfair level playing fields. Refer to the table on the next page.

Main malls in Mauritius	Average monthly footfall	Name of pharmacies	Part of
Bagatelle Mall	697,122[10]	ForMe Pharmacy	Scott Health
Grand Baie La Croisette	500,000[11]	ForMe Pharmacy	Scott Health
Le Caudan Waterfront	500,000[12]	Pharmalink	Unicorn
		MedActiv	IBL
Cascavelle Mall	300,000[13]	MedActiv	IBL
Phoenix Mall	484,916[14]	MedActiv	IBL
Soflo	175,850[15]	Billadam's Pharmacy	Independent
Les Alles Shopping Mall	-	Pharmacie Helvetia	Independent
La City Trianon	-	MedActiv	IBL
Kendra	209,682[16]	Planet Health Pharmacy	HyperPharm
Bo Valon Mall	-	ForMe Pharmacy	Scott Health
Riche Terre Mall	310,722[17]	Unilink Pharmacy	Unicorn
Plaisance Shopping Village	-	MedActiv	IBL
Mont Choisy Le Mall	-	Love Life	Independent

[10] https://www.ascenciamalls.com/bagatelle

[11] PAM estimate based on similar size of malls where data is publicly available
[12] PAM estimate based on similar size of malls where data is publicly available
[13] PAM estimate based on similar size of malls where data is publicly available

[14] https://www.ascenciamalls.com/phoenix-mall

[15] https://www.ascenciamalls.com/soflo-0

[16] https://www.ascenciamalls.com/kendra

[17] https://www.ascenciamalls.com/riche-terre-mall

6.2.6.2 As a matter of illustration, the pharmacy to population ratio has been estimated by the Commission to be 3,803 for the Moka Region (covering 22 retail pharmacies) – translating into a theoretical monthly footfall of 114,090 per retail pharmacy. However, ForMe Pharmacy (which is a vertically integrated pharmacy of Scott Health), through its presence at Bagatelle Mall, can capture almost 6 times the same footfall based on ENL's estimate of its average monthly footfall. This has a direct economic impact on the 22 retail pharmacies based in Moka and reinforces the fragile nature of the retail business model in light of mall developments, smart city developments and other significant real estate developments on the island.

6.2.7 Based on our analyses, retail pharmacies in commercial malls tend to be concentrated in the hands of two vertically integrated pharmacies, namely: IBL and Scott Health and given these groups are relatively large, they could influence their position to win tenancies on major future malls or other real estate developments.

6.2.8 With regards to the comments made in 6.1.4, it is difficult to ascertain to what extent vertically integrated players have an economic incentive to favour their retail outlets to the detriment of other retail pharmacies.

6.2.9 Our discussions within pharmacy outlets at random do point out that:

6.2.9.1 the discounts/loyalty cards issued by conglomerates such as IBL is not a fair-trading practice as smaller outlets are unable to offer the same service; and

6.2.9.2 given the dominance of vertically integrated pharmacies at malls, they are in a strong bargaining power position to impose payment terms, minimum retail margins, bulk discounts, etc.

6.3 Impact of the application of a regressive mark-up system

6.3.1 The fragile nature of the retail business model is compounded by the complex, competitive interaction between independently owned pharmacies and vertically integrated pharmacies both competing within the same regions in some cases but with significantly more firepower at the hands of vertically integrated pharmacies.

6.3.2 The application of the regressive mark-up system is likely to shift the bargaining power to pharmacies that can drive volumes, and these would typically be vertically integrated pharmacies in malls or other large real estate developments such as smart cities.

6.4 Conclusion

6.4.1 It is evident that the retail pharmacy model requires a careful review to ensure its sustainability in Mauritius in light of changes in demographics, movement of people and others irrespective of the proposed mark-up changes by the Commission.

6.4.2 It is critical that the Commission reviews how the commercial tenancy negotiations for future commercial mall projects or smart cities are conducted and whether they operate are in a fair and considerate manner and free from any influence so that retail pharmacies who are not part of large conglomerates have equitable access to.

7. Evaluating the case of parallel imports of medicines in Mauritius and its implications

7.1 Observations from the Market Study

7.1.1 Parallel import will bring a reduction in the prices of branded pharmaceutical products but also act as a complement to control strategies, and this will lead to a more competitive price.

7.2 General observations and analyses

7.2.1 The Market Study does not adequately explain:

7.2.1.1 the rationale of allowing for parallel imports in the Market Study and the granular details around what would be allowed or not allowed;

7.2.1.2 how parallel imports are expected to assist in control prices;

7.2.1.3 how are the risks associated with parallel imports will be mitigated; and

7.2.1.4 whether a careful evaluation of those risks and their significant implications on the reputational damage of the Mauritius IFC has been undertaken.

7.2.2 Our focus in this Report relates to 7.2.1.3 and 7.2.1.4.

7.2.3 Based on the review of authoritative literature[18], the risks relating to the parallel import of drugs can be classified into three categories:

7.2.3.1 Health and safety risks;

7.2.3.2 Money laundering risks; and

7.2.3.3 Increased unfair competition.

7.2.4 With regard to our comments on 7.2.3.1, reference is made to the effective use of parallel imports globally to infiltrate counterfeit and falsified medicines which could have life-threatening consequences for patients. The following critical technical areas would have to be foolproof:

7.2.4.1 Traceability and liability should be guaranteed. If a patient suffers any adverse effects, the local parallel importer or the overseas wholesaler could be liable. For manufactures and their accredited distributors in Mauritius, these elements are already guaranteed;

7.2.4.2 Mauritius is in the climatic zone IV A and products which are dispatched by manufacturers ensure that tests are done, and products are stable under these conditions. Importing the same brands from wholesalers overseas does not necessarily guarantee the stability of products under this climatic zone. It could represent a potential risk to patients in case of non-adherence. Hence stability under the prevailing conditions in Mauritius would need to be shown; and

7.2.4.3 The parallel importer would need to show adherence to the pharmacovigilance and product recalls as these are essential elements in the pharmaceutical supply chain process to ensure the safety of patients.

