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An Assessment of Regional Pharmaceutical Pricing Policies

Final Report—February 20, 2020

Stax

This report has been privately commissioned for the perusal of Sri Lanka Chamber of the Pharmaceutical Industry (SLCPI) and its stakeholders. The policy review herein is based on secondary research carried out by Stax on seven reference countries, namely India, Bangladesh, Malaysia, Thailand, UAE, Turkey and Vietnam, as proposed by SLCPI.

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Pharmaceutical Pricing Policy Assessment in Regional Countries

Executive Summary

Stax was commissioned by the Sri Lanka Chamber of the Pharmaceutical Industry (SLCPI) to conduct a review of pharmaceutical pricing policies in regional countries. Over a 1.5-week engagement, Stax conducted secondary research on seven countries in the region to understand and highlight successful aspects of drug pricing policy in the context of each country's local health system.

Key considerations in formulating a mutually beneficial pricing policy include:

1) Pricing Formulae

The formulae used to calculate price ceiling of drugs plays a critical role in the pharmaceutical industry. If the price ceiling of a drug is too high, then there is room for excess profit for pharmaceutical companies at the expense of the patient. However, if price ceilings are too low, then while the patient may immediately benefit, manufacturers will be unable to maintain required quality levels at a distressed price point and will exit the market, leaving room for sub-standard and counterfeit brands to enter the market, which ultimately affect the patient negatively. The most common price ceiling formulae are cost-plus pricing, external reference pricing and market-based pricing:

	Cost Plus Pricing	*External Reference Pricing (ERP)*	*Market Based Pricing*
Overview	A pricing mechanism which considers the production cost and allowances for promotional expenses, manufacturers' profit margins, and charges & profit margins in the supply chain	ERP uses the ex-manufacturers' price (or another common point within the distribution chain) of the pharmaceutical drug in one or several countries to derive a reference price for the setting of the potential price in the given country. Reference prices can be assigned to single-sourced or multi-sourced products.	A mechanism which sets price ceilings based on the average of prices of drugs/ drug classes etc. Recently, countries such as India and China have moved towards less centralized, market-driven pricing control for their pharmaceutical sectors.
Merits	▪ Cost plus pricing is believed to stabilize drugs.	▪ With minimal price revisions, prudent selection of medicinal basket size and reference countries, also considering transaction prices, ERP is expected to be an effective mechanism to enhance equitable access to drugs and helps promote industry innovation.	▪ Market-based pricing is relatively easy to develop and roll-out when compared to other mechanisms which consider several factors and variables.
Criticism	▪ As per WHO guidelines, countries are generally not expected to use cost-plus as an overall	▪ A key risk in the incorporation of ERP mechanism is the incorrect use of reference countries for benchmarking— i.e., countries with significantly different market	▪ Pharmaceutical companies in countries with a market-based pricing mechanism may discontinue or reduce production capacities of price-controlled drugs and shift

	pharmaceutical pricing policy.	dynamics and prices— which could potentially lead to inflated prices.	manufacturing focus to more lucrative drugs, which could potentially lead to lower competition or regional shortages.
	▪ While the formula may seem clear to implement, determining the manufacturers' costs can be deemed challenging, and would require periodic reviews of the mechanism to mitigate any risks involved with the policy.	▪ Prices published under such a system may not always reflect actual prices as many could be negotiated or conceal rebates, based on the legal structures in place. Countries using ERP may not always be aware of whether the published prices are actual or special/ adjusted rates.	▪ While price controls are enacted to lower medical spending, companies who were ex-ante pricing below the price ceiling are not required to lower their prices, meaning the most price-sensitive consumers do not necessarily benefit.

India adopted market-based pricing since their 2013 drug price control order, before which they were using cost-plus pricing to determine price ceilings. The cost-plus pricing was adopted in 1979 in India during a period of industrial licensing and import controls, when the pharmaceutical industry was in a nascent stage. Cost-plus pricing does not recognize costs incurred for R&D and export market development, and generally favors importers of drugs as the landed cost cannot be investigated the way a manufacturer's cost can.

Furthermore, in a heterogenous domestic industry, cost-plus pricing does not provide a level playing field to all players in the market. Such price ceilings are either unfair or too liberal. Wherever it is unfair, companies find it difficult to sustain production and make profits—potentially affecting the market negatively as some manufacturers adjust compositions to escape price control, curtail supply, or suspend production. Wherever it is liberal, it leads to abnormal and unfair trade margins at the patient's expense.

India's move to market-based pricing was positive as it allowed for free market forces to play a role in determining the price ceiling, as opposed to completely artificial price ceilings. Coupled with exemptions for patented drugs, processes or delivery systems, this move fostered domestic innovation.

However, market-based pricing has had its criticisms in that, the reduction in price was insignificantly small to benefit the patient—the prices of 43% of price-controlled formulations reduced by less than 10%. While prices may not have reduced drastically, such price ceilings are indicative of what the market is willing to pay.

The UAE, a heavy importer of pharmaceutical drugs, has been relatively successful in employing ERP to control its prices. What the UAE has got right with an ERP mechanism was that it has been significantly improved over time with regard to its design, specifically through a carefully thought out and an inclusive (considering views of all key stakeholders) process with minimal pricing revisions, a prudent selection of basket size and countries, and a consideration of transaction prices. When done right, ERP is an effective mechanism which enhances welfare, equitable access to medicines within countries, and helps promote industry innovation.

2) Framework for Price Revisions

While well formulated pricing policy is paramount, regulators need to craft a dynamic policy that accounts for macro and industry-specific changes so that price ceilings do not become irrelevant and counterproductive.

For example, in India, a key adjustment which promoted the entry of innovative drugs offered by multinational corporations was the 2019 adjustment for exemptions on price controls. Prior to the adjustment, exemptions were only provided on new drugs, processes and delivery systems which were **indigenously developed** and patented in India. In 2019, the constraint on local development was relaxed (for drugs only) so that innovative drugs which are developed

internationally are also exempt from price controls for the first 5 years in the country—providing patients with access to better drugs.

Additionally, price ceilings also need to be dynamic to update routinely to account for rising costs. For instance, Bangladesh, Turkey and India allow for annual increases/decreases to price ceilings based on inflation, pegged to the Wholesale Price Index. For a country whose pharmaceutical industry relies more on imports than domestic manufacturing, price ceilings may need to be adjusted to foreign exchange rates instead.

Furthermore, the mechanism for how routine changes are implemented is also pertinent. In Bangladesh and Turkey, drug suppliers must apply to their respective regulators in order to receive a price increase whereas in India, suppliers are able to increase prices without prior approval from the National Pharmaceutical Pricing Authority but must inform the NPPA of the change.

Finally, a pricing policy framework should also allow for extenuating circumstances, where a revision to a price ceiling would be pertinent. In December 2019, the Indian government raised the price of 21 formulations under price control by 50% due to the rise in prices of APIs from China.

3) **Fostering Innovation**

Price controls have the potential to hamper the development of innovative drugs, which is critical to the pharmaceutical industry. The development of originator drugs requires significant R&D investment which manufacturers will need to recoup if they are to enter the market. Hence, price controls must provide exemptions for innovation, both domestic and foreign.

India—under the drugs price control order, exemptions are provided for new drugs (local and foreign), new processes (locally developed) and delivery systems (locally developed) for the first 5 years after the product enters the market.

Additionally, drugs for treating orphan diseases are also exempt from price controls as access to affordable treatment is a challenge when it comes to orphan diseases. Prices are usually very high, many orphan drugs are rarely available in India, and Indian patients must import these drugs directly. Price controls on such drugs which require significant R&D investment would limit their local availability.

4) **Transparent and Clear Framework**

In order to ensure that all stakeholders including the patient are aware of which drugs are price-controlled and reasons for price controls, it is essential for regulators to develop a clear and transparent framework for price controls. Looking at regional pricing policies, several countries offer good examples of precise policy for each type of drug, transparency of prices and clarity on which drugs are price controlled and why.

Different policy for each drug type:

Pricing policies in India and Turkey are quite robust, elaborating on how price controls may vary depending on the type of drug (essential vs. non-essential, existing drug vs. new drug, branded vs. generic, formulation vs. API, etc.). Such policies leave no room for interpretation and provide a clear framework for price controls:

- India
  - Ceiling price of a scheduled formulation
  - Retail price of a new drug for existing manufacturers of scheduled formulations
  - Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition
  - Non-Scheduled Formulations (non-essential medicines)
- Turkey
  - Imported reference products
  - Manufactured reference products

- Imported equivalent products
- Manufactured equivalent products

Transparent prices made available to patients:

Countries like Bangladesh and Vietnam have introduced online portals where patients can access information on drugs they purchased, such as the maximum retail price, manufacturer name, brand name and generic name. The regulatory bodies collect information from pharmaceutical suppliers and validate the information periodically to ensure patients have access to real-time information:

- Bangladesh
  - Bangladesh's Directorate General of Drug Administration website includes a portal for its Allopathic Drug Database that provides patients with essential information relating to price, pack size, manufacturer name, brand name, and generic name for a specific drug.
- Vietnam
  - With the aim of achieving the 'National Strategy to Develop Pharmaceutical in the Period to 2020 and Vision to 2030', Vietnam established some new concepts such as the 'Drug Bank', a database which includes information on over 13.3K types of pharmaceutical drugs, and ~41K pharmaceutical producers, distributors, and pharmacists. Such initiatives are aimed at providing better awareness to the public on drug information, including the prices and level of quality, and finding healthcare establishments that meet the standards set in the Good Pharmacy Practice.

Clarity on which drugs are price controlled:

It is critical for all stakeholders to understand which drugs are price-controlled and why. India and Bangladesh offer examples of transparency into price-controlled drugs, via an essential list of medicines, as per WHO guidelines. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

- India
  - India publishes a national list of essential medicines (NLEM) highlighting formulations and all formulations from the NLEM are subject to price control. However, there are other drugs under price control which may not be on the NLEM. As per DPCO 2013, the Government may, in case of extraordinary circumstances and in public interest, fix the ceiling price or retail price of any drug, whether scheduled, non-scheduled or a new drug.
  - Furthermore, India has a clear and concise framework for what constitutes an essential medicine, including specific criteria for inclusion and deletion from the essential list
- Bangladesh
  - In Bangladesh, all price-controlled drugs are those that have been cited on the list of essential medicines.

