

RESEARCH REPORTS

Dynamics of Import of Pharmaceutical Products into Maldives: A policy perspective analysis

FAZEEL NAJEEB

The Maldives National University

ABSTRACT *This article analyses some of the import dynamics of pharmaceutical products imported into Maldives. The objective is to inform policy discussion and development in this area. The analysis relied on import statistics and relevant regulatory authorities' data. The research finds that Maldives is heavily dependent on a single country for access to medicine (importing pharmaceutical drugs), and concludes that it is desirable to reduce this dependence as a matter of policy aimed at ensuring access to medicine and medicine security.*

Keywords: Pharmaceutical products; access to medicine; medicine security; import of medicine; medicine policy.

Introduction

Maldives depends on foreign countries for the supply of pharmaceutical products (the words, “pharmaceuticals”, “pharmaceutical products”, “products”, “drugs”, and “medicines” are used interchangeably in this article unless otherwise mentioned). According to Maldives Food and Drug Authority, the country depends on imports for the continuous supply of pharmaceuticals (Maldives Food and Drug Authority, 2023). As Maldives does not manufacture any pharmaceutical products, (World Health Organization, July 2014), this paper treats the import of pharmaceutical products as the country’s entire demand for these products.

Despite the importance, there appears to be a lack of published policy research on the import of pharmaceutical products into Maldives. This article aims to contribute to informing the development of policy in this area by analysing the import dynamics of pharmaceutical products imported into the country. This eliminates the need for having a predetermined hypothesis or specific research questions. Notwithstanding, this article analyses 1) the Approved Drugs Lists published by MFDA to establish what the manufacturing countries of the approved drugs are; and 2) import data of pharmaceutical products to identify the main import sources (countries) and patterns of import.

The analysis is based on import data as available on the Maldives Customs Service (MCS) website (customs.gov.mv/Statistics) between 2006 and 2022 (the reason for beginning with the year 2006 is because this is the earliest year for which data is published on the MCS website at the time of writing). Data was analyzed by

using MS Excel. The results of the analyses are discussed below in the respective sections in the context of the research objectives of the article.

As Maldives is a contracting party to the International Convention on the Harmonized Commodity Description and Coding System, MCS maintains import data in accordance with the Harmonized Commodity Description and Coding System, commonly known as the Harmonized System (HS) developed by the World Customs Organisation (WCO). Pharmaceutical products are coded under chapter 30 of HS (World Customs Organization, n.d.). Maldives acceded to this convention in July 2000 (World Trade Organization, 2016, p. 31).

HS is a multipurpose international product nomenclature which contains over 5,000 commodity groups, each identified by a six-digit code (World Customs Organization, n.d.). The first two digits indicate the chapter, the first four digits indicate the heading, and the six digits together indicate the HS code. This is illustrated in Table 1.

Table 1.
An example of HS codes and descriptions

Heading	HS code	Descriptions
30.04		Medicaments (excluding goods of heading 30.05 ,30.02 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.
	3004.10	- Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives
	3004.20	- Other, containing antibiotics

Source: World Customs Organization, 2023.

An HS Committee established under Article 6 of the HS Convention reviews the HS and updates the HS every 5-6 years (World Customs Organization, n.d.). The latest version published at the time of writing is HS Nomenclature 2022 Edition (World Customs Organization, n.d.). The preceding versions were HS 2017, HS 2012, HS 2007, HS 2002, and HS 1996. The MCS website does not make clear which version of the HS was used for a given year of import data.

A contracting party to the HS is allowed to append digits at the end of the six digits that are the minimum for description. The digits that a country appends may be used to provide additional product description beyond that given in the HS. However, even with appended digits a country may or may not provide additional description.

The MCS data is published at ten-digit level, appending four digits at the end of the minimum six digits prescribed in the HS. However, MCS does not always provide additional description to correspond to the four added digits. Table 2 provides an example.

Table 2.
An example of pharmaceutical imports data based on HS codes

HS code	HS description	Country of consignment	Unit	Quantity	CIF (mvr)	Rate
3004900012	Medicaments NES	India	NMB	158,622,400.00	308,445,637.34	0
3002410000	Vaccines for human medicine	U.S.	NMB	4,930.08	60,250,874.64	0
3004900011	Medicaments NES	India	LTR	457,715.62	49,409,808.91	0
3004900012	Medicaments NES	Sri Lanka	NMB	23,959,523.00	32,061,081.32	0
3004900012	Medicaments NES	Pakistan	NMB	15,801,092.00	29,587,100.09	0

Source: Maldives Customs Service, 2023.

In the left column, the HS code is given in ten digits, but the description given in the second column is undetailed. NES in the description column indicates that the product is *not elsewhere specified*. Country of consignment in the third column is the port country from where the shipment was originally shipped. It is not necessarily, but sometimes it may also be, the country of origin of the products. For example, while it is possible that products consigned from India are also products made in India, the country of consignment indicated as India does not necessarily mean that they were made in India; it simply means that the products were originally shipped from India. The unit column NMB is for number, and LTR for litre. Quantity is the total quantity of units for the given HS code and description. CIF (MVR) indicates that the import value is in Maldivian Rufiyaa and includes the cost of the products, insurance and freight. Rate is the import duty in per cent of the import value of the product.

Demand, Supply, and Regulation: A Literature Review

The degree of influence of the various factors that impact the demand for pharmaceutical products is likely to be market specific, and sometimes product specific. Thus, the factors that impact the demand for pharmaceutical products in, say Maldives, may not be the same as in, say the UK. However, since a discussion of such factors is not an objective of this article, the analysis in this article does not attempt to examine them.