7.2.5 With regard to our comments on 7.2.3.2, reference is made to the use of parallel imports for money laundering purposes:

7.2.5.1 In 2007, Mauritius was severely reprimanded by the international community as being responsible for facilitating financial flows on Operation Singapore[19]. It involved counterfeiting of three prescription-only medicines – Plavix (clopidogrel), Casodex (bicalutamide) and Zyprexa (olanzapine), used for the treatment of psychosis, heart disease and prostate cancer, respectively in the UK;

7.2.5.2 This operation involved the import of medicines from Asia, which landed in Belgium and were transported overland and arrived in Britain. In Britain, these medicinal products were assembled and then re-introduced in the legal supply chain. It involved a multitude of players, and some of them were aware of the illegal activity. However, other players who were hired for specific market activity,

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[18] Combatting Falsification and Counterfeiting Of Medicinal Products in the European Union: A Legal Analysis, PhD Series, No. 1.2018, Provided in Cooperation with: Copenhagen Business School (CBS)

[19] https://www.lexpress.mu/article/maurice-bien-servi-de-plaque-tournante-pour-un-vaste-trafic-de-faux-m%C3%A9dicaments

such as printing packaging material and were unaware of the counterfeiting process; and

7.2.5.3 At a crucial cross-road where the Mauritius IFC is struggling to strike its name from the EU Blacklist and the global business industry at stake, we fail to understand whether the Commission has measured and evaluated the seriousness of any misuse of parallel imports on the financial services industry.

7.2.6 With regard to our comments on 7.2.3.37.2.3.2, reference is made to the fact that manufacturers and their accredited local wholesalers/ distributors invest in creating awareness of the products to ensure that new products are brought in the market so that Mauritius can benefit from innovative products. Importer/ distributor also invests heavily in their storage and distribution capabilities as per WHO GDP/GSP norms to ensure that the final product is delivered under the same optimal conditions as that received from the manufacturer. Manufacturers regularly audit premises of their accredited distributors to ensure adherence to these norms to ensure the safety of patients. Parallel importers do not go through these processes of audit and investments, and thus create an unfair trading advantage between the parallel importer and local wholesalers/distributors.

7.3 Impact of parallel imports

7.3.1 As indicated above, the technical and economic repercussions of the introduction of parallel imports are severe and should be addressed seriously. Any reckless or hasty application of parallel imports (specifically to medicines) could endanger not just the health and safety of Mauritians but cause wider uncontrollable collateral damage.

7.4 Conclusion

7.4.1 The Market study only considers the pricing aspects of parallel imports and ignore other critical factors mentioned above. It is evident that the risks associated with parallel imports do not outweigh benefits in view of all the arguments we have put forward in earlier sections of this Report. Mauritius cannot afford to implement parallel imports without comprehensive and systematic consultations with stakeholders in order to mitigate risks. Should the authorities take this issue lightly, the repercussions could be life-threatening and disastrous to our global business sector.

7.4.2 Unless, parallel importers are imposed foolproof financial, technical and operational health and safety conditions prior to them being able to operate as well as contributing a significant share to the investments already made by existing wholesalers, the introduction of parallel imports will create a disequilibrium in the competitive landscape which may not be reversible.

8. The registration process by the Pharmacy Board

8.1 PAM is agreeable to most of the recommendations made by the Commission regarding the registration process. Below are some additional considerations from PAM regarding the registration process. We set out below some additional considerations which the Commission needs to consider:

8.2 The Board should be more transparent in terms of registration guidelines and its implementation, publication of the list of registered products, acknowledgement of receipt, tracking of registration dossiers and most importantly the reasons for rejection of applications and the right to appeal.

8.3 There should be more transparency in terms of the functions of The Board. The latter should not only look after the registration of products but look at the pharmaceutical industry in its entirely. It is crucial to have onboard pharmacist members from different sectors of the industry, such as retail, hospital, wholesale, academia, etc. Governance rules must be put in place to avoid potential conflicts of interests. The implementation of the National Single Window will help to achieve accountability and transparency as far as the list of imported pharmaceutical product is concerned.