5) Monitoring Drug Supply

While price controls are important to ensure that drugs are affordable to the patient population, pharmaceutical regulation should also monitor the supply and availability of drugs in case the supply is threatened by the applied price controls. For instance, if price ceilings are too low, a manufacturer may be tempted to either half manufacturing or limit supply in order to sustain profit margins.

In India, the Government monitors the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation. Any manufacturer of scheduled formulation, intending to discontinue manufacturing must issue a public notice and inform the Government at least 6 months prior.

In the interest of the patient population, the Government may direct the manufacturer to continue with required level of production or import for up to one year.

Additionally, the government has placed controls where no manufacturer or distributor can withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons and no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug.

Summary Tables

Country Snapshot

	Healthcare Exp— % of GDP	Healthcare Exp. per Capita, PPP	Domestic Private Health Exp. (% of CHE)	Domestic General Govt. Health Exp. (% of CHE)	Out-of-pocket Exp. (% of CHE)	Cvge. of Essential Health Services
India	3.7%	$242	73.55%	25.43%	64.58%	55%
Bangladesh	2.4%	$91	74.42%	17.96%	71.89%	48%
Turkey	4.3%	$356	21.56%	78.44%	16.47%	74%
UAE	3.5%	$2,546	27.52%	72.48%	18.57%	76%
Malaysia	3.8%	$1,053	49.51%	50.47%	37.60%	73%
Thailand	3.7%	$635	21.63%	78.14%	12.11%	80%
Vietnam	5.7%	$356	48.50%	47.43%	44.57%	75%
Sri Lanka	3.9%	$491	55.81%	43.09%	50.12%	66%

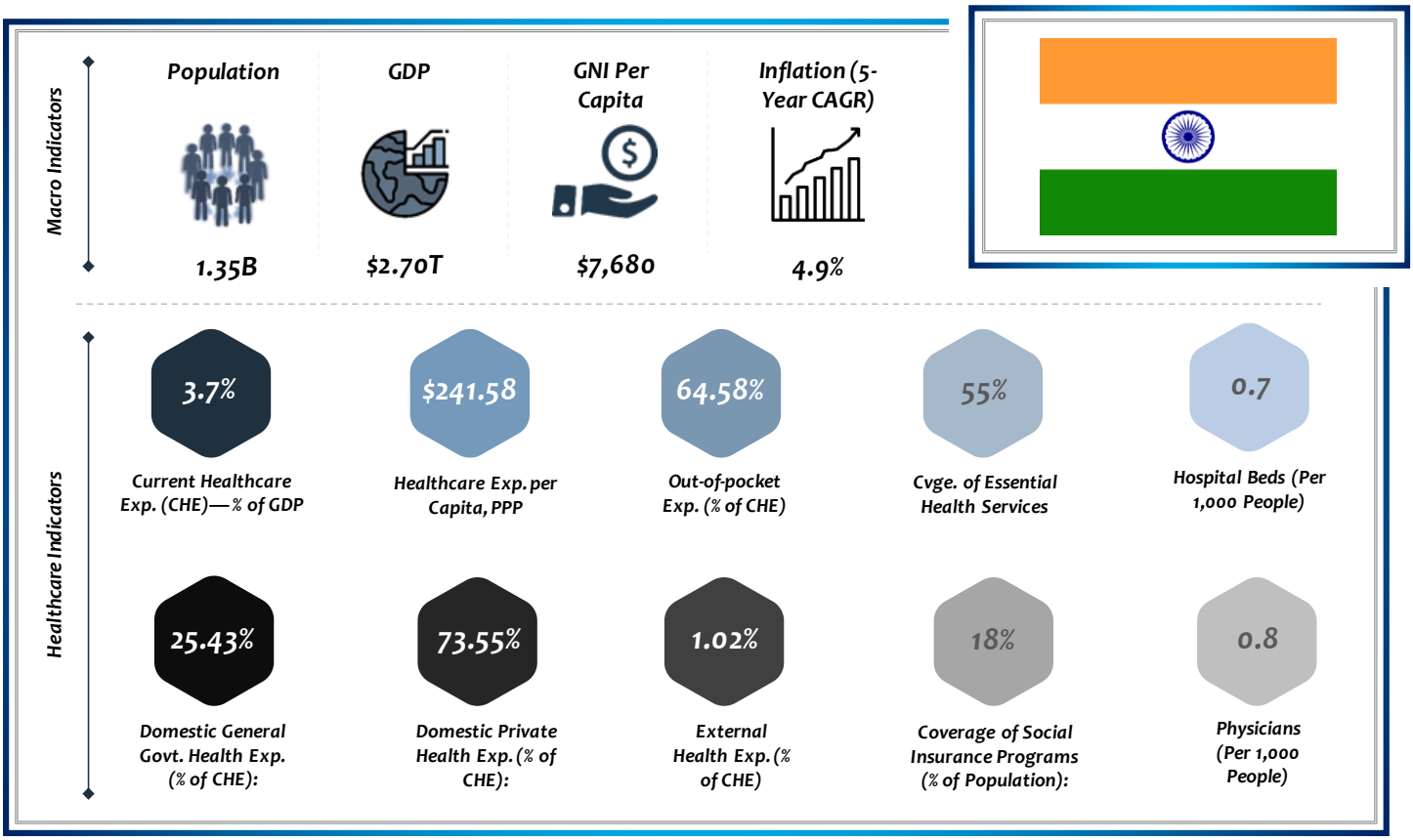
Price Control Snapshot

	Pricing Formulae (Private Sector)	*Description*	*Framework for Price Revisions*	*Merits*	*Demerits*
India	Market-based Pricing	Simple average of prices of all players with >1% market share	Annual revisions for inflation Provisions for revisions in extenuating circumstances	Positive Outlook for Domestic Manufacturing Promote R&D & Incentivize MNC Offerings Accurate Pricing Data	Profit Margins Still High Manufacturers Moving to Non-essential Drugs Increase in Frivolous Patents Arbitrary Price Hikes
Bangladesh	Cost-plus Pricing	Considers raw material and packaging cost with a markup	Annual revisions for inflation requiring prior approval	Stabilization of Drug Prices Increasing Affordability Across Income Levels	Significant Effort in Information Validation Potential for Low Quality Drugs Discourages Innovation Delay in Adjusting Prices
Turkey	External Reference Pricing	Reference Countries (France, Spain, Italy, Portugal, Greece)	Annual price revisions for inflation and exchange rate fluctuations	N/A	Drug Shortages Inability to Align with Current Market Conditions Companies Withholding Innovative Drugs
UAE	External Reference Pricing	Reference Countries (GCC, UK)	N/A	High Demand for Generic Drugs Balance Between Affordability & Innovation Healthcare Fraud on the Decline	Opposition for Controls Citing Conflict of Free Market Principles
Malaysia	External Reference Pricing (Proposed)	N/A	N/A	Advocation for Access to Affordable Drugs Transparency of Drug Prices at Multiple Levels of the Supply Chain Initiation of Detailed Studies Before the Enactment of Controls	Disparities in Countries Used as References in Mechanism Controls on Single Sourced Drugs Discriminatory Towards MNCs Difficulties in Covering Operational Expenditure Adverse Effect on Medical Tourism

Thailand	N/A	N/A	N/A	Focus on the Majority of Population Treated in Public Sector Considering Input from All Stakeholders in Pricing Policy	Proposed Price Controls May Limit Healthcare Investment and Innovation Thai Patients at Private Hospitals Do Not Need Price Controls
Vietnam	External Reference Pricing	Reference Countries (Thailand, Malaysia, Indonesia, Philippines, Cambodia)	N/A	Maintaining of Drugs below Consumer Price Inflation Minimizing Price Discrimination & Eliminating Price Gouging	Lack of Definition of Prices for International Comparisons Lack of Formula for Calculating the Declared Price Unclear Implementation of Retail & Wholesale Price Margins Inflated Prices

Country in Focus: India

Country Overview



Source: World Bank Data, Accessed February 2020

Healthcare Overview

The Indian healthcare system is categorized into public and private care. The Government healthcare system comprises of limited secondary and tertiary care institutions in key cities and focuses on providing basic healthcare facilities via a network of primary healthcare centers in rural areas. The private sector provides a majority of secondary, tertiary and quaternary care institutions with a major concentration in metros, tier I and tier II cities.

India is the largest provider of generic drugs globally. The Indian pharmaceutical industry supplies over 50% of global demand for vaccines, 40% of generic demand in the U.S. and 25% of all medicine in the U.K. The pharmaceutical industry was valued at $33B in 2017 and is expected to reach $55B by 2020. Pharmaceutical exports stood at $19B in 2019, up 11% from 2018.

Pricing Policy Overview

Governance Framework

Drugs (Prices Control) Order (DPCO)

Drug prices in India are controlled using the Drugs (Prices Control) Order (DPCO). The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 1955, which enables the Government to declare a ceiling price for essential and lifesaving medicines as per a prescribed formula to ensure that these medicines are available at a reasonable price to the general public.

The Order provides the list of price-controlled drugs, procedures for the fixation of prices of drugs, methods for implementation of prices fixed by the Government, penalties for contravention of provisions, etc.

The latest DPCO was issued in 2013 superseded the previous DPCO which was introduced in 1995.

Objectives of the DPCO:

- To ensure availability, at reasonable prices of essential and lifesaving and prophylactic medicine of good quality.
- To maintain adequate availability and to regulate the distribution of drugs—the government may direct any manufacturer of any API or formulation to increase production and to sell to other manufacturers or direct formulators, and to subsequently sell the formulations to institutions, hospitals or any agency.
- To promote the rational use of drugs in the country to encourage cost-effective production with economic sizes.

In order to inform the government on actions mentioned above, the government can call for information from manufacturers of APIs or formulations, as necessary and such manufacturers must furnish the required information.