An article on the demand for pharmaceuticals in the United States (U.S.) asserted that demand for pharmaceuticals is unique as it is determined by four parties: the patient, the physician, the insurer, and the pharmacist (Schweitzer & Lu, 2018). The patient is the direct consumer of drugs, the physician—often serving as the consumer’s agent—considers drugs as an input in the production of health for the patient, the insurer usually pays most of the cost of the drug that is purchased, and the pharmacist decides which version of a drug to dispense, fills the prescription and frequently provides the patient with health counseling and additional information on the drug’s action, administration and side effects.

An earlier empirical research found that three out of four patients who asked

a physician for a drug got it prescribed (Wosinska, 2002) as direct-to-consumer advertising impacted the choice probability albeit with two caveats. Firstly, the impact of promotions aimed directly at physicians was significantly higher, and consequently, advertising affected the treatment probability benefiting all competing brands. Secondly, advertising influenced demand only for drugs that had preferential status with the patient's insurer. Overall, the high ratio of fulfilled drug requests was driven less by the patient's influence than the physician's existing preference for the drugs.

Another research conducted in the U.S. providing empirical evidence affecting prices of new pharmaceuticals at introduction and after 4, 6 and 8 years, concluded that the most important factor that influenced the price was the therapeutic advance embodied in a new product (Lu & Comanor, 1998). Drugs invented with important therapeutic gains are priced two to three times higher compared to existing drugs for the same purposes. Drugs that largely duplicate the actions of currently available products are typically priced at comparable levels, and the number of branded substitutes has a substantial negative effect on launch prices. The study also concluded that duplicate drugs thereby play an important economic role in pharmaceutical markets.

A study on the average per capita retail pharmaceutical expenditure, which is a measure of demand, in OECD countries found that it increased from USD 308 in the year 2000 to USD 554 in 2018 (García-Goñi, 2022), albeit with significant differences among countries, from USD 1,220 (n 2017) in the U.S. to USD 251 in Mexico and USD 123 in Costa Rica (both in 2017). On average, pharmaceutical expenditures was 16.4 per cent of health expenditures but with sizeable differences across countries, from 18.6 per cent in Spain, to 16.7 per cent in Canada, to 7.6 per cent in the Netherlands, to 11.9 per cent in the UK.

One may assume that in a less developed country, corresponding numbers are likely to be lower. Although not exactly comparable, a study on the import of pharmaceutical products into Tanzania found that the import of human medicinal products totaled approximately USD 739 million from 2013 to 2016 (Wande, et al., 2019), with an average of USD 185 million per year. The country's population for these four years was 49 million in 2013, 51 million in 2014, 52 million in 2015, and 54 million in 2016 (Data Commons, n.d.), giving an average population of 51.5 million over the four years. Therefore, average per capita import of human medicinal products would amount to USD 3.6 million. It has to be noted, however, that this study was confined to importers of pharmaceuticals in the private sector supply chain.

During the above period, the private sector imported from 74 countries, with India, Egypt, Switzerland, U.S. and South Africa ranking the top five suppliers. In each of the four years, India was the top supplier, and for the four years combined, it accounted for 54 per cent of the total pharmaceutical imports, followed by Egypt as the second top supplier at a distant 12 per cent.

On the supply side, since the development of new innovative pharmaceutical products is a long and expensive process (Scott-Morton & Kyle, 2012) which, if successful, culminates in the entry of an original product to a market usually protected by a patent, the companies that have developed a product use their power over the market and the lack of substitutes, to seek high profits in order to compensate for the high costs of research and development.

On the regulatory side, the pharmaceutical industry is one of the most research-intensive industries (Scherer, 2000, pp. 1297-336). It is also one of the most regulated markets, mainly due to the prevalence of power which suppliers have over marks for pharmaceutical products.

Such supplier power transcends across their own boundaries, thanks to the obligations on countries that are members of the World Trade Organization, whose Agreement on the Trade-Related aspects of Intellectual Property Rights (TRIPS Agreement) requires the protection of their intellectual property rights at the borders of importing countries at the time of importing, and at domestic level as well (TRIPS Agreement Section 5, Articles 27-35). Nonetheless, the TRIPS Agreement also provides important flexibilities that may be more important to developing countries, particularly to those that have capabilities to produce generic drugs and to those that do not have such capabilities. One such important flexibility is what is commonly known as *compulsory licensing*, a term used to refer to a government allowing someone other than the right holder of a protected product to produce a patented product or process, without the consent of the right holder (Najeeb, 2019, p. 64).

Countries like Maldives, for example, that do not have any capability to produce pharmaceuticals may also benefit from this TRIPS Agreement flexibility since they are allowed to import products manufactured under compulsory licensing (TRIPS Agreement Article 31bis). The recent COVID-19 pandemic was an example of a situation where this flexibility was in effect both in producing countries and importing countries.

Medicine security, just like food security, is an important question particularly for countries like Maldives that do not have any capability to produce pharmaceutical products. Yet, how may a country approach to define medicine security?

A Google search for “medicine security” returned numerous results. At the top was a website that carried the following definition:

“Medicine security means that every clinic, health worker and patient – everyone – around the world has reliable, equitable access to the medicine and supplies they need to achieve good health.”
(Americares, n.d.)

The same search returned a result towards the bottom of the list with a link to a WHO web page entitled “Health security” (World Health Organization, n.d.). The page gave the following definition: “Global public health security is defined as the activities required, both proactive and reactive, to minimize the danger and impact of acute public health events that endanger people’s health across geographical regions and international boundaries.”

This should not prevent a country that does not have any capability to produce pharmaceuticals from developing their own approach to ensure that their people have uninterrupted access to medicine.