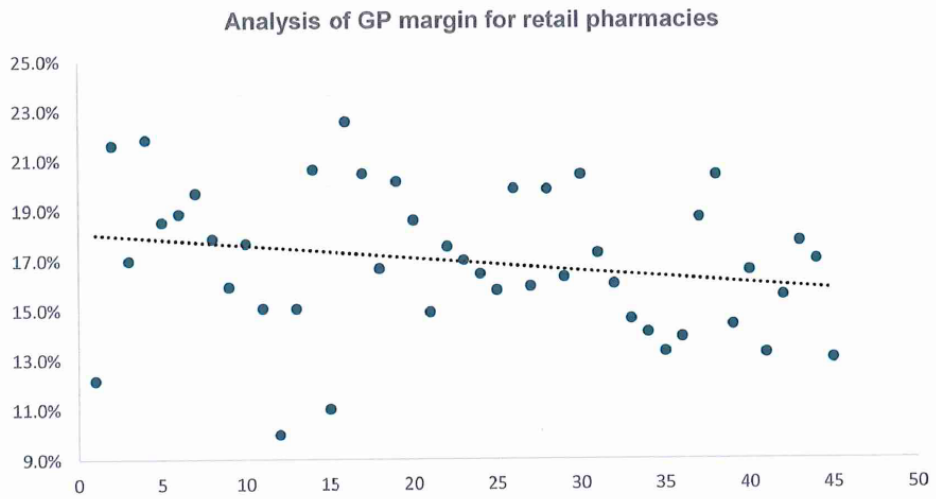
Appendices

Appendix 1 – Sanitised sample of retail pharmacies

No	Pharmacies	Turnover	GP Margin	PBT Margin	PAT Margin	Total expenses as a % of total income	Gearing Ratio	Inventory days
		MUR	%	%	%	%	%	Days
1	Terre Rouge - 1	37,383,661	12.2%	-0.3%	-0.3%	100.0%	40.0%	85.0
2	Port-Louis - 1	31,183,221	21.6%	9.3%	7.8%	90.3%	0.0%	23.0
3	Port-Louis - 2	45,114,267	17.0%	3.5%	2.9%	95.6%	0.0%	12.9
4	Tamarin, Rivere Noires, Rose-Hill	103,687,634	21.8%	2.2%	1.8%	95.4%	30.3%	72.1
5	Rivere des Anguilles - 1	11,362,264	18.5%	-1.4%	-1.4%	96.4%	100.0%	31.8
6	Pamplemousses - 1	27,633,710	18.9%	2.5%	2.1%	96.3%	10.3%	46.2
7	Triolet - 1	26,910,755	19.7%	1.2%	0.7%	90.9%	88.4%	5.1
8	Triolet - 2	23,901,016	17.9%	0.5%	0.3%	97.8%	0.0%	40.5
9	St Pierre - 1	20,721,452	15.9%	4.4%	3.7%	94.8%	1.0%	20.7
10	Quatre Bornes - 1	67,597,115	17.7%	3.2%	2.4%	94.2%	3.6%	40.6
11	Lallmatie - 1	23,418,662	15.1%	1.1%	0.9%	98.4%	41.2%	30.2
12	Goodlands - 1	7,828,427	10.0%	-9.1%	-9.1%	108.5%	7.9%	70.5
13	Quatre Bornes - 2	22,811,045	15.1%	-5.1%	-5.1%	102.1%	100.0%	45.5
14	Beau-Bassin - 1	6,027,526	20.6%	0.6%	0.5%	99.4%	69.2%	114.7
15	Quatre Bornes - 3	11,604,677	11.0%	0.5%	0.3%	99.5%	31.9%	118.6
16	Vacoas - 1	7,082,206	22.6%	1.3%	1.2%	96.2%	46.3%	21.5
17	Vacoas - 2	12,881,844	20.5%	-1.0%	-1.0%	95.3%	100.0%	53.7
18	Port-Louis - 3	7,121,182	16.7%	-6.6%	-6.6%	106.2%	62.3%	139.7
19	Rivere Noires - 1	11,798,871	20.2%	6.5%	5.4%	90.3%	29.6%	29.6
20	Quatre Bornes - 4	10,177,040	18.6%	0.8%	0.5%	99.0%	70.6%	37.5
21	Pailles - 1	22,180,229	14.9%	1.3%	1.1%	98.1%	54.7%	29.7
22	St Pierre - 2	6,074,097	17.5%	-0.2%	-0.2%	99.2%	72.3%	183.3
23	Quatre Bornes - 5	45,114,267	17.0%	3.5%	2.9%	95.6%	0.0%	12.9
24	Quatre Bornes - 6	5,475,316	16.4%	3.1%	2.7%	96.9%	100.0%	-
25	Beau-Bassin - 2	10,784,674	15.8%	0.3%	0.2%	95.3%	25.9%	39.8
26	Rose-Hill - 1	7,468,994	19.9%	3.0%	2.5%	96.2%	50.6%	4.5
27	Rose Belle - 1	7,629,664	15.9%	-2.1%	-2.1%	102.0%	0.0%	39.8
28	Vacoas - 3	5,307,049	19.8%	-1.3%	-1.3%	100.8%	0.0%	62.6
29	St Pierre - 3	9,903,616	16.3%	-2.5%	-2.5%	102.2%	100.0%	18.3
30	Goodlands - 2	8,387,886	20.4%	-9.0%	-9.0%	107.9%	-	74.1
31	Port-Louis - 4	14,497,453	17.3%	2.4%	2.1%	97.5%	0.0%	35.2
32	Port-Louis - 5	11,763,198	16.0%	3.4%	2.9%	95.1%	37.3%	-
33	Port-Louis - 6	5,966,824	14.6%	3.6%	3.6%	94.0%	0.0%	87.0
34	Pamplemousses - 2	11,717,916	14.1%	1.8%	1.5%	93.5%	61.7%	63.5
35	Beau-Bassin - 3	10,578,299	13.3%	0.4%	0.4%	98.7%	0.0%	63.3
36	Vacoas - 4	13,024,755	13.9%	3.3%	2.8%	96.7%	0.0%	52.4
37	Port-Louis - 7	17,672,701	18.7%	5.9%	4.9%	93.8%	75.8%	23.6
38	Vacoas - 5	26,092,301	20.4%	2.1%	1.9%	97.3%	61.7%	71.7
39	Port-Louis - 8	14,381,606	14.4%	0.9%	0.9%	98.1%	94.7%	70.4
40	Pamplemousses - 3	51,298,728	16.6%	1.7%	1.3%	96.7%	22.8%	65.0
41	Grand Baie - 1	65,639,347	13.2%	0.7%	0.6%	99.1%	61.3%	186.5
42	Beau-Bassin - 4	32,650,090	15.6%	4.9%	4.2%	84.4%	85.7%	70.5
43	Vacoas - 6	25,568,236	17.7%	1.5%	1.1%	97.8%	3.6%	51.5
44	Vacoas - 7	25,720,844	17.0%	1.9%	1.5%	95.8%	40.8%	44.2
45	Pamplemousses - 4	15,431,700	13.0%	3.4%	2.9%	94.6%	52.0%	49.3
	Median value	14,381,606	17.0%	1.3%	1.1%	96.7%	40.4%	45.54