National Pharmaceuticals Pricing Policy (NPPP)

In 2012, the Government finalized the National Pharmaceuticals Pricing Policy, which replaced the Drugs Policy of 1994. The NPPP's central objective is to promulgate the principles for the pricing of essential drugs as laid down in the National List of Essential Medicines that currently monitors and regulates prices of essential medicines in the country.

The NPPP seeks to regulate drug prices on the basis of essentiality of the drug through a market-based pricing (MBP) of formulations as opposed to regulating bulk drug prices through cost-based pricing (CBP) of bulk drugs under the previous Drug Policy of 1994.

Regulation of drug prices is on the basis of:

- Essentiality of drugs as specified under NLEM. This was done to abide by the Supreme Court's ruling which directed the Government to consider and formulate appropriate criteria to ensure that essential and lifesaving drugs do not fall out of price control.
- Regulating the prices of formulations only (Medicines which are used by consumers and not applicable to any upstream products such as bulk drugs or intermediaries), as opposed to regulation of both bulk drugs and their formulations under DPCO 1995.
- Fixing the ceiling price of formulations through Market Based Pricing (MBP) as opposed to cost-based pricing in DPCO 1995 as it is easier to obtain price data than cost data.

National List of Essential Medicines (NLEM)

Under the Essential Commodities Act, 1955, the DPCO gives power to the NPPP 2012 to regulate prices along with their specified strengths and dosages under NLEM 2011. There were 348 medicines listed in NLEM 2011. A total of 106 medicines have been added, and 70 medicines have been deleted to prepare the NLEM 2015 which now contains a total of 376 medicines. NLEM 2015 contains 870 net scheduled drug formulations spread across 31 therapeutic groups.

This does not mean that all drugs brought under price control are essential medicines. As per DPCO 2013, the Government may, in case of extraordinary circumstances and in public interest, fix the ceiling price or retail price of any drug, whether scheduled or non-scheduled or a new drug.

Year	# of Medicines on WHO Essential Medicines List	# of Medicines on NLEM
2003	331	354
2011	358	348
2015	414	376

Medicines in NLEM are listed with reference to the levels of healthcare; Primary (P), Secondary (S) and Tertiary (T). There are 209 medicine formulations listed for all three levels of health care (P, S, T), 115 medicine formulations for secondary and tertiary levels (S, T) and 79 medicine formulations for the tertiary level (T). While formulations of certain medicines are listed at different levels of care but are counted as one item—and the total number of medicines remains 376.

The essentiality of a medicine has also been considered in terms of its dosage form and strength.

The NLEM 2015 has been prepared adhering to the basic principles of efficacy, safety, cost-effectiveness, and considering those diseases which are public health problems in India—essentially a best fit list.

The criteria for inclusion of a medicine in NLEM are as follows:

- The medicine should be approved/licensed in India.
- The medicine should be useful in treating a disease which is a public health problem in India.
- The medicine should have proven efficacy and a safety profile based on valid scientific evidence.
- The medicine should be cost effective.
- The medicine should be aligned with the current treatment guidelines for the disease.
- The medicine should be stable under the storage conditions in India.
- When more than one medicine is available from the same therapeutic class, preferably one prototype / medically best-suited medicine of that class is to be included after evaluation of their relative safety, efficacy, and cost-effectiveness.
- Price of total treatment to be considered and not the unit price of a medicine.
- Fixed Dose Combinations (FDCs) are generally not included unless the combination has an unequivocally proven advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.

The criteria for deletion of a medicine from NLEM are as follows:

- The medicine has been banned in India.
- There are reports of concerns on the safety profile of a medicine.
- A medicine with better efficacy or favorable safety profiles and better cost-effectiveness is now available.
- The disease burden for which a medicine is indicated is no longer a national health concern in India.
- In case of antimicrobials, if the resistance pattern has rendered a medicine ineffective in an Indian context

National Pharmaceutical Pricing Authority (NPPA)

The pricing of drugs is administered under the provisions of the Drug Price Control Order (DPCO) and National Pharmaceutical Pricing Policy by the National Pharmaceutical Pricing Authority (NPPA) which is a part of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

The NPPA (National Pharmaceutical Pricing Authority) controls and regulates the prices of pharmaceutical drugs in India, and has limited authority to fix, review and justify pharmaceutical prices under the Drug Prices Control Order (DPCO), 1995. The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

According to the Chairman of the NPPA, the primary aim of the NPPA is to ensure adequate availability of essential and lifesaving drugs at affordable prices and in doing so, it carefully balances the interest of both the producers and the consumers.

Current Policies

Price controls are applicable to "Scheduled formulations", which are listed out in Schedule I of the Drug Price Control Order DPCO issued by the Government of India. Since 2013, scheduled formulations consist of the "Essential Medicines" declared by the Government through its NLEM.

Out of the INR 1.37T value of the overall pharmaceutical market in India, 18% is currently placed under price controls.

The current price-controlled drugs fall under the following therapeutic categories:

1. Anesthetic agents
2. Analgesics, Antipyretics, Nonsteroidal Anti-inflammatory Medicines, Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders
3. Antiallergics and Medicines used in Anaphylaxis
4. Antidotes and Other Substances used in Poisonings
5. Anticonvulsants/ Antiepileptics
6. Anti-infective Medicines
7. Antimigraine medicines
8. Antineoplastic, immunosuppressives and medicines used in palliative care
9. Antiparkinsonism medicines
10. Medicines affecting the blood
11. Blood products and Plasma substitutes
12. Cardiovascular medicines
13. Medicines used in dementia
14. Dermatological medicines (Topical)
15. Diagnostic agents
16. Dialysis solution
17. Disinfectants and antiseptics
18. Diuretics

19. Ear, nose, throat medicines
20. Gastrointestinal medicines
21. Hormones, other endocrine medicines and contraceptives
22. Immunologicals
23. Muscle Relaxants (Peripherally acting) and Cholinesterase Inhibitors
24. Medicines used in neonatal care
25. Ophthalmological Preparations
26. Oxytocics and Antioxytocics
27. Psychotherapeutics
28. Medicines acting on the respiratory tract
29. Solutions correcting water, electrolyte and acid-base disturbances
30. Vitamins and Minerals

Ceiling price of a scheduled formulation

The ceiling price of a scheduled formulation (for both imported and domestically manufactured drugs) of specified strengths and dosages under the first schedule is calculated using the following:

1. First, the average price to the retailer of the scheduled formulation, P(s) is calculated:

   P(s) = (Sum of prices to retailer of all brands and generic versions of the medicine having a market share more than or equal to 1% of the total market turnover) / (Total number of such brands and generic versions of the medicine having market share more than or equal to 1% of total market turnover on the basis of moving annual turnover for that medicine)

2. Thereafter, the ceiling price of the scheduled formation, P(c) shall be calculated as below:

   P(c) = P(s) x (1+M/100) where M (% retailer margin) = 16

The maximum retail price of scheduled formulations is fixed by the manufacturers based on ceiling price notified by the government plus local taxes wherever applicable.

Retail price of a new drug for existing manufacturers of scheduled formulations

1. If the new drug is already available in the domestic market, the retail price is calculated as above.
2. If not available in the domestic market, the price to the retailer is fixed by the Government "on the principles of the "Pharmacoeconomics" of the new drug", on the recommendation of a Standing Committee of Experts.
3. The retail price of such new drug shall be fixed by adding a 16% margin on the price to retailer.

The maximum retail price of a new drug is fixed by the manufacturers based on retail price determined by the government plus local taxes wherever applicable.

Ceiling price of a scheduled formulation in the event of no reduction in price due to absence of competition

When there are less than 5 manufacturers for a formulation who have 1% market share or more, and if there is no reduction in the average price to retailer as a result:

1. First the Average Price to Retailer of such scheduled formulation i.e. P(s) is calculated:

   $P(s) = P_m \times (1-(P_{i1}+P_{i2}+\dots)/(N*100)\}$ Where

P_m = Price to Retailer of highest priced scheduled formulation under consideration

P_i = % reduction in Average Price to Retailer of other scheduled formulations/strengths and dosage forms (varies depending on whether other strengths or dosage forms of the same scheduled formulation is available in the list of scheduled formulations or if there are other scheduled formulations in same subtherapeutic category)

N = Number of such other strengths or dosage forms or both in the list of schedule formulations

2. Thereafter, the ceiling price of the scheduled formation, P(c) is then calculated:

   P(c) = P(s) x (1+M/100) where M (% retailer margin) = 16

Non-Scheduled Formulations

The Government monitors the maximum retail prices (MRP) of all drugs, including non-scheduled formulations, and ensures that no manufacturer increases the MRP of a drug by more than 10% in a 12-month period. If a company violates this regulation, it must reduce their price to the level of 10% above the MRP for the next 12 months. In addition, the manufacturer is liable to deposit the overcharged amount along with interest and the penalty.

For non-scheduled formulations, the companies are at liberty to decide their margins.

Minimum Local Content Requirement for Publicly Procured Drugs

Since January 2019, the Department of Pharmaceuticals (DoP) decided to push "Make in India" in the pharmaceutical sector, setting out requirements on minimum local content in Indian pharmaceuticals, whether domestically manufactured or imported. The order will be applicable to procurement of medicines made by state governments or public sector units (PSUs) under state governments, or local bodies under centrally sponsored schemes.

For formulations that are not manufactured in India, the minimum local content was capped at 10% during 2018-19. An order by the DoP said that this will go up to 15% in 2019-21, 20% in 2021-23 and up to 30% in 2023-25 for formulations not manufactured in the country.

Additionally, the DOP's preference for public procurement programs in the pharmaceutical sector is to be given to domestically produced drugs with a minimum of 75% local content in 2018-19, which will go up to 90% by 2023-25, the DoP said in a notification

Availability of Drugs

The Government also monitors the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation.

Any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market must issue a public notice and also inform the Government at least 6 months prior to the intended date of discontinuation. The Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with a required level of production or import for up to one year from the intended date of such discontinuation.

No manufacturer or distributor can withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons. No dealer shall withhold from sale or refuse to sell any drug available to a customer intending to purchase such a drug.