For Maldives, the Strategic Action Plan (SAP) 2019-2023 being pursued by the Maldivian government acknowledges that the weak and inadequate regulatory mechanisms, including poor enforcement of regulatory functions, limited capacity for quality assurance related to medicine and health services, are among other challenges that the health sector is experiencing (Government of Maldives, 2019, p. 104). SAP 2023 goes on to target, strategy and action levels to address this challenge. Target 2.4 states that “By 2023, Laboratory Capacity for quality testing

of medicines and medicinal products at MFDA is established” (Government of Maldives, 2019, p. 111). At strategy level, Strategy 2.3 speaks to “Enhance the functioning of MFDA to ensure that quality of pharmaceuticals meets international standards”, and at action level, Action 2.3b seeks to “Develop a monitoring and quality assurance mechanism for pharmaceutical drugs imported into Maldives to ensure internationally recognized standards of pharmaceutical quality and practice rational use of medicines” (Government of Maldives, 2019, p. 112).

A situation analysis on medicines in health care delivery in Maldives reported that private pharmacies were supplying most of the OPD medicines needed, as seen by 85-95% of all prescribed drugs being dispensed in all facilities visited by the study team (World Health Organization, July 2014). The document also reported that “MFDA has now created a database of all drug imports and for the first time an ABC analysis and price analyses can be done once the data is cleaned.” No such analyses, however, appear to have been published. A discussion of the domestic price of pharmaceuticals imported into Maldives is beyond the scope of this article (albeit it briefly mentions in subsection Price administration below) the existence of a price administration.

Regime for Import and Sale of Pharmaceutical Products in the Maldives

Import of pharmaceutical products is subject to Export and Import Act 1979 as amended by the 18th Amendment Act 2020 of Export and Import Act 1979.

At the time of the introduction of the HS into the Export and Import Act 1979 in the late 1990s, the import duty levied on all pharmaceutical products falling under chapter 30 of the HS was 5 per cent. This was reduced to 0% in the 9th Amendment Act 2011 of Export and Import Act 1979. The effective import duty on all products falling under chapter 30 remains at 0% at the time of writing.

However, approval of the Maldives Food and Drug Administration (MFDA) is required prior to importing (Article 6 of the Regulation on Medicine 2014/R-46 as amended by Regulation 2016/R-49 to Amend the Regulation on Medicine 2014/R-46). Sale of pharmaceutical products is also regulated by MFDA (Article 7 of the Regulation on Medicine 2014/R).

MFDA publishes an Approved Drugs List (AD List) which contains four lists categorised as List 1: Registered Product List; List 2: Primordial Products List; List 3: Pre-Authorisation List; and List 4: Radio Contrast Media (Table 3).

Table 3.

MFDA categorisation of pharmaceutical product lists

List	List category	List description	Notes	N.o. products in list
List 1	Registered Products List	These are pharmaceutical products registered and approved with full dossier submission. Product safety, quality and efficacy has been evaluated based on the submitted documents and certificates of the manufacture and the product.	Once registered and approved, it is the responsibility of the marketing authorization holder to provide all necessary information required and if there is any change in the product/ packaging etc., and to ensure that the product is available in the market.	1,711

List 2	Primordia Products List	These are the products that has been in the Approved Drugs List from the beginning as approved products but not registered with full dossier submission. These have been kept in the Approved Drugs List due to the unavailability of any alternatives, plus that these products are kept on the fact that it has been in the market for a long time.		1,199
List 3	Pre-Authorisation List	These are in generics. Pre-authorization has to be taken prior to importing. Pre-authorization is an approval taken to import these products. Approval is issued for one year.		1,978
List 4	Radio Contrast Media			13

Source: MFDA Approved Drugs List, number MTG/RE-AL/Li 0009/2022-0013, as updated on 13 Dec 2022.

Those included in List 1 are 1,711 products that are registered and approved with full dossier submission, and they have been evaluated for product safety, quality and efficacy, based on submitted documents and certificates of the manufacture and the product (Maldives Food and Drug Authority, 2022). Of the total in the list, 46% is manufactured in India. Over half the way below, 22% is manufactured in Malaysia. Together with these two countries, Pakistan (8%), Bangladesh (4%), the

UK (3%), Switzerland, Indonesia, and Sri Lanka (2% each) and Belgium (1%) are the top 11 manufacturers of pharmaceuticals in List 1 (Figure 1). Among others, there are 10 products whose manufacturing countries are not given.