- Financial statements for all the retail companies were downloaded from CBRIS. For most of the companies, turnover figures for the year 2019 have been used (where available). Alternatively, we have carried out our analyses on 2018 figures.

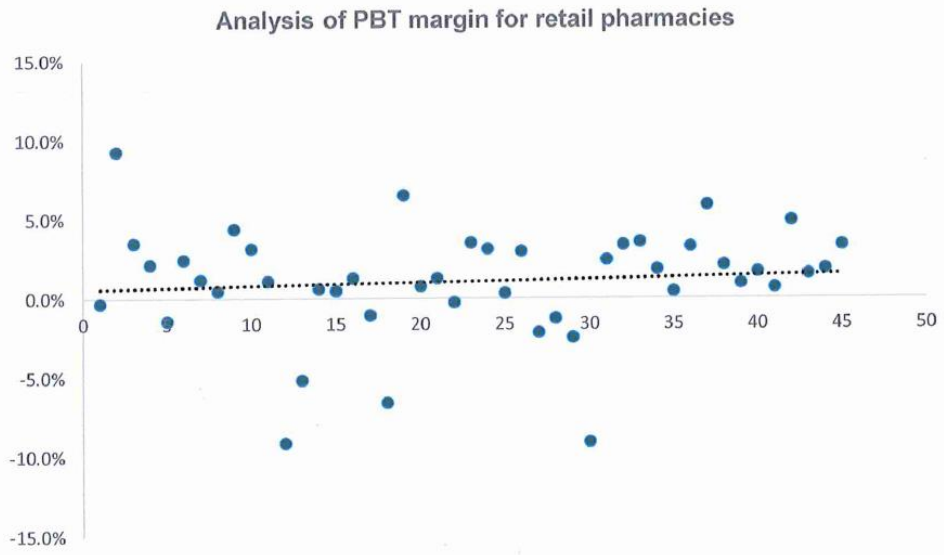
Appendix 2 – Analysis of GP margin for retail pharmacies



Source: Data extracted from CBRIS

- The above shows the analysis of the Gross Profit ("GP") margin for the different retail pharmacies in our sample list. The GP margin is a profitability ratio that compares the gross margin of the company to its revenue. It shows how much the company is making after paying off its cost of goods sold.
- The median GP margin, as shown by the dotted line on the graph for the different retail companies, is around 17.0% which is significantly low. The maximum GP margin was about 22.6% while the lowest being 10%.

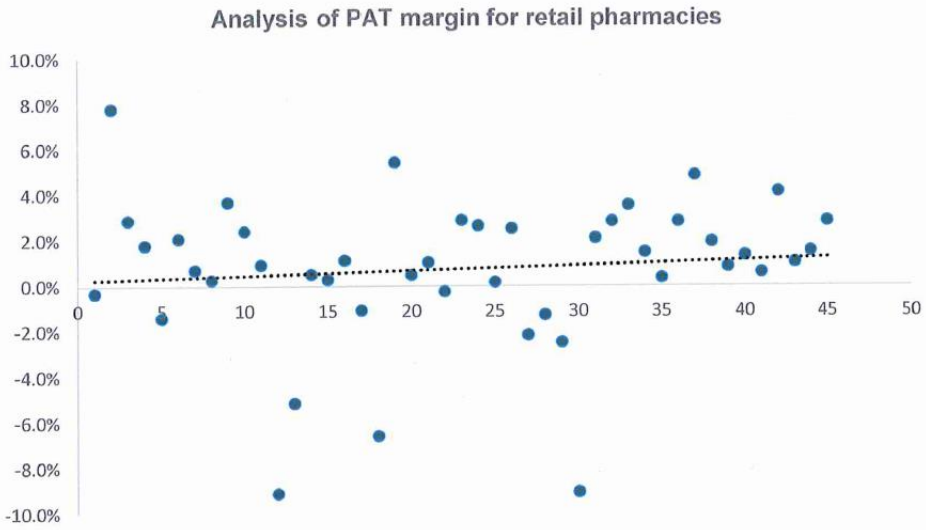
Appendix 3 – Analysis of PBT margin for retail pharmacies



Source: Data extracted from CBRIS

- The above shows the analysis of the Profit Before Tax ("PBT") margin for the different retail pharmacies in our sample list. The PBT margin is a measure of the company's profitability which looks at the profit before any tax is paid. It includes all the company's expenses, excluding payment of tax.
- The median PBT margin, as shown by the dotted line for the different retail companies, is around 1.30% which is significantly low. The maximum PBT margin was about 9.31% while the lowest being negative at 9.05%. Out of the 45 companies in our sample list, around ten companies are making negative PBT.