Exceptions

The provisions of the DPCO shall not apply to:

1. A manufacturer producing a new drug patented under the Indian Patent Act, 1970 for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country.
2. A manufacturer producing a new drug in the country by a new process developed through indigenous research and development and patented under the Indian Patent Act, 1970 (process patent) for a period of five years from the date of the commencement of its commercial production in the country.

3. A manufacturer producing a new drug involving a new delivery system developed through indigenous research and development for a period of five years from the date of its market approval in India.
4. Drugs for treating orphan diseases as decided by the Ministry of Health and Family Welfare, Government of India.

A new drug for the purposes of the "New Drug Exemption" is a drug that has received marketing permission or approval from the Central Drugs Standards Control Organization ("CDSCO"). The permission/approval is given to the following kinds of drugs:

1. A drug, including a bulk drug substance, which has not been used in India to a significant extent and whose safety, efficacy and therapeutic value has not been established in India.
2. A drug which is already approved and is now proposed to be marketed with modified or new claims such as indication, dosage, dosage forms or route of administration.
3. A Fixed Dose Combination ("FDC") of two drugs individually approved earlier but which are now proposed to be changed for the first time or if the ratio of drugs in an FDC is sought to be changed.
4. All vaccines and Recombinant DNA (r-DNA) derived drugs, unless certified otherwise.

The patent law gives inventors 20 years of absolute ownership after which other manufacturers can produce and sell the same drug

Framework for Price Revisions

2019 DPCO Adjustments

New Drug Exemption

Prior to the 2019 revision, the scope of price control exemptions was limited to only those manufacturers who were producing patented new drugs that were developed through indigenous research & development and not produced elsewhere. The New Drug Exemption removed localization requirements associated with claiming the price control exemption.

Therefore, even importers and marketers of patented new drugs developed and manufactured outside India are now eligible for price control exemption for a period of five years from the start of its commercial marketing. Conversely, domestic manufacturers who manufactured patented new drugs in India and outside India have also become eligible for price control exemption, which was not the case earlier.

The Health Ministry noted that there had been a decline in R&D since DPCO 2013, resulting in fewer introductions in India. Post DPCO 2013, the average number of new introductions in DPCO molecules had declined, which also indicates increasing concentration and reducing competitive intensity.

Orphan Drug Exemption

Access to affordable treatment is a challenge when it comes to treating orphan diseases. Prices are usually very high, with some costing as much as $400K annually. Many of these drugs are rarely available in India, and Indian patients suffering from rare diseases must import these drugs directly.

Price controls on such drugs which are expensive and require significant R&D investment would not allow such drugs to be domestically available to patients which is why the exemption was welcomed.

However, prices for orphan drugs can vary considerably—e.g., the cost of treatment with enzyme replacement therapies can exceed $150K per treatment per year. The affordability of orphan drugs has become a major issue for payers and is thus a strong driver of tensions between different stakeholders.

Adjustments from Previous Policy Iterations

In the earlier DPCOs (those prior to DPCO 2013), NLEM was not taken into consideration for price fixation or price monitoring. Further, in the earlier DPCOs, only bulk drugs were mentioned in Schedule I and prices were fixed by the Government for both bulk drugs as well as formulations of these bulk drugs.

The NPPP 2012 envisages regulation of the prices of formulations only, identified based on essentiality of drugs. Further, the basis of fixing the ceiling price of formulations has been changed from cost based to Market Based Pricing (MBP) in NPPP 2012. Thus, as per NPPP 2012, the three aspects of the regulation of prices of drugs are as follows:

- Earlier policy was based on market share criteria, whereby prices were brought under control if there were possibilities of monopoly and cartelization, given the market share of companies producing it.
- Regulating the prices of formulations only (i.e., medicines used by consumers and not applicable to any upstream products such as bulk drugs or intermediaries), as opposed to regulation of both bulk drugs and their formulations under DPCO-1995
- Fixing the ceiling price of formulations through Market Based Pricing (MBP) as opposed to cost-based pricing in DPCO-1995 as it is easy to obtain price data than cost data. All the previous DPCOs, 1970, 1979, 1987 and 1995 were based on cost to manufacturers with allowance for post manufacturing expenses.

Adjustments for Inflation

The Government revises the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for the preceding year. Manufacturers may increase the maximum retail price (MRP) of scheduled formulations once a year, on the basis of the wholesale price index with respect to the previous calendar year, and no prior approval from the Government is required. In the case of a decline in wholesale price index, there would be a corresponding reduction in the MRP.

Adjustments for Changes in Revenue

The revision of ceiling prices based on moving annual turnover value shall be carried out:

- As and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order, whichever is earlier
- When the number of manufacturers of a scheduled formulation, whose price is 75% or more than the fixed ceiling price, has decreased by 25% or more.
- When the number of manufacturers of a scheduled formulation, whose price is less than 25% of the fixed ceiling price, has increased by 25% or more.

Extraordinary Circumstances

The Government may, in case of extra-ordinary circumstances, if it considers necessary to do in public interest, fix the ceiling price or retail price of any Drug.

Where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price irrespective of the annual wholesale price index for that year.

Merits

Positive Outlook for Domestic Manufacturing

- DPCO 2013 places price controls on drug formulations and not individual bulk drugs/APIs. Theoretically, this provides a positive outlook for API/Bulk drug manufacturing which had declined for years prior to 2013. The intended outcome, however, was not achieved immediately as several manufacturers of formulations began to import APIs from China instead.
- However, with the 2019 Department of Pharmaceuticals stating that preference for public procurement will be given to formulations with local content (both imported and manufactured), this has strengthened the outlook for local manufacturing, particularly of APIs.

Promote R&D & Incentivize MNC Offerings

- DPCO 2013 promotes R&D by offering price control exemptions to new drugs, new processes or novel drug delivery systems (NDDS) which are patented for 5 years from the date of commercial marketing/production/market approval respectively.
- For new processes and NDDS, exemptions are offered to those developed through indigenous/local R&D whereas for drugs, any new drug patented under the Indian Patent Act is exempt from price controls.
- This has also made the Indian market more attractive to multi-national pharmaceutical companies, encouraging them to introduce new drugs into India. In the past, India's price control regime has forced the exit of innovative products from India.

Able to Obtain Accurate Pricing Data

- The 2019 amendments to DPCO also allowed the Government flexibility to obtain drug price data, required under the DPCO for the purpose of price fixation, from any pharmaceutical market data specializing company the Government chooses.
- Earlier, drug price data had to be sourced exclusively from IMS Health. However, in practice, the NPPA was frequently relying on AIOCD-Pharmatrac data to fix prices. The NPPA has also developed its own in-house database of drug prices, called IPDMS, and this amendment allows the Govt. to rely on data from AIOCD-Pharmatrac, IPDMS or other sources it deems fit.

Demerits

Prices and Profit Margins Still High

- The Department of Pharmaceuticals noted in their annual report, instances of price differentials where certain branded medicines were 17 times costlier than their generic counterparts. In certain Indian states, prices have dropped by over 30% when drugs are publicly procured through an open tender, indicating the high profit margins still available to manufacturers in some cases.
- Since DPCO 2013, when market-based pricing was introduced to the Indian pricing policy, it was observed that price ceilings calculated this way, using a simple average, were higher than the market leader's price in several cases. This has brought MBP into question as to whether it in fact makes a significant impact and benefits the patient. Excerpts from annual reports of the Department of Pharmaceuticals highlight the percentage reduction in scheduled formations under DPCO:

% Reduction from Maximum Price	# of Formulations
0% – 5%	**218**
5% – 10%	**134**
10% – 15%	**94**
15% – 20%	**97**
20% – 25%	**89**
25% – 30%	**63**
30% – 35%	**44**
35% – 40%	**24**
Above 40%	**58**
Total Formulations with fixed prices	**821**

- The Competition Commission of India noted that retailers' margins are a primary cause for high drug prices.

- To review the DPCO 2013, Government of India formed an inter-ministerial committee, following the Supreme Court verdict in 2015 that termed the drug pricing policy as irrational and unreasonable. This committee, with representatives from DIPP (Department of Industrial Policy and Promotion), Ministry of Health, NPPA, and Department of Pharmaceuticals (DoP), was intended to examine the drug pricing mechanism.

Drug	Disease	Market-based Pricing (Weighted Average)	Market-based Pricing (Simple Average)	Cost-plus Pricing
Metformin	**Diabetes**	**Rs. 33**	**Rs. 35**	**Rs. 14**
Atorvastatin	**High blood cholesterol**	**Rs. 142**	**Rs. 127**	**Rs. 17**
Atenolol	**High blood pressure**	**Rs. 51**	**Rs. 38.50**	**Rs. 8**

Manufacturers Moving to Non-essential Drugs

Many manufacturers migrated to non-essential drugs (80% of total drugs are in the non-essential list) or stopped promoting essential drugs. Some pharmaceutical companies in India have started promoting different drug categories: non-National List of Essential Medicines (NLEM), FDCs (Fixed-Dose Combination, not on NLEM) and non-standard dosages (for instance, doctors routinely prescribe splitting of medicines).

Combination drugs are not covered (if a price-controlled drug is combined with one that is not price-controlled, the formulation will not be price-controlled)

Increase in Frivolous Patents

As 5-year exemptions from price controls are provided to drugs (developed locally or overseas), processes or delivery systems patented in India, pharmaceutical manufacturers are incentivized to create patented drugs, whether they truly benefit from the patent or not.

According to the DPCO, new drugs are defined as:

1. A drug, including a bulk drug substance, which has not been used in India to a significant extent and whose safety, efficacy and therapeutic value has not been established in India.
2. A drug which is already approved and is now proposed to be marketed with modified or new claims such as indication, dosage, dosage forms or route of administration.
3. A Fixed Dose Combination ("FDC") of two drugs individually approved earlier but which are now proposed to be changed for the first time or if the ratio of drugs in an FDC is sought to be changed.
4. All vaccines and Recombinant DNA (r-DNA) derived drugs, unless certified otherwise.

Arbitrary Price Hikes in Extraordinary Circumstances

The increase in price caps was criticized by healthcare activists.

"The one-time 50% price increase is arbitrary and lacks application of mind. The Government needs to put in place a system for monitoring API prices and fluctuations," S. Srinivasan, co-convener, All India Drug Action Network (AIDAN) said in a statement.