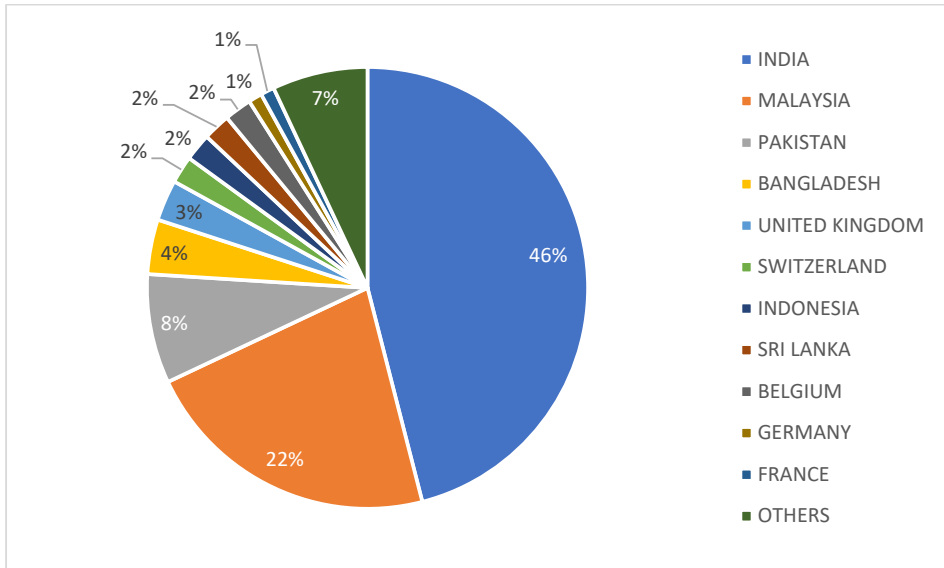


Figure 1. Top 11 manufacturing countries of pharmaceuticals in List 1

List 2 contains 1,199 products which have been in the AD List from the beginning albeit not registered with full dossier submission; these remain in the list due to the unavailability of alternatives, and also because they have been in the market for a long time (Maldives Food and Drug Authority, 2022). Of the total products in the list, 59% is manufactured in India, followed by Pakistan way below with 14% (Figure 2). Manufacturing countries for some 81 products in this list are not given.

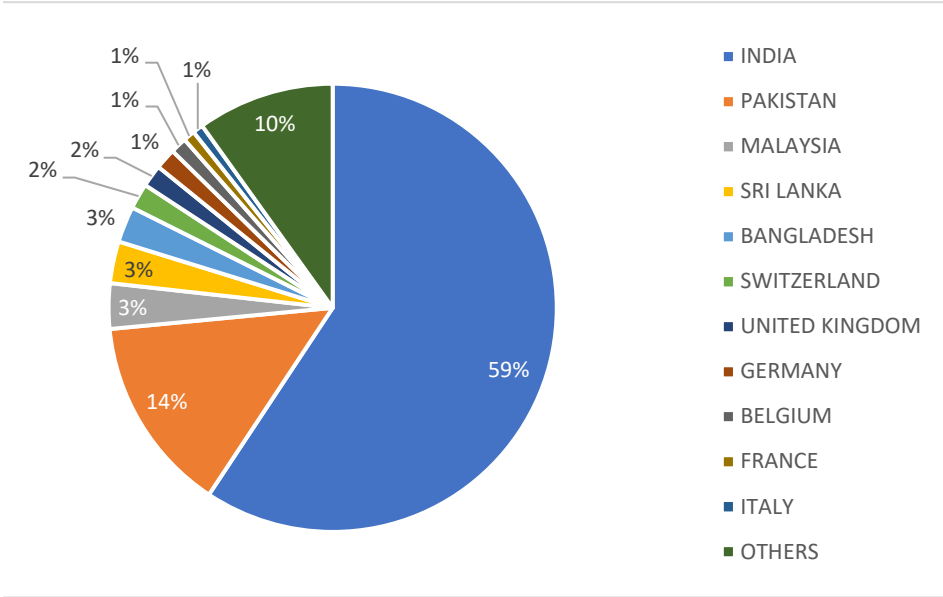


Figure 2. Top 11 manufacturing countries of pharmaceuticals in List 2

List 3, which is the longest with 1978 products, is for generics, for which pre-authorization is required prior to importing; approval is issued for one year (Maldives Food and Drug Authority, 2022). Of the total products, manufacturing country is named only for 372 products. Of the named countries, 85% of the products are manufactured in India, and 5% in Pakistan (Figure 3). Manufacturing countries for 1,606 products are not given.

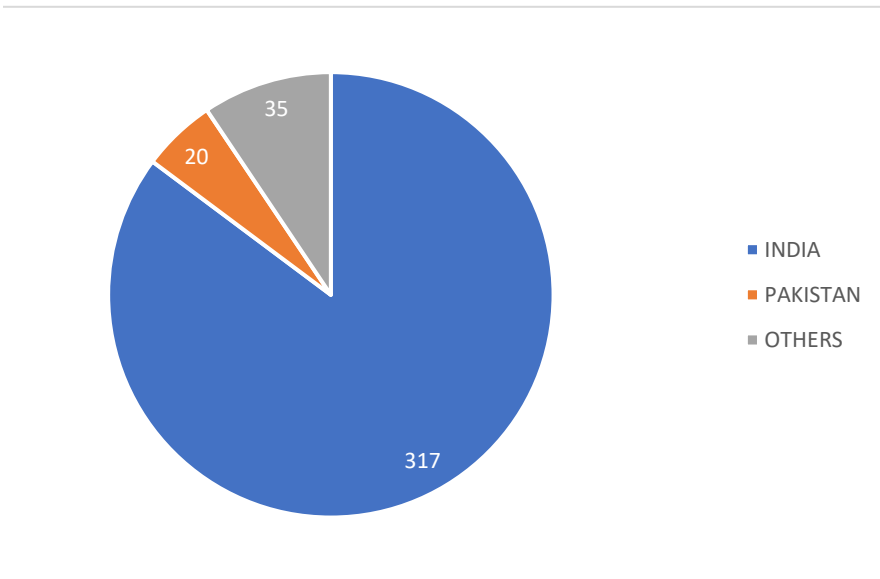


Figure 3. Manufacturing countries of pharmaceuticals given in List 3

List 4 is for radio contrast media contains 13 products with no mention of countries. Radio contrast media are the agents used to increase the contrast of an image, to enhance the visibility of internal structures in imaging technology. Radiocontrast media can be given orally or intravenously. The agents commonly used are barium-based (orally) and iodinated agents (intravenously) (Mahajan & Singh, 2019).