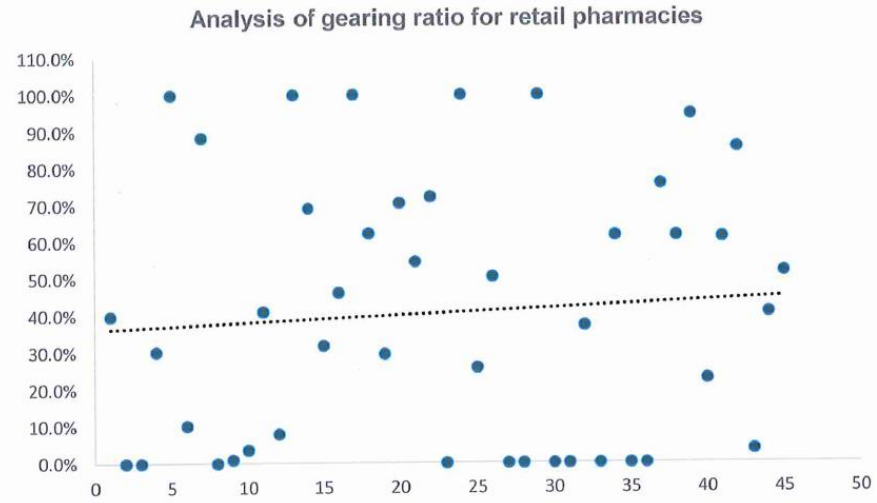
Appendix 4 – Analysis of PAT margin for retail pharmacies



Source: Data extracted from CBRIS

- The above shows the analysis of the Profit After Tax ("PAT") margin for the different retail pharmacies in our sample list. The PAT margin is a financial ratio used to calculate the percentage of net profit a company produces from its revenue.
- The median PAT margin, which is indicated by the dotted line on the graph for the different retail companies is around 1.06% which is statistically low. The maximum PAT margin was about 7.81% while the lowest being negative at 9.10%. Out of the 45 companies in our sample list, around 11 companies are making negative PAT.

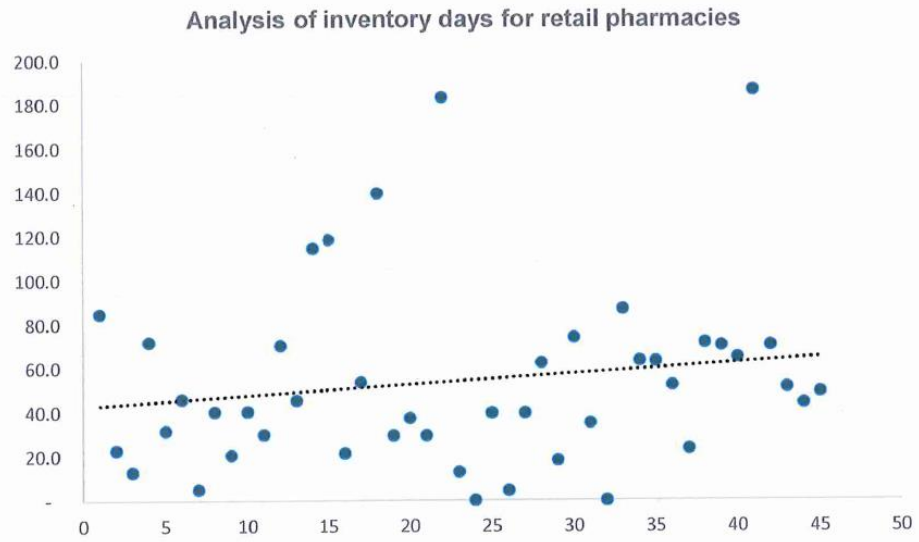
Appendix 5 – Analysis of gearing ratio for retail pharmacies



Source: Data extracted from CBRIS

- The above shows the analysis of the gearing ratio for the different retail companies. Gearing ratio is the amount of debt in proportion to a company capital equity that the company uses to fund its operation. A company possessing a high gearing ratio usually indicates a high debt to equity ratio, which potentially increases the risk of the financial failure of the business.
- The median gearing ratio, which is indicated by the dotted line on the graph for the different retail companies is around 36.99% which is statistically a good percentage. For retail pharmacies, a gearing ratio above 50% is considered as high.

Appendix 6 – Analysis of inventory days for retail pharmacies



Source: Data extracted from CBRIS

- The above shows the analysis of the inventory days for the different retail pharmacies in our sample list. The day's inventory calculation shows how quickly a company can turn its inventory into cash. It is a liquidity metric and an indicator of the company's operational and financial efficiency.

- The median inventory days which is indicated by the dotted line on the graph is around 46 days which means that the retail companies in our sample list usually takes approximately 46 days to convert its inventories into cash. The maximum days required recorded in our analysis to convert inventory into cash was around 187, while the lowest one was about 5 days.

ANNEX VII: MSJ LTD (UNICORN)

Schedule to letter of MSJ Ltd dated 12 October 2020

Re: MARKET STUDY- PHARMACEUTICAL INDUSTRY IN MAURITIUS - MS/004 - Report for Consultation 11th September 2020 – (the 'Report')

With regard to the Conclusion and Recommendations of the Report, specifically.

Under paragraph 5.2

1. With regard to the term "wholesale pharmacies" as used in the Executive Summary of the Report, it is commented that a fundamental distinction must be made between wholesale pharmacies or wholesalers in the pharmaceutical industry in other jurisdictions whose role and function is only to import pharmaceutical products on a wholesale basis and wholesalers in Mauritius. In Mauritius, 'wholesale pharmacies' or 'wholesalers' do not only import pharmaceutical products but also and more importantly are involved in the following processes in the chain relating to pharmaceutical products: sourcing, registration, funding of stock, storage and distribution, marketing, post-marketing and pharmacovigilance. Wholesalers also need to meet the requirements of major international pharmaceutical companies and laboratories in terms of quality assurance management. The wholesalers in Mauritius also have a regulatory function involving registration of products, renewals and variations management and obligation to recall pharmaceutical products on any issue arising, as imposed by the Ministry of Health.