"This shows again the limitations of market-based pricing. Cost based pricing is best placed to deal with such price fluctuations."

Srinivasan also called for transparently laying out the method for arriving at the 50% price increase.

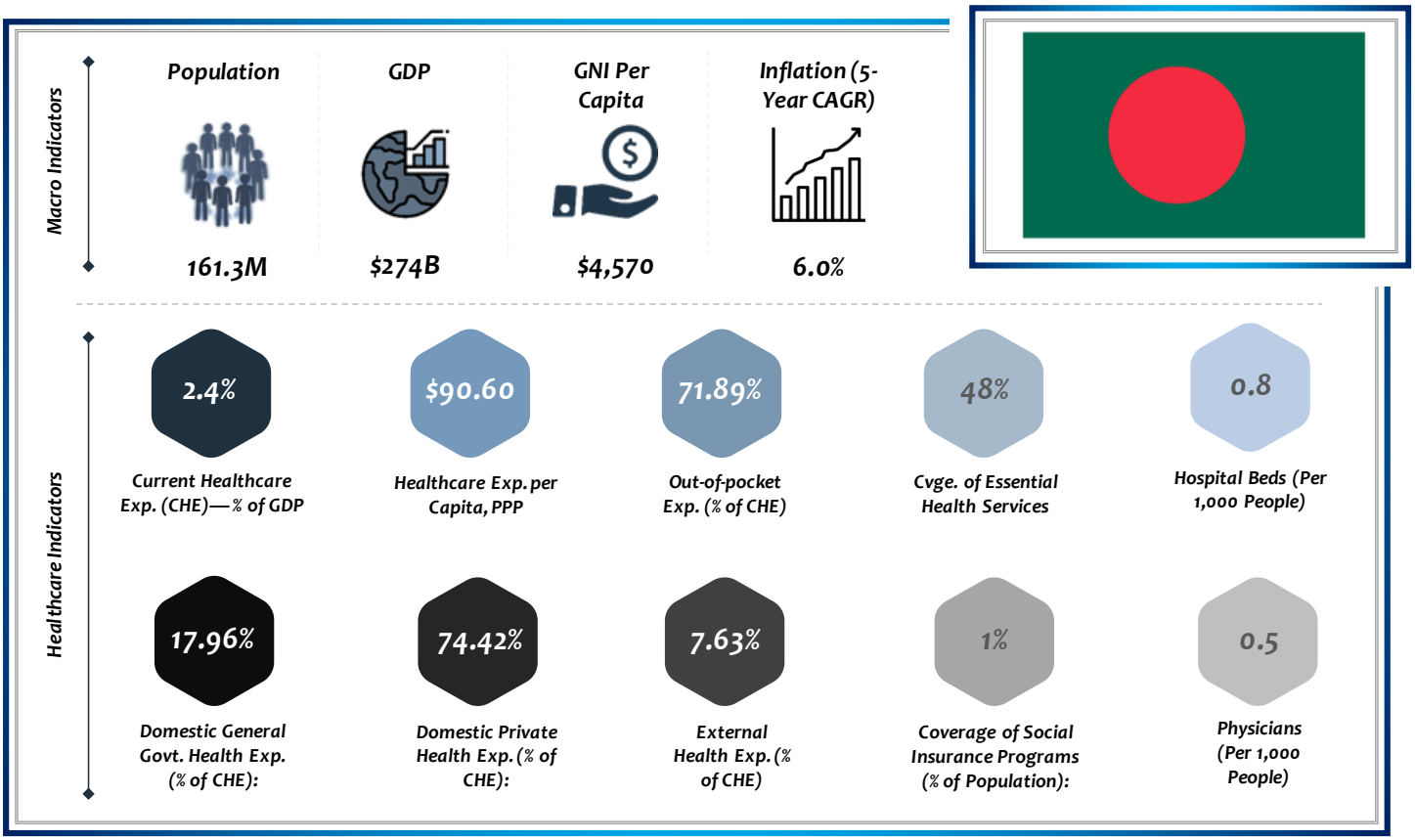
AIDAN is fighting a case in the Supreme Court against the government, wherein it has sought the use of cost-based pricing for capping prices of essential medicines instead of the market-based pricing currently used.

Bibliography

- "National Health Policies", Vikaspedia, February 2019
- "Drug Price Control Orders (DPCO)", Arthapedia, October 2015
- "Rise in imported API costs may lead to hike in drug prices", Business Line, February 2019
- "Pharma companies seek hike in drug rates under price control", The Economic Times, December 2019
- "Ceiling prices of 21 key medicines raised by 50%; NPPA invokes DPCO 2013", Business Standard, December 2019
- "Violation of drug price control order: Drug cos under NPPA lens for self-exemption from price cap", The Economic Times, December 2019
- "National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012)". The Gazette of India, December 2012
- "Department of Pharmaceuticals Annual Reports", Government of India, Accessed February 2020
- "Pharmaceutical Pricing Policy and Control: Indian Perspective", Asian Journal of Pharmaceutical and Clinical Research, Vol 9 Issue 6 2016.
- "Govt. forms committee to review drug pricing policy", The Hindu, November 2015
- "India lifts price caps on innovative and orphan drugs; major fillip for Big Pharma", The Pharma Letter, January 2019
- "Decision of Market Based Pricing of Medicines", Peoples Health Movement – India, November 2012
- "India's price control policy has destroyed drug manufacturers. This is how they can be saved", Sarthak Pradhan, December 2019
- "How Beneficial Is the Recent Price Control Exemption for Innovative Drugs in India?", Pharma Board Room, July 2019
- "Drugs (Prices Control) Order, 2013", Government of India Department of Pharmaceuticals, 2013
- "Report of the Core-Committee for Revision of National List of Essential Medicines November 2015", WHO, October 2015
- "Patented New Drugs and Orphan Drugs Out of Price Control in India", Mondaq, February 2019

Country in Focus: Bangladesh

Country Overview



Source: World Bank Data, Accessed February 2020

Healthcare Overview

Bangladesh has been making significant strides in developing their healthcare sector in recent years. As a means of minimizing the impact of healthcare expenditure, the Government is targeting to achieve universal health coverage by 2023—paying 70% of the medical expenses compared to the 26% paid in 2016. Additionally, the private sector has also advanced in the country and is becoming a critical supplier for the overall healthcare sector.

The local pharmaceutical sector has also transformed over the past four decades, moving from a largely import dependent sector to satisfy 98% of the country's demand in 2019. The pharmaceutical sector grew at a CAGR of 15.6% over the last 5 years and is expected to grow at an annual rate of 15% till 2023. Additionally, Bangladesh also increased its pharmaceutical export revenue to USD 130M in 2019, a 25.6% growth compared to 2018.

Pricing Policy Overview

Governance Framework

Bangladesh has made significant strides over the last four decades as a key pharmaceutical manufacturing destination. Having imported over 80% of its drug needs in the 1970s, Bangladesh has now progressed to locally manufacture ~98% of its drug demand. The National Drug Policy formulated in 1982 and the subsequent revisions in 2005 and 2016 have been the underlying policy frameworks governing the pharmaceutical sector through this evolution. While the focus of each policy has changed overtime—based on changes in the global and local pharmaceutical landscape—the fundamental considerations of all policies have been ensuring drug safety & quality, access to affordable drugs, and promoting local drug manufacturing.

National Drug Policy – 1982

The first drug policy of Bangladesh was focused on ensuring drug safety, quality, and the control of drug prices. Further, the policy also addressed the need to reduce dependence on imported drugs by enhancing capacities of local manufactures and providing assistance for raw material imports. The committee also identified a list of 150 essential drugs and established price controls to remove the price fluctuations in the market and ensure affordability across all income levels.

National Drug Policy – 2005

The 1982 Drug Policy was revised in 2005, considering the changes in the global pharmaceutical landscape. While the quality and affordable essential drugs remained as a key objective, the policy did not re-evaluate the list of essential drugs that are price controlled. At this point in time, the original list of 150 essential drugs were reduced to only include 117 drugs. Despite having initiatives to further strengthen the industry, the policy faced criticism that it supported manufacturers over consumers.

National Drug Policy – 2016

As the 2005 policy did not achieve the expected outcomes, the Government undertook the task of formulating a revised drug policy that protected the interest of consumers and also aligned the pharmaceutical sector to changes and opportunities, both locally and globally.

Objectives of the 2016 National Drug Policy

Overall, the 2016 policy is expected to facilitate the growth and expansion of the sector, enhance capabilities to produce higher quality drugs, and promote drug exporting opportunities for local manufacturers.

The main objectives of the drug policy are as follows:

- To ensure people can have easy access to safe, effective and good quality drugs at affordable prices.
- To ensure rational and safe use of drugs and proper dispensing.
- To achieve self-sufficiency in the manufacture of drugs and raw materials by providing services and facilities on a priority basis to all local drug manufacturing industries.
- To expand the export of drugs that are manufactured in the country.
- To establish an effective surveillance system of medicines.

Essential Drugs List

Bangladesh developed its first essential drug list in 1982, identifying 150 drugs considered adequate for most therapeutic purposes. These drugs were given preferential treatment in terms of licensing, import authorization, duties and other

financial benefits. Additionally, these drugs were subject to price controls to ensure affordable access to all consumers. This list was subsequently revised in 1994/95, reducing the list to 117.