MFDA also publishes a National Essential Medicine (NEM) List, the latest update to which was made on 28 February 2023. It aims to act as a guide for facilities in formulating their essential lists according to their needs (Maldives Food and Drug Authority, 2023, p. 2).

Essential medicine is defined as “medicines that satisfy the priority health care needs of the population. These are medications to which people should have access at all times in sufficient amounts” (Maldives Food and Drug Authority, 2023). The NEM List sets out the following as objectives:

1. To safeguard the accessibility and affordability of essential medicines to the Maldivian population.
2. To *rationalize* [emphasis added as this is ambiguous, but is not explained in the document] the procurement of medicines and encourage the rational use of medicines.
3. The medicines in the appropriate dosage forms should be made accessible to individuals or communities, in appropriate quantities with guaranteed quality and at affordable prices.

The NEM List states that there are challenges in ensuring the continuous supply of pharmaceuticals. MFDA expects that:

“... through this list it can be ensured that essential medicines are rationally used and accommodate the increasing needs for accessing medicines. Medicine importers [are] require[d] to register essential medicines, which can guarantee that there is an uninterrupted supply of the listed essential medicines” (Maldives Food and Drug Authority, 2023, p. 1).

The document does not provide details about how the objectives are to be pursued. But it mentions that commitment by importers and pharmacies is “crucial” to ensure the uninterrupted supply of essential medicines.

Price Administration

Ministry of Economic Development (MED) used to administer prices of pharmaceutical drugs through a price administration regime maintained internally within MED itself. In Dhivehi, the term used was “*dakutaree beyhuge konturoal agu*”, which may be interpreted as “*the administered price of conventional medicine*”. The Export and Import Act 1979 also uses the term “*dakutaree beys*”. The regime was maintained as follows:

1. The price of conventional drugs sold by importers for prescriptions was capped at *import price (CIF or C&F) plus 50 per cent*.
2. The importer’s wholesale price to bulk purchasers was capped at *import price*

(CIF or C&F) plus 30 per cent.

3. The bulk purchaser's retail price for prescription drugs was capped at *wholesale price plus 15 per cent*.
4. CIF and C&F prices were determined by MCS.

While it is unclear if the regime was formally abolished, it does not appear to have been in practice since the old Consumer Act 1996 was replaced by a new Consumer Act 2020. Thus, it appears that domestic prices of pharmaceutical drugs are now left to be determined by importers, wholesalers and retailers themselves. However, the new Consumer Act 2020 does provide for the discretion to administer prices or quantities of goods and services (Chapter 10, Article 65(a) and 65(b) of the Consumer Act 2020).

Import of Pharmaceutical Products

Import of pharmaceutical products into Maldives shows a steady upward trajectory as shown in the trendline in Figure 4. As can be seen in Figure 4, imports increased from MVR 86 million in 2006 to MVR 832 million in 2022.

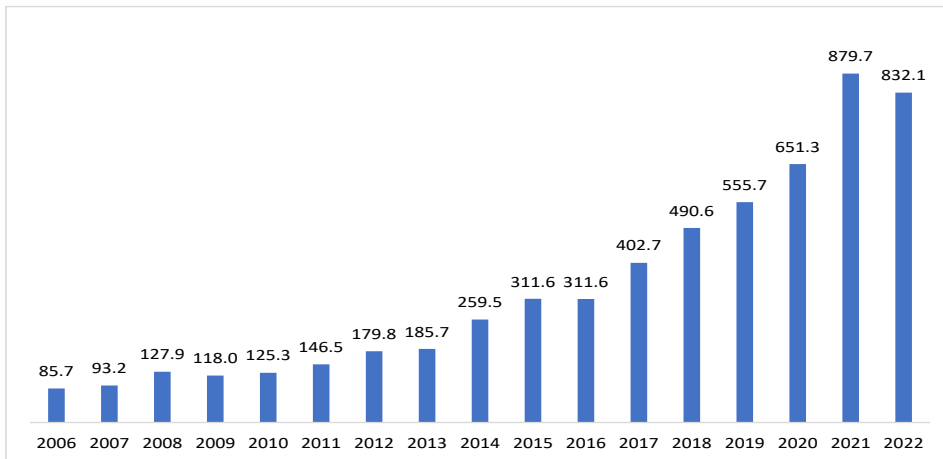


Figure 4. Import of pharmaceutical products, MVR million

On an annual basis, growth ranged from a negative of 7.7 per cent in 2009 to a peak of 39.8 per cent in 2014 (Figure 5), averaging 16.2 per cent per year.