2. The role of both wholesalers/importers and retailers are essential for the pharmaceutical industry and have their own distinct respective roles, functionalities, processes and cost structures which involve essential components of the chain of supply and their role in the industry.

3. Whereas the role of the wholesale pharmacies has been described in view of clarifying the scope of their initiatives and effort in bringing the best available pharmaceutical products to Mauritius, attention is drawn that in the end result, it is medical practitioners who prescribe medication to their patients in their ultimate professional discretion, on the basis of their respective training, experience and objective of procuring the good health of their patients on a medical and cost-effective basis. 80% of medicines/pharmaceutical products are prescribed by medical practitioners and only 20% of medicines/pharmaceutical products are sold over the counter in retail pharmacies. The view that wholesalers and retailers favour more expensive pharmaceuticals is therefore based on incorrect assumptions.

4. The figures referred to in the Executive Summary, especially with regard to market share are based on the turnover of wholesalers on the assumption that wholesalers only deal in pharmaceutical products. Attention is drawn that MSJ Ltd (Unicorn), for instance, deals with a mix of products which includes pharmaceutical as well as non-pharmaceutical products. Unicorn's turnover on pharmaceuticals represents 60% of its total turnover; this would therefore represent a total market share of 14% of the pharmaceutical sector instead of 20% as mentioned in the Report. We take the view that this will be also be the case for other wholesalers. The increase in the number of wholesalers from 24 in 2010 to reach 40 in 2019 is an indication of the healthiness of the pharmaceutical industry in terms of competition.

Under paragraph 5.3 of the Conclusion and Recommendations

5. Specifically, although it is noted that the Guidelines of the Pharmacy Board (the 'Guidelines') are not publicly available, it is submitted that it is not sufficient that such Guidelines should be available but more importantly that such Guidelines should be judiciously used and applied by the Pharmacy Board.

6. It is also submitted that the best and most efficient use and application of the Guidelines will be made by competent, trained and experienced pharmacists, irrespective of whether they belong to wholesale pharmaceutical organizations or not. This comment applies equally to retail pharmacists. The Pharmacy Board must not deliberately and unjustifiedly deprive itself of the competence, training, professional and research, exposure and experience of professionals merely on the ground that they belong to wholesalers' organizations.

7. Attention is drawn that the Pharmacy Board is not a body which only deals with applications for the registration of pharmaceutical products but is also a multi-functional and multi-disciplinary body which also tackles other aspects of the pharmaceutical industry. . The multi-disciplinary approach which the Pharmacy Board must adopt necessarily requires that its members must have different experience and background in order to maximize its efficiency and quality in deliberations and decision-making. It is submitted that emphasis must be laid on the quality of input of members to the Pharmacy Board.

8. With regard to the "conflict of interest" which is averred, it is commented that a workable and practical solution can be proposed around 'good governance principles'.

9. Rules governing the internal functioning of the Pharmacy Board must be amended to reflect and clarify that members will not be able to vote on matters where they is actual or potential conflict. To take this point further, it can also be proposed that in certain cases, members of the Pharmacy Board can participate in deliberations and even vote, where they declare their interest and the Pharmacy Board determines that further to such declaration of interest, the 'potentially conflicted members' may nevertheless participate and/or vote. Specifically and for instance, the Pharmacy Board may have a register of interests where the actual or potential interests of its members are declared and managed for the benefit of the Pharmacy Board and enhance the level and quality of its deliberations and decisions.

10. In light of the above, there may be a case for a review and amendment of the rules of the Pharmacy Board to reframe its governing principles and internal functionality.

Under paragraph 5.4 of the Conclusion and Recommendations

11. We agree with the contents of paragraph 5.4 and comment that if the recommendations are followed, this will bring transparency and predictability.

Under paragraph 5.5 of the Conclusion and Recommendations

12. The analysis which is set out therein is based on a comparison with international reference pricing as defined in the Report which relates to sales to non-profit organizations and is therefore not applicable for the purposes of the Report.

13. We further comment that the recent rise in prices for pharmaceuticals is due to a number of factors including the major depreciation of the Mauritius Rupee with respect to major currencies of imports (USD/EUR) and the rise in the cost of freight (due to the pandemic). The prices will normalize if the currencies and the freight revert to pre-COVID era.

Under paragraph 5.6 of the Conclusion and Recommendations

14. Wholesalers and Retailers have different business models, operations, functionalities and constraints.

15. Currently Wholesalers work on a gross mark-up of 11% based on the landed costs. This mark-up is insufficient to support the costs of the operations of wholesalers which as previously explained go beyond the simple and unique scope of selling pharmaceuticals on a wholesale basis and embrace a whole set of operations and activities.

16. The mark-ups for wholesalers have been regularly reduced over the years. Businesses need adequate mark-ups in line with other normal businesses, to survive.

17. The pharmaceutical industry is a regulated one with a maximum mark-up system of price control; so a regressive mark-up is unwarranted. The price increases are due to external factors independent of Importers/wholesalers and in fact, are tantamount to increasing financial resources required to import, store and distribute their stock.

18. Importers/wholesalers source their products directly from the manufacturers and thus benefit from their international prices applicable to Africa.

19. To cater for the increasing cost of health care in Mauritius due to external factors, the Government should expedite the implementation of the proposed medical insurance scheme for the civil service and that the private sector should be incentivised to do the same. This will create an awareness for people to save for their present and future health care costs and ensure affordability.