The 2016 drug policy re-evaluated the list of essential drugs and recommended the preparation of separate drug lists for Allopathic, Ayurvedic, Unani and Homeopathic systems of medicine. Specifically, the policy states:

- *"To effectively protect the public health of the country, especially considering the emergency needs, affordability and accessibility of the majority of the people, separate "essential drug lists" have been published, selecting a few number of drugs from systems of treatment (Allopathic, Ayurvedic, Unani and Homeopathic) which exists in the country."*
- *As per WHO recommendations and opinions of experts of respective system of drugs, the lists will be updated every two years. The production and distribution of the essential drugs will be ensured as per the need."*
- *"To Adopt the fundamental principle of formulating the essential drug list nationally, a committee will be formed headed by the Secretary of Health and Family Welfare and members from Principals of Different Medical Colleges, Specialists in Different disciplines, Professors of Universities, representative from Concerned professional body, representative from Unani-Ayurvedic and Homeopathic Board, Director General of the Health Services, Director General of livestock and Director General of Drug Administration."*

As per the policy paper, the updated number of essential drugs include:

- Allopathic – 285
- Ayurvedic – 100
- Unani – 223
- Homeopathic – 197

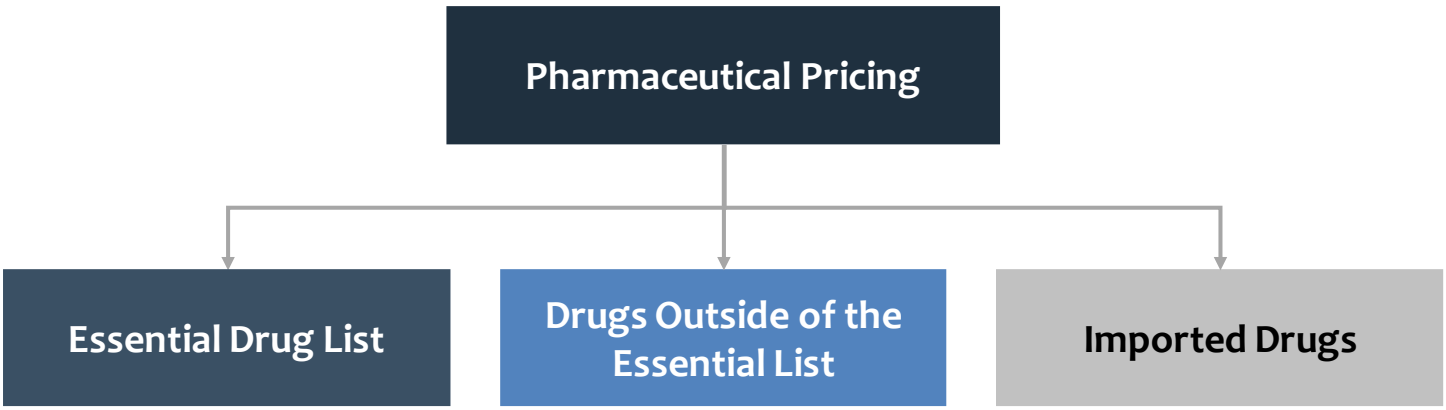
Policy Recommendations on Pharmaceutical Pricing

A key policy element included within the 2016 drug policy is to ensure accessibility to drugs at affordable prices to all consumers. For this purpose, the policy recommends price fixation using transparent and rational methods. Specifically, the policy highlights the following guidelines:

- The Government is required to regularly update the guidelines for the control of drug prices, taking public health interest into account
- Drug prices are recommended to be updated at least once a year, based on the government formulated guidelines
- The retail prices of all drugs will be published in the official website of Directorate General of Drug Administration for public usage.
- Prices of Ayurvedic, Unani, Herbal, Homeopathic and Biochemical system of drugs that are locally produced and imported will be fixed-up by the government
- Person or establishments associated with selling of drugs above the fixed price should be legally prosecuted

Pharmaceutical Pricing Methodology

The methodology used to determine the maximum retail price differs based on the type of drugs.



Pricing of Essential Drugs

The price of essential drugs is controlled by the Government—a maximum retail price for these drugs are established using a "Cost-Plus" pricing methodology. Pharmaceutical companies must submit pricing proposals based on the prescribed format to determine their maximum retail price below the pricing ceiling. Once this proposal is evaluated, the licensing authority provides the final price for the drug and issues the required certificates.

Bangladesh uses a combination of raw and packaging material as cost and adds a markup to obtain the maximum retail price of essential drugs.

MRP (without VAT) = {Price of RM (Ac + Ex) + Price of PM} X Markup

MRP	-	Maximum Retail Price
RM	-	Raw Material
Ac	-	Cost of Active Ingredients
Ex	-	Cost of Excipients
PM	-	Cost of Packaging Material

If a pharmaceutical company wishes to challenge the established price ceiling, it can apply for an increased pricing after submitting the required supporting documentation (raw material and excipients purchase invoice, bill of exchange, and costing sheet. This will then be validated based on the above-mentioned formula—using the combined value of the last six month's average cost of Active Ingredients & Excipients and material cost and multiplying using the markup value.

The price fixation procedure provides the scheduled markups for types of essential drugs:

#	Medicine Type	Markup
1.	Re-packaging (re-packing) medicine	1.50

2.	All types of oral medicine (except antibiotics and birth control pills) and tropical preparation	2.25
3.	All oral antibiotic medicine	2.30
4.	All sterile medicines and birth control pills	2.80
5.	All aseptic preparation	34.00
6.	Steroids and hormones	3.40
7.	Antiviral, antifungal, anti-infective medicines	2.30
8.	Sustained Release Tablet/Capsule	2.80
9.	Dispersible Tablet	3.00

Drugs Outside of Essential Drug List

Prices of drugs outside of the essential list is termed as indicative prices and is determined by respective pharmaceutical organizations based on the Ministry of Health and Family Welfare Notification No. - Public Health – 1/Oushadh-18/93/63 dated-26/02/. Once companies have established prices and have paid VAT, an application should be submitted to obtain the price certificate. Additionally, companies should also provide the recommended price, an annexure with validity period, copy of the approved blocklist of active ingredients, and copies of pre-issued price certificates.

While the pharmaceutical companies can set respective prices, it is indicated that manufactures should not set exorbitant prices, as the set prices must be approved by the drug control committee. However, in practice the committee accepts the prices provided by the manufacturers for non-essential drugs.

Imported Drugs

Imported drugs are priced by applying a markup on the cost and freight prices of finished goods. To obtain the maximum retail price, companies are requested to submit an application along with the indent, invoice, bill of exchange, and copy of Import Registry Certificate.

MRP = C&F Value X Ex. Rate X Markup

MRP - Maximum Retail Price

C&F - Cost and Freight Value

Ex. Rate - Exchange Rate

Three markups are used to calculate the maximum retail price:

- Tariff and VAT free & other taxable (AIT 5% + ATV 3%) items markup - 1.6086
- VAT free, 5% tariffs and other taxable (AIT 5% + ATV 3) items markup - 1.6809
- 5% tariff, 15% VAT and other taxable (AIT 5% + ATV 3%) items markup - 1.9030

AIT - Advanced Income Tax

ATV - Advanced Trade VAT

Drug Enforcing Authority

The Director General of Drug Administration (DGDA) under the Ministry of Health & Family Welfare is the primary drug regulatory authority of Bangladesh. The DGDA supervises and implements all drug regulations and controls all activities related to the import of raw and packing material, production and import of finished drugs, exporting of drugs, price regulations, and regulating exports for all drugs.

The Chief Directorate General of the DGDA is authorized by the Government to act as the Licensing Authority of drugs—to issue licenses to manufacture, store, sell, import and export drugs and medicines. The DGDA currently has 55 district offices and all officers of the DGDA function as "Drug Inspectors" ensuring drug laws are adhered across the country.

The DGDA website also includes a portal for its Allopathic Drug Database providing patients with essential information relating to price, pack size, manufacturer name, brand name, and generic name for a specific drug.

The DGDA also consists of a number of committees comprising of experts that advise the Chief Directorate General on critical matters related to the drug policy and regulations.

Key Committees of DGDA

- Drug Advisory Committee
- Drug Appellate Authority
- Drug Control Committee
- Drug Technical Sub- Committee
- Drug Pricing Committee
- Drug Pricing Technical Sub- Committee
- Manufacturing Project Evaluation Committee
- Standing Committee for Import
- Herbal Drug Advisory Committee
- Adverse Drug Reaction Advisory Committee

Framework for Price Revisions

It is stated that the prices of the essential list should be updated at least once a year based on Government defined guidelines. Accordingly, the DGDA's pricing committee will convene to evaluate and determine prices. Additionally, companies can also submit applications to the pricing committee for drug price revisions.

Merits

Stabilization of Drug Prices

While prices can vary within the established price ceiling, as the Cost-Plus strategy only allows companies to charge a pre-defined margin on their manufacturing and packaging cost, the overall price levels stabilize over time. The assessment conducted during the 2005 drug policy review found that drug prices had stabilized since 1982, increasing by only 20% (a drop in price in real price terms) compared to an increase of 179% in the consumer price index within the same period.

Increasing Affordability Across Income Levels

According to experts, a Cost-Plus strategy benefits developing nations such as Bangladesh as it allows the Government to keep prices of essential drugs affordable across income levels. This policy is considered to be more consumer centric and beneficial to a country where a majority of drug costs are privately paid as consumers do not have or cannot afford health insurance.

Demerits

Significant Effort in Information Validation

The Cost-Plus pricing methodology requires significant technical and human effort to obtain and validate estimates provided by companies for components such as Active Pharmaceutical Ingredients. This also can create instances where companies are able to manipulate the policy to charge higher prices while using low cost ingredients.

Potential for Low Quality Drug Manufacturing

Given the tight price control and low profit margin, established medium and large local pharmaceutical companies are becoming more focused on exporting drugs to other countries rather than supplying to the local market. In the absence of these companies, smaller pharmaceutical companies with inadequate quality control mechanisms are now competing for this market share. Unless tighter quality control measures are implemented, experts believe that current price control strategy could create a market for low quality, cheaper products.

Discourage Innovation on Essential Medicine

Additionally, price control of essential medicine could discourage pharmaceutical companies to invest in innovation and efficiencies as these costs will not be taken into consideration when deciding on the maximum retail price. In instances where companies believe prices are held below natural levels, they may invest in non-price-controlled drugs or on export-oriented products. As later drug policies have not required local manufacturers to allocate a certain percentage of their capacity to produce essential drugs, manufacturers can focus production capacity on alternative drugs.