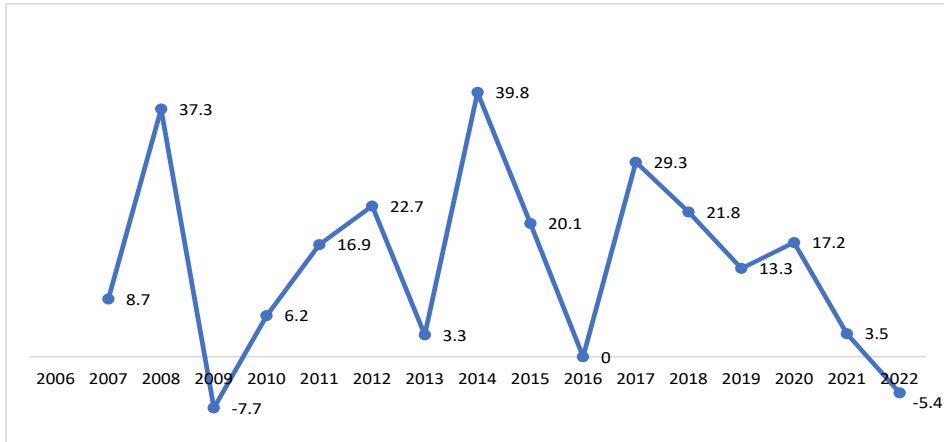


Figure 5. Annual change in import of pharmaceutical products, per cent

The volatility of the annual change in import of pharmaceutical products as depicted in Figure 5 does not give a true picture about the magnitude of change that has taken place since 2006. The import of pharmaceutical products has actually increased 871.4 per cent from 2006 to 2022 (Table 4). To better appreciate the magnitude of this change, one can compare this with the changes in total imports, government expenditure on health, and GDP for the same period. As Table 4 shows, between 2006 and 2022, total imports increased by 356.2 per cent, government expenditure on health increased by 552.7 per cent and GDP increased by 151.9 per cent. These numbers show that the increase in the import of pharmaceutical products has been disproportionately high. While it would have been desirable to understand why such increase has taken place, for example by examining variable indicators such as prescriptions written, which is likely to be the most influential on the import of pharmaceutical products, such data is not readily available, and collecting such data is beyond the scope of this article.

Table 4.
Contrast in increase in import of pharmaceutical products

	2006	2007	2008	2009	2010	2011	2012	2013	2014
Import of pharmaceutical products, MVR millions	85.7	93.1	127.9	118.0	125.3	146.5	179.8	185.7	259.5
Total imports (all goods), MVR million	11,859.5	14,032.5	17,760.1	12,368.5	14,017.5	20,486.2	23,884.6	26,634.9	30,649.2
Gov expenditure on health, MVR million	688.0	782.2	1,326.4	1396.2	990.9	368.3	296.7	1,391.7	1,866.0
GDP, MVR million	37,811.4	40,728.1	44,591.3	41,367.8	44,373.3	48,174.6	49,387.3	52,983.3	56,866.7

	2015	2016	2017	2018	2019	2020	2021	2022	Increase from 2006 to 2022, %
Import of pharmaceutical products, MVR millions	311.6	311.6	402.7	490.6	555.7	651.3	879.7	832.0	871.4
Total imports (all goods), MVR million	29,147.8	32,661.2	36,301.8	45,572.7	44,419.2	28,270.6	39,562.4	54,099.8	356.2
Gov expenditure on health, MVR million	2,526.0	3824.1	3,750.4	3,408.1	3,372.3	4,305.4	4,752.2	4,490.3	552.7
GDP, MVR million	58,507.1	62,215.4	66,701.1	72,119.3	77,238.0	51,368.8	72,812.8	95,241.1	151.9

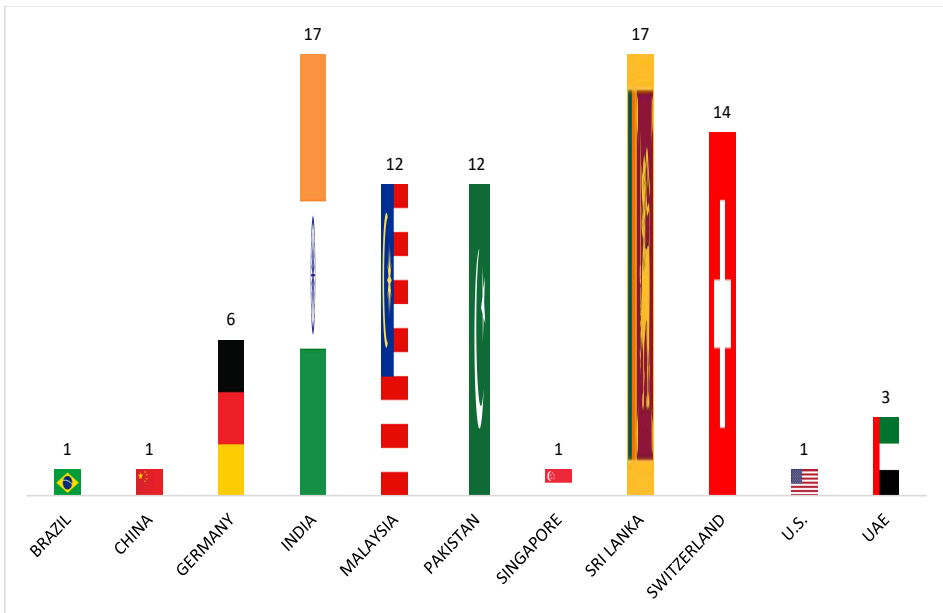


Figure 6. Frequency in which suppliers made the top five list

From 2006 to 2022, Maldives imported pharmaceutical drugs from a combined total of 66 countries. Out of this, 11 countries (Brazil, China, Germany, India, Malaysia, Pakistan, Singapore, Sri Lanka, Switzerland, U.S. and UAE) made the top five suppliers in terms of import value. Only India and Sri Lanka made the list every year (Figure 6). They were followed by Switzerland that made the list in 14 of the 17 years, Malaysia and Pakistan (12 each), Germany (6), UAE (3) and Brazil, China, Singapore and U.S. (each once).

Table 5.
Frequency in which countries were top five suppliers by rank

	1st	2nd	3rd	4th	5th
Brazil	0	0	0	0	1
China	0	0	1	0	0
Germany	0	0	3	2	1
India	17	0	0	0	0
Malaysia	0	0	0	3	9
Pakistan	0	0	5	5	2
Singapore	0	0	0	0	1
Sri Lanka	0	15	1	1	0
Switzerland	0	1	5	6	2
U.S.	0	1	0	0	0
UAE	0	0	2	0	1

India made the top supplier in all 17 years (Table 5). Sri Lanka was the second in 15 years and Switzerland and the U.S. were the second in 1 year each. Pakistan and Switzerland were the third largest suppliers in 5 years each, followed by Germany as the third top in 3 years, UAE as the third in 2 years, and China and Sri Lanka as the third in 1 year each. The top fourth suppliers were Switzerland (6 years), Pakistan (5 years), Malaysia (3 years), Germany (2 years) and Sri Lanka (1 year). The top fifth suppliers were Malaysia (9 years), Pakistan and Switzerland (2 years each), Brazil, Germany, Singapore, and UAE (1 year each).