20. Mauritius is a mature market with already a range of innovated drugs and generics available. Please refer to the table set out in Annex 1.

Under paragraph 5.7 of the Conclusion and Recommendations

21. We agree with the analysis with regard to the impact of the exchange rate. Attention is drawn that major depreciations of the Mauritius Rupee against USD and EUR as well as the rise in the cost of freight compared to the pre-Covid era which have impacted drastically on the price of pharmaceuticals in Mauritius.

Under paragraph 5.8 of the Conclusion and Recommendations

22. Please refer to our comments at our consolidated paragraphs 38 to 47 on parallel import.

Under paragraphs 5.9 to 5.12 of the Conclusion and Recommendations

23. We are agreeable to the recommendations of the Report.

Under paragraphs 5.13 and 5.14 of the Conclusion and Recommendations

24. The fixed mark-up system has been applied for a long time in Mauritius and probably generates the minimum revenue which enables businesses in this sector to be viable; there is no reason to review it. As mentioned above, the market is already mature with a mix of originator brands and generic medicines, as shown in Annex 1.

Under paragraphs 5.15 and 5.16 of the Conclusion and Recommendations

25. It is already a fact that wholesalers and retailers operate on a very low mark-up which affects their profitability. As shown in Annex 1, there is already a good mix of originator and generic medicines available on the market at different prices to ensure affordability of drugs in Mauritius.

26. There is already a price-control mechanism in Mauritius which is operated by the Ministry of Commerce and they monitor prices.

Under paragraphs 5.18 to 5.21 of the Conclusion and Recommendations and with regard to the proposed enabling of parallel import of pharmaceutical products generally

27. In the Mauritius context and as understood, parallel imports, if authorized, will relate to pharmaceuticals produced or sold abroad with the consent of the owner of the applicable intellectual property right (the 'IP Right') which are intended to be imported in Mauritius without the consent of the owner of the IP Right.

28. In light of the above and as a consequence of the above, pharmaceuticals imported through the parallel import route would originate from wholesalers and their agents but not from the manufacturer/IP Right owners.

29. The concepts of quality and traceability are critical for optimal control and treatment of patients affected with different pathologies since pharmaceuticals relate to public health. Pharmaceuticals which are brought to Mauritius through parallel import must adhere to requirements of quality, criticality and traceability.

30. Under the Pharmaceutical Products (Fees) Regulations 2016 (the '**Regulations**') a registration and annual renewal fee must be paid by the trademark owner to obtain the registration with the Pharmacy Board the introduction of their brands in Mauritius and maintain it on the register of brands that can be imported in Mauritius. The applicable and relevant registration documents need to conform to international guidelines and should be in the common technical document ('**CTD**') format with various modules in terms of criteria which include efficacy, quality, safety, stability, bioequivalence (for generics).

31. Mauritius has adopted a national exhaustion IP regime allowing owners of registered trademarks to withhold their consent with regard to parallel imports of registered pharmaceutical products.

32. In the event that duly registered pharmaceutical products in Mauritius would be considered to be brought to Mauritius through parallel import, consideration must be given to the following factors, bearing in mind the specifications of the pharmaceuticals:

a) The parallel importer must register the brands, submit CTD applications and pay the mandatory fees as per the Regulations.
b) The wholesaler/agent from abroad should submit certifications that they can export the products (issued by the drug regulatory authority of their country of origin/manufacturer) and that they adhere to GDP/ GSP practices.
c) Traceability and liability should be guaranteed. If a patient suffers any adverse effects through the use of a pharmaceutical imported by a local parallel importer , the latter and/or the overseas wholesaler should be

liable for inherent defect in the product and the local parallel importer- for defect due to improper storage/distribution, as applicable. For manufacturers and their accredited distributors in Mauritius, the elements of traceability and liability are already guaranteed

d) Mauritius is in the climatic zone IV A and products which are sent by manufacturers ensure that tests are done, and products are stable under these conditions. Importing the same brands from wholesalers overseas do not necessarily guarantee stability of products under this climatic zone and could represent a potential risk to patients in case of non-adherence. Hence stability under the prevailing conditions in Mauritius would need to be shown.

e) Parallel importers must be able to show adherence and observance to procedures pertaining to Pharmacovigilance/ Product recalls-as these are important elements in the pharmaceutical supply chain process to ensure the safety of patients.

f) The manufacturer and their accredited local wholesaler/ distributor invest in creating awareness of the products to ensure that new products are brought in the market (after registration) so that Mauritius can benefit from innovative products. Furthermore, HCPs are kept abreast in terms of continuous education programs and clinical studies so that they take cognizance of new protocols for treatment. Importer/ distributor also invests heavily in their storage and distribution capabilities as per WHO GDP/GSP norms to ensure that the final product is delivered under the same optimal conditions as that received from manufacturer. Manufacturers regularly audit premises of their accredited distributors to ensure adherence to these norms to ensure safety of patients.

33. It will be unfair if parallel importers were allowed to operate without observance to the above principles and without incurring appropriate and applicable costs, as it is the case with existing regularized importers. This would ensure that quality, safety and efficacy of medication are be compromised.

34. Genuine sources of supply, therapeutic equivalence and authenticity are critical in evaluating the option of parallel imports of pharmaceuticals in Mauritius.

35. The market for pharmaceutical products must remain highly regulated because it relates to public health. To the extent that there must be a fair competition between importers of pharmaceutical products, all players must be subject to the same rules in their importation of pharmaceutical products. It is submitted that as from the time certain importers of pharmaceutical products may not be obligated to satisfy the same requirements – as this is understood for eventual parallel importers, this situation will undermine fair competition, which is precisely, in our view, what the Competition Commission must prevent.