Delay in Adjusting Prices

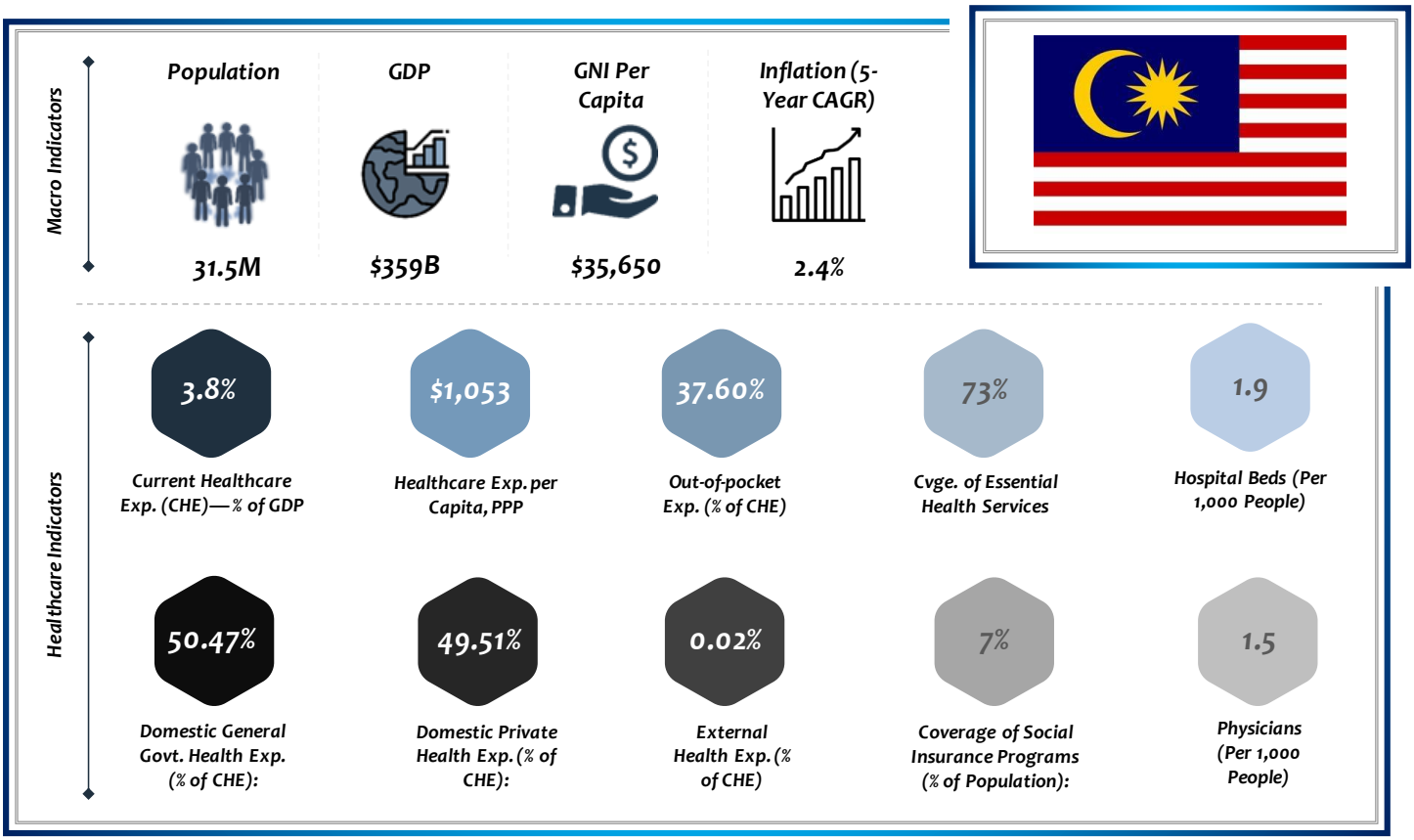
As the adjustments to price controls will require a lengthy legal and political review and also due to the difficulty of validating information provided by companies, experts state the Cost-Plus method can in most instances become disadvantageous either to the consumer or the manufacturer. In the situation of Bangladesh, experts state that the 2005 policy was more advantageous to the manufacturer which resulted in the 2016 revision.

Bibliography

- "National Drug Policy 1982", Accessed February 2020
- "National Drug Ordinance 1982", Accessed February 2020
- "National Drug Policy 2005", Accessed February 2020
- "National Drug Policy 2016", Accessed February 2020
- "Essential Drug List 2016" Accessed February 2020
- "Directorate General of Drug Administration", Accessed February 2020
- "Bangladesh Price Fixation Policy 2015", Accessed February 2020
- "Bangladesh National Drug Policy 1982-2016 and Recommendations in Policy Aspects", Murshid, Haque, 2019
- "National drug policy of Bangladesh: Some pitfalls in implementation", Chowdhury, Ahasan, Rahman, 2006
- "Intellectual Property and Public Health in the Developing World", Monirul Azam, 2016
- "Bangladesh Pharmaceuticals Industry: An Emerging Generic Drug Hub in Asia", BlueKonsult Global, September 2019
- "WHO Guidelines on Pharmaceutical Pricing Policies", WHO, 2015
- "Pharmaceutical Industry in Bangladesh", EBL Securities Limited, 2018
- "Pharmaceutical sector flourishing", The Financial Express, November 2019
- "Bangladesh pharmaceutical industry blooms bigger", Dhaka Tribune, August 2019
- "Evaluation of Healthcare Development in Bangladesh", Daily Sun, October 2017
- "Bangladesh Healthcare Industry: The Thriving Industry that is Growing Faster than the GDP", LightCastle Partners, April 2016
- "Industry frets about possible drug price hike", The Financial Express, August 2019
- "What LDC graduation will mean for Bangladesh's drugs industry", United Nations, Accessed February 2020
- "HC questions legality of pharmaceutical industries fixing price of medicines", The Daily Star, July 2018

Country in Focus: Malaysia

Country Overview



Source: World Bank Data, Accessed February 2020

Healthcare Overview

Malaysia currently encompasses a two-tiered healthcare system which includes a government-led and funded public sector, and a thriving private sector creating a dichotomous yet synergistic public-private model.

- The public sector system currently caters to ~65% of the general population but is served by only 45% of all doctors registered in the country, and a significantly lower 25-30% of specialists.
- Heavily subsidized by the national government, this public healthcare system is almost entire borne by budget allocations, with patients paying only nominal amounts for access to both outpatients and hospitalizations.
- The private healthcare sector in the country has been growing rapidly over the last 25 years and services are mainly located in urban areas, through private hospitals and physician clinics with specializations on curative care.
  - Imported medicinal drugs accounted for 63%, which was RM5.4B (~$1.3B), the largest portion of the pharmaceutical market, while exports only amounted to RM 0.7B (~$169M). During 2016, generic medicines accounted for ~55% of the controlled (prescription) medicinal drugs market by value.

Pricing Policy Overview

Governance Framework

Malaysia's Ministry of Health (MOH), the country's apex governmental body responsible for the overall healthcare system and wellbeing of its people, has numerous pivotal governmental agencies under its purview, responsible for the administration, monitoring, and control of pharmaceutical products, traditional medicines, health related products, veterinary, cosmetic products and medical devices.

- The National Pharmaceutical Regulatory Agency (NPRA), which was formerly known as the National Pharmaceutical Control Bureau (NPCB), is tasked with the implementation of quality controls on pharmaceutical products through evaluation of scientific data and laboratory tests on all products before they are marketed in the country, under the Control of Drug and Cosmetics Regulations 1984.
- The Drug Control Authority (DCA), is entrusted with the regulation of combination products, whilst also ensuring the quality, efficacy, and safety of pharmaceutical products, traditional medicines, health related products, veterinary and cosmetic products marketed in the country.
- The Malaysian Adverse Drug Reaction Advisory Committee (MADRAC), under the DCA, exists to carry out pharmacovigilance for registered drugs in the country. All reports assessed by the MADRAC are sent to the central World Health Organization (WHO) Global ICSR database.
- The Medical Device Authority (MDA) is entrusted with controlling and regulating medical devices in accordance with the Medical Device Act of 2012 for registration of the medical devices, issuances of licenses, training, and awareness.
- The Malaysian Pharmaceutical Services Program (Pharmaceutical Division), is the enforcement agency of the MOH, responsible for ensuring that safe, efficacious, and high-quality pharmaceutical products are made available to the general public.

Current Policies

The country's pharmaceutical market is currently dominated by prescription drugs which account for ~60% of the pharmaceutical market share by value.

- While medicinal drug procurement in the public sector is mainly through volume-based national tenders, which involves the Malaysian government picking up the tab for the medicine, and patients getting their medicine for free, prices in the private sector are purely determined by free market forces.
  - However, the need for pricing controls for the public sector arose from studies such as the Malaysian Competition Commission's 2017 report titled "Market Review on Priority Sector Under Competition Act 2010 – Pharmaceutical Sector" which described the existence of opaque direct-negotiation mechanisms, inherent monopolies and the use of middlemen acting as intermediaries or tender agencies throughout the public sector's drug procurement process. These middlemen were paid commission for practically every pill, solution & tablet which went through this process.
- Studies conducted on the pricing of a range of pharmaceutical drugs in the private sector have shown that price mark-ups or higher profit margins for generic drugs or innovator drugs were in effect by as much as 400% in some cases, when compared to the same products in other countries.
  - Prices of innovator brands and generic medicines in 32 community pharmacies and 20 dispensing doctors were ~15 and 6.6% times higher, respectively, than their international reference prices (IRPs).