Imported product descriptions at HS code 10-digit level may be accounted in two ways: 1) as described by the number of unique codes; and 2) as enumerated by the number of times these products were imported. In 2006, the number of descriptions by unique codes was 64, and the number of times these products were imported was 290 (Figure 7). The corresponding numbers for 2022 were 60 and 372 respectively.

The number of code entries (i.e. all products imported) as described at the ten-digit HS code level totals 5,460, and the number of unique codes for all years is 1,135 between 2006 and 2022. Throughout all the years from 2006 to 2022, the total number of unique codes (i.e. the number of unrepeated product names) is 117.

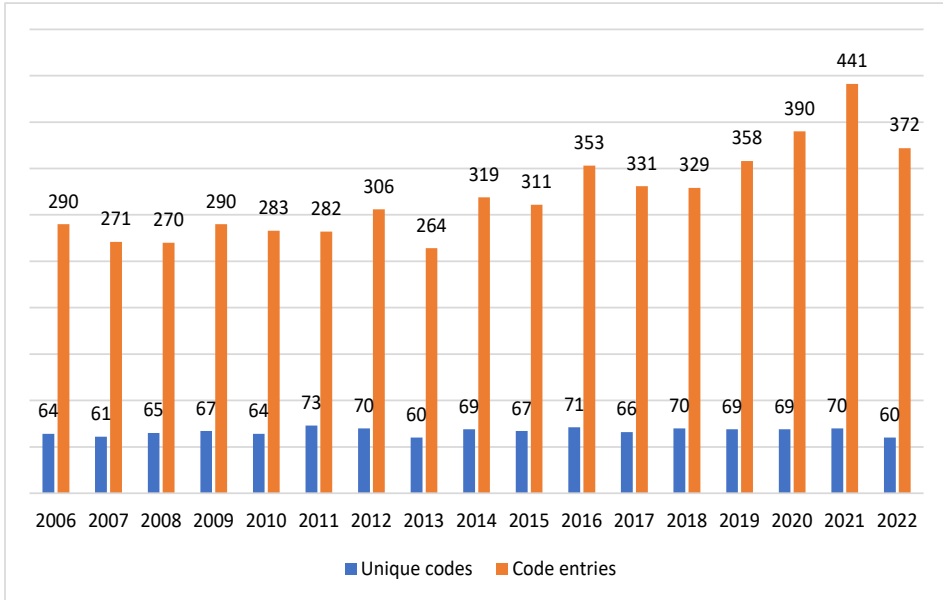


Figure 7. Number of products by all code entries and by unique codes

The top 10 imported pharmaceutical products each year totals up to 170 descriptions for all 17 years. The total includes 147 duplicate descriptions and when this is removed there are only 23 descriptions that are in the top 10 imports for all years. Out of these 23 descriptions the largest number of counts are for “Medicaments Nes” (Table 6), with no further description of the product albeit the item corresponds to a 10-digit HS code.

Table 6 also shows that the product description “MEDICAMENTS NES” has the highest total import value (MVR) for all the years, and its unit price is among the lowest. This is an item whose unit (not shown here) is published as “Kgs”. Table 6 also shows that the top 10 imported pharmaceutical products do not appear to be expensive products considering their unit prices shown here.

Table 6.

Unique product descriptions making up top 10 imports and their counts and import total in all 17 years

DESCRIPTION	COUNT	IMPORT VALUE, MVR	AVERAGE UNIT PRICE
Medicaments NES	44	3,103,632,122	5.01
Other medicaments of vitamins and other products	12	381,178,323	4.50
Medicaments of other antibiotics	11	170,982,503	6.05
Plaster (adhesive) for medical purposes	10	32,456,741	4.38
Dressings (adhesive) for medical purposes	11	82,609,846	6.40
Bandages (not adhesive) with pharmaceutical substances	11	24,569,742	6.11
Bandage (adhesive) medical	13	132,497,229	11.35

Medicaments of other hormones	2	2,423,545	4.29
Vaccines for human medicine	3	8,026,951	8.45
Gauze (not adhesive) with pharmaceutical substances	4	30,803,417	15.83
Materials for surgical sutures; laminaria; absorbable haemostatics	2	6,637,754	5.06
Vicks inhaler	8	14,590,825	6.98
Medicaments of insulin	4	34,999,331	10.83
Metered dose inhaler	2	2,659,240	12.34
Medicaments of adrenal cortical hormones	2	42,143,083	4.59
Medicaments of penicillins, streptomycins & derivatives	3	9,567,742	8.55
Strepsil	2	5,529,113	2.27
Balm	2	6,260,848	6.60
Adhesive dressings and other similar articles for medical purpose NES	6	212,529,010	14.26
Medicaments containing antibiotics	6	202,570,788	11.88
Other medicaments containing vitamins or other products of heading 29.36	5	271,158,062	5.89
Non-adhesive dressings and other similar articles for medical purpose NES	2	6,611,278	11.04
Other medicaments containing hormones or other products of heading. 29.37 NES	5	71,181,126	15.21
	170	4,855,618,619	

Conclusion

Maldives has to meet all its demand for pharmaceutical products by importing them because Maldives does not have any capability to produce and manufacture them.