36. To the extent that the Competition Commission must ensure fair competition, it must see to it that all operators in the pharmaceutical sector which fulfill the same roles and functions enjoy the same entitlements but are also subject to the same rules and requirements for the benefit of Mauritian patients.

ANNEX 1

Active Ingredient	Trade Name	Lab	Wholesaler	R.P per unit (Rs.)
Metformin 500mg Tabs				
	Glucophage	Merck	PNL/Unicorn/Mauritius Pharmacy/Anichem/Keenpharm	2.45
	Glyciphage	Franco-Indian	Pharmacie A.E.Patel & Co	1.16
	Marphage	MarsLife	PNL	0.95
	Metformin-CCM	CCM	Socimed	1.1
	Metformin-Denk	Denk Pharma	PNL/Anichem/Keenpharm	3.32
	Neomet	Neopharma	Phbusiness	2.83
	Sandoz-Metformin	Sandoz	Mauritius pharmacy	2.78
Losartan 50mg Tabs				
	Angilock	square	Pharmacie A.E.Patel & Co	5.26
	Cozaar	MSD	Unicorn/Scott Health/Anichem	8.07
	Losar-Denk	Denk Pharma	PNL/Keenpharm/Anichem	8.57
	Losartas	Intas	Ftm/Keenpharm	13.28
	Losatec	RPG	Unicorn	7.16
	Tacardia	Ashford	Curepharma	3.9
	Zaart	cipla	Scott Health	4
Salbutamol 2mg Tabs				
	ButoAsma	Aldo-Union	Scott Health	2.92
	Venteze	Aspen	Mauritius Pharmacy/Unicorn/ibl	1.64
	Ventolin	GSK	KeenPharm/anichem	1.1
Atenolol 50mg Tabs				
	Adco-atenolol	adcock ingram	unicorn	2.76
	Atenolol-Denk	Denk Pharma	PNL/Keenpahrm/Anichem	3.2
	Blokium	almirall	Scott Health	8.66
	Normaten	Xepa	Anichem	4.25
	Tenormin	Astrazeneca	Unicorn	15.95
	Tensig	Arrow	Scott Health	5.06
	Tredol	Deloris	Socimed	4.9
Amlodipine 10mg Tabs				
	Amaday	Ajanta	unicorn	9.8
	Amlibon	sandoz	IBL	11.4
	Amlo-Denk	Denk Pharma	PNL/Keenpharm/Anichem	11.1
	Amlopress	cipla	Scott Health/keenpharm/IBL	7.63
	Lofral	Mepha	Socimed	14.67
	Lomanor	Pfizer	PNL/IBL	19.36
Fluoxetine 20mg Caps				
	Fludac	cadila	Ftm/Keenpharm	10.45
	Flunil	intas	Ftm/Keenpharm	4.26
	Fluxil	Deloris	socimed	7.3
	Nuzak	cipla	keenpharm/scott health/ibl	9.7
	Prohexal	sandoz	Mauritius Pharmacy	8
	Prozac	lilly	PNL	21.96
	Salipax	mepha	Socimed	12.2
	Sandoz-Fluoxetine	sandoz	Mauritius Pharmacy	4.46
Omeprazole 20mg caps				
	gasec	mepha	socimed	34.57
	ocid	cadila	ftm/keenpharm/anichem	12
	omar	marslife	pnl	13.4
	omepren	bluecross	unicorn/keenpharm	10.39
	omilock	leben	curepharma	7.21
	risek	julphar	pharmatrade	15.35
	zep	sarabhai	scott health	6.33
Diclofenac 50mg Tabs				
	adiflam	leben	Curepharma	4.96
	rhumalgan	Lagap	mauritius pharmacy	2.25
	cataflam	novartis	ibl/unicorn/anichem/keenpharm	9.2
	sandoz diclofenac	sandoz	mauritius pharmacy/unicorn/ibl	6.55
	clofenac	hovid	anichem	1.2
	dicio-denk	Denk Pharma	keenpharm/pnl/anichem	4.08
	voltaren	novartis	ibl/unicorn/anichem/keenpharm	9.5
	diclorapid	NPI	patel	6.95
	diclowal	walter-Ritter	mauritius pharmacy	7.9
	dolotren	FaesPharma	scott health	5
	grofenac	grossmann	patel	16.87
	k-fenac	cipla	ibl/scott health	6.53
	k-flam	Neopharma	phbusiness	5.95
	olfen	acino	socimed	15.4
	remethan	remedica	pharmacie tropicale/Lemex	5.2
Amoxicilline+Clavulanic Acid 625mg tabs				
	acinet	charak	patel	10.8
	augmentin	gsk	mauritius pharmacy/ibl/unicorn	20.18
	augpen	emcure	mauritius pharmacy	15.93
	bactoclav	micro	Ftm/Keenpharm	11.7
	curam	sandoz	mauritius pharmacy/unicorn	12.85
	julmentin	julphar	pharmatrade	13.75
	rapiclav	ipca	mauritius pharmacy	25.9

	sandoz-coamoxyclav	sandoz	mauritius pharmacy/ibl	12.46
Metronidazole 500mg Tabs.				
	flagyl	sanofi	unicorn/pnl/anichem/mauritius pharmacy	13.65
	metrolag	lagap	mauritius pharmacy	4.55
	negazole	julphar	pharmatrade	4.35
	supplin	sandoz	mauritius pharmacy	6