Drug prices are an important factor for *access to medicine*, particularly in countries that do not have a pharmaceutical industry. Prices are also important in cases where the drug concerned is not covered under insurance in which case the patient must pay for the drugs they need. However, price is not the only factor that public policy officials should consider in pharmaceutical drugs policy. There are others.

The above analysis provided evidence that Maldives depends on a single country for meeting the bulk of the country's demand for pharmaceutical products. Such large dependence on a single source inherently involves risks as commonsense would inform. Therefore, diversification of sources of import may also be considered an important strategy in ensuring access to medicine and medicine security going forward. This is likely to require a comprehensive, in-depth study examining all aspects of demand, prices, quality of drugs, as well as the import and administration regimes, among possible others.

While the scope of this article did not include and therefore did not examine many possible issues related to the generation, maintenance and administration of data, it has been observed from data, both at MFDA and MCS, that there is room for improving the way in which data is presented and published. For example, it is impossible to relate the MFDA's AD List to MCS import data. Similarly, it is also

the case for MFDA's NEM List and MCS import data. The possibility to make these links is important in analysing the policy and regulation of pharmaceutical products.

Separate at these two institutions, there is also room for improving data. For example, among others, at MCS, given that data is published at HS 10-digit level, commensurate description details need to be provided.

Such matters are important to ensure the maintenance of at least sufficient analysis so that relevant policies can be informed and based on evidence.

MFDA may also consider issuing a schedule of publication which should give, among others the date on which the lists of approved drugs are to be published during the year, for example, quarterly on the last day of the month following each quarter.

References

- Americares. (n.d.). *Medicine Security: Americares*. Retrieved February 27, 2023, from Americares Web site: <https://www.americares.org/what-we-do/medicine-security/>
- Data Commons. (n.d.). *Place Explorer: Data commons*. Retrieved March 30, 2022, from Data Commons Web site: <https://datacommons.org/place/country/TZA>
- Dudovskiy, J. (2022, January 11). *Research Methodology*. Retrieved July 5, 2022, from Research-Methodology Website: <https://research-methodology.net/research-methodology/types-literature-review/>
- García-Goñi, M. (2022, September). *Rationalizing Pharmaceutical Spending*. IMF Working Paper WP/22/190. Washington, DC: International Monetary Fund.
- Government of Maldives. (2019). *Strategic Action Plan 2019-2023*. Malé, Maldives: President's Office.
- Lu, Z. J., & Comanor, W. S. (1998). *Strategic Pricing of New Pharmaceuticals*. *Review of Economics and Statistics*, 80 (Feb)(1), 108-118.
- Mahajan, R., & Singh, P. (2019). *Radiocontrast Media: Applications and Concerns*. *International Journal of Applied Basic Medical Research*, 191-192.
- Maldives Customs Service. (n.d.). *Customs Statistics*. Retrieved 2022, from Maldives Customs Service Web site: <https://www.customs.gov.mv/Statistics>
- Maldives Food and Drug Authority. (2022, December 13). *MFDA Approved Drugs List, number MTG/RE-AL/Li 0009/2022-0013*. MFDA.
- Maldives Food and Drug Authority. (2023, February 28). *National Essential Medicine List 2023*. Malé, Maldives: MFDA.
- Najeeb, F. (2019). *The TRIPS Agreement: A contextual analysis of key rights and obligations*. Malé, Maldives: Novelty Printers and Publishers.
- Scherer, F. M. (2000). "The Pharmaceutical Industry," *Handbook of Health Economics*, Vol. 1.
- Schweitzer, S. O., & Lu, J. Z. (2018). *The Demand for Pharmaceuticals*. In S. O. Schweitzer, & Z. John Lu, *Pharmaceutical economics and policy : perspectives*,

- promises, and problems (3rd edn) (pp. 145-170). New York: Oxford University Press.
- Scott-Morton, F., & Kyle, M. (2012). Chapter Twelve – Markets for Pharmaceutical Products. In *Handbook of Health Economics*, Vol. 2 (pp. 763-823).
- Wande, D. P., Sangeda, R. Z., Tibalinda, P., Mutta, I. K., Mkumbwa, S., Bitegeko, A., & Kaale, E. (2019). Pharmaceuticals imports in Tanzania: Overview of private sector market size, share, growth and projected trends to 2021. *PLOS ONE*.
- World Customs Organization. (n.d.). HS Nomenclature 2022 Edition. Retrieved March 31, 2023, from World Customs Organization Website: <https://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs-nomenclature-2022-edition/hs-nomenclature-2022-edition.aspx>
- World Customs Organization. (n.d.). Nomenclature and Classification of Goods: Overview: What is the Harmonized System (HS)? Retrieved November 20, 2022, from WCO Web site: <https://www.wcoomd.org/en/topics/nomenclature/overview/what-is-the-harmonized-system.aspx>
- World Health Organization. (n.d.). Health security: WHO. Retrieved February 27, 2023, from WHO Website: https://www.who.int/health-topics/health-security#tab=tab_1
- World Health Organization. (July 2014). *Medicines in Health Care Delivery: Maldives Situation Analysis: 26 May - 5 June 2014*. New Delhi: World Health Organization, Regional Office for South East Asia.
- World Trade Organization. (2016). *Trade Policy Review - Maldives: Report by the Government*. Geneva: World Trade Organization.
- Wosiska, M. (2002, October). *Just What the Patient Ordered? Direct-to-Consumer Advertising and Demand for Pharmaceutical Products*. Harvard Business School Marketing Research Papers (No. 02-04).