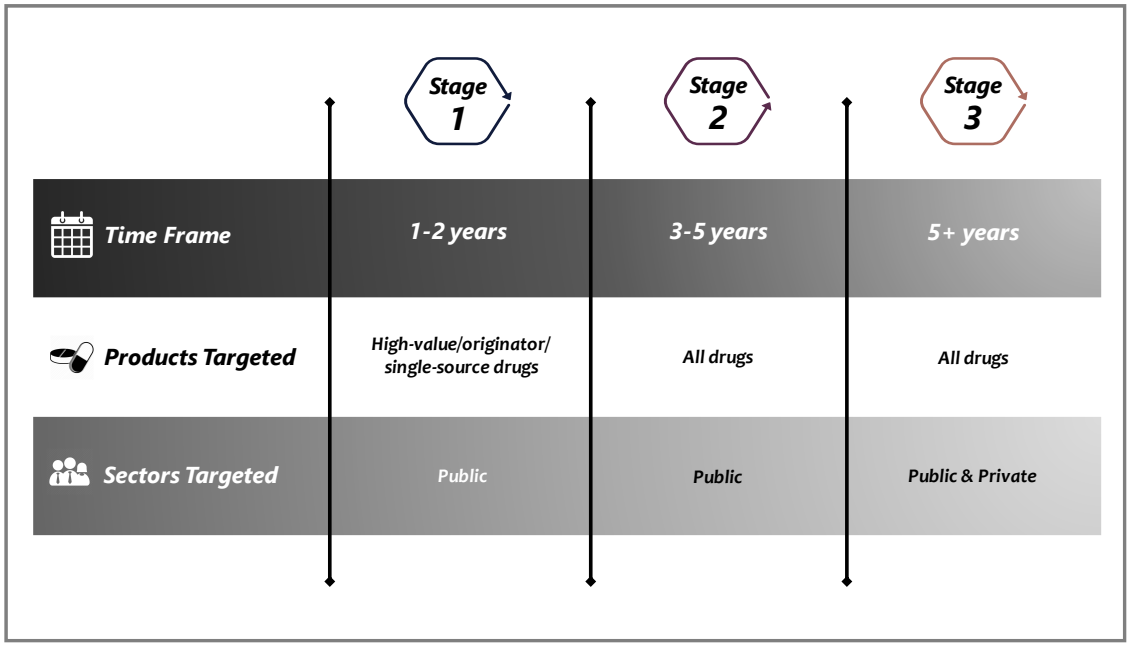
  - Price markups in dispensing doctors' clinics ranged between 50% and 76% for innovator drugs, and up to as much as 316% for generics.
  - In retail pharmacies, medicinal prices ranged between 25-38% for innovators, and 100-140% for generics.
  - Further, according to the 2017 Medicine Prices Monitoring report, the medium mark-up for originators' and lowest-priced generics' retail prices in private hospitals was 51% and 167% respectively.
- Public healthcare facilities in Malaysia abide by a formulary, an official list giving details of medicines which can be prescribed by public facilities, and lists 1694 types of medicines, complete with information of each one from its generic name to dosage (https://www.pharmacy.gov.my/v2/en/apps/fukkm), provided free or nominal prices at MOH facilities to the public.
- The MOH indirectly controls and reduces drug prices with bulk purchases through concession supply and national tenders to provide better accessibility and affordable medicines, and are guided by the Finance Ministry guidelines:
  - Supplying by concession companies— medicines and non-medicines listed on the approved product purchase list (APPL) are selected via open tender and price negotiations at the national level every 3 years.
  - National tender— processed centrally by the MOH for annual purchases over RM 500K (~$120K) with contractors with the best price supplying the required medicines at the contracted price and volume for a period of 2-3 years.
  - Local purchases— individual purchases by public institutions including hospitals and/or health clinics at prices valid at pint of purchase or for one year. Procurement is done via direct purchase for items with annual value less than RM50,000 or via quotation for items with annual value between RM50,000 and RM500,000.
- However, with the budget allocation by the government showing a downward trend for medicines since 2015, the public is experienced in recent times, cases where certain medicines are not available at the MOH facilities and, as a result, are then required to obtain them from private pharmacies, thus facing severe issues of affordability.

In April 2019, Malaysia's Cabinet approved a joint effort between the Ministry of Health (MOH) and the Ministry of Domestic Trade and Consumer Affairs (KPDNHEP) to regulate medicinal drug prices, under the Price Control & Anti-Profiteering Act of 2011. Under the current purview, price controls fall under the KPDNHEP.

- The MOH sought to use External Reference Pricing (ERP) to benchmark drug prices in Malaysia, selecting the lowest three prices and then obtaining the average in order to select the ceiling price.
- The MOH has stated that it has not yet decided on which country's system it planned to model the control mechanism, nor the specific drugs to be targeted by the price controls, but plans to impose the ceiling price at both wholesale and retail/consumer levels at such establishments as clinics, hospitals, and pharmacies. (*Appendix*)
- Experts stated that the differences in reference countries for its use in Malaysia's ERP mechanism due to various reasons:
- The government plans to enforce such controls using a 3-phased roll-out plan over a period exceeding 5 years:
  - The initial phase (next 1-2 years) will focus on the public sector, where most government officials feel that price controls are easily enforceable, as evidenced by other countries which have implemented reference pricing. In addition, price controls are likely to target high-value or single-source, or originator drugs, as medicinal drug priced in Malaysia across mature therapy areas are already lower, on average, than in other countries.
  - Phase II (following 3-4 years), will continue to stay focused on the public sector, but with price control mechanisms established in the first phase extended to a broader range of drugs including generics, where even small price adjustments to high volumes could yield significant cost benefits to the public.
  - Phase III (5 years+), will see some concrete efforts made towards containing prices in the private sector. However, there are likely to materialize in the form of pricing guidelines rather than legally binding controls

which could potentially risk violations of WTO free trade agreements. In the short term, price containment for the private sector is expected to come through databases for drug price transparency that mandate disclosure of ex-manufacturer, wholesaler & recommended retail price and is then made available to the public.

Illustration: *Phased timeline of Malaysia's proposed price controls implementation plan:*



Merits

Advocation for Access to Affordable Healthcare & Drugs

- The Federation of Malaysian Consumers Association (FOMCA) advocates the Government's move to set up price controls for pharmaceutical products in the country.
  - FOMCA argues for such controls stating that medicinal drugs are not a commodity and that healthcare is a basic consumer right, with the administration of medicines being a key component of a healthcare system. The organization further states that the Malaysian government needs to play a critical role to ensure that all consumers, especially low- and middle-income segments of the population, have access to affordable healthcare and drugs.
  - Further, the organization cites the World Health Organization (WHO) stating that an 'affordable and fair price is one that can be funded by health budgets and patients and simultaneously sustains R&D production and distribution within a country'. The WHO proposes that all countries in their efforts towards universal healthcare and coverage should have policy measures to control and regulate medicinal prices.

Support for Transparency of Drug Prices at Multiple Levels of the Supply Chain

- NGO's in Malaysia also welcome the move to initiate drug price controls by the government, stating that currently there is a lack of transparency in such pricing at different levels— manufacturers, distributors, pharmacies, hospitals, and clinics— and highlighting the need for some regulation of the price range for mark ups.
  - Such stakeholders also highlighted the need to tighten up unnecessary patent monopoly & additional patents that extend monopolies beyond 20 years, pushing up the cost of some crucial medications.

Initiation of Detailed Studies Before the Enactment of Controls

- While implementation of such controls is expected to commence in 2020 using a phased approach, key stakeholders in the pharmaceutical sector of Malaysia have made several recommendations to the government to consider before such regulations are enacted including the following:
  - Conducting a Regulatory Impact Analysis (RIA) of the proposed controls to determine impact of drug price controls on the general practitioners, patients, hospital service providers, pharmaceutical manufacturers, and other key stakeholders with such results from the analysis made public.
  - A Cost Benefit Analysis (CBA) carried out by an independent organization/ party and the results present to cabinet before gazettement in order to determine impacts to the industry.
  - Reference of price regulations to the Parliamentary Select Committee on Health, Education, Community, and Social Development before the policy is rolled-out.

Demerits

Disparities in Countries Used as References in Mechanism

- Experts stated that the differences in reference countries for its use in Malaysia's ERP mechanism due to various reasons:
  - There could be potential disparities in the burden of disease, willingness and income levels, market structures, and components included in drug prices which include distributor margins, sales taxes etc. between the countries of reference.
  - Certain medicinal drugs could be at various stages of their respective lifecycles in different countries and with different IP protection.
  - Dissimilarities in package sizes and presentation could complicate comparisons.

Controls on Single Sourced Drugs Deemed Discriminatory Towards Foreign Companies

- A phased implementation of the price control roll-out which includes an initial application on single-source products, which are usually patent-protected, without considering other drugs with generic alternatives are deemed as discriminatory against foreign companies.

Difficulties in Covering Operational Expenditure by Community Based Healthcare Providers

- ERP price controls could affect healthcare providers across various dispensing channels with low margins including community pharmacists, general practitioner (GP) clinics etc. which will face difficulties to cover operational expenditure, leading to foreclosure particularly in rural regions, worsening the congestion in government healthcare facilities.

Adverse Effect on Medical Tourism

- The growth of medical tourism in Malaysia is expected to be severely affected with the 2M+ international patients estimated to visit the country by 2020 at risk, as such price controls may erode patient experience, treatment options, & impede access to innovative medicine, downgrading the attractiveness of Malaysia for medical tourism.

Appendix

Table 1: Comparison of reference pricing across select countries:

Country	Board	Products	Mechanism
Taiwan (1995) 	National Health Insurance Administration (NHIA)	Originator drugs	▪ External reference pricing is based on the medium retail price in Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, the UK, and the US.
		Generics	▪ Prices are capped at 80% of the lowest listed originator price, and prices of subsequent generics cannot exceed the lowest price of generics already listed in the reimbursement scheme that have the same ingredient, specification, dosage form and dose.
South Korea (2000) 	Health Insurance Review & Assessment (HIRA)	Originator drugs	▪ Maximum allowable price (MAP) is set through external reference pricing of the average wholesale prices of the same drug in Germany, France, Japan, Italy, Switzerland, the UK, and the US. ▪ No markup is allowed between the wholesale price and the retail price; instead, the government provides retailers with a fulfilment fee for each filled prescription
		Generics	▪ There has been a single price system since 2012: off-patient originators and their generic counterparts are priced uniformly at 53.55% of the prices of the originator before patient expiry
South Africa (2004) 	Pharmaceutical Economic Evaluations (PEE)	All drugs	▪ A single exit price (SEP) was set for drugs sold in the private sector to limit allowable markups from dispensing pharmacists on four different tiers (5%- 46%) depending on the type of drug ▪ External reference pricing is done for both on- and off-patient products based on ex-manufacturer pricing in Australia, Canada, New Zealand, and Spain ▪ A number of other policy changes were introduced with SEP, including mandatory prescription of at least one generic where available, as well as the removal of bonuses and trade discounts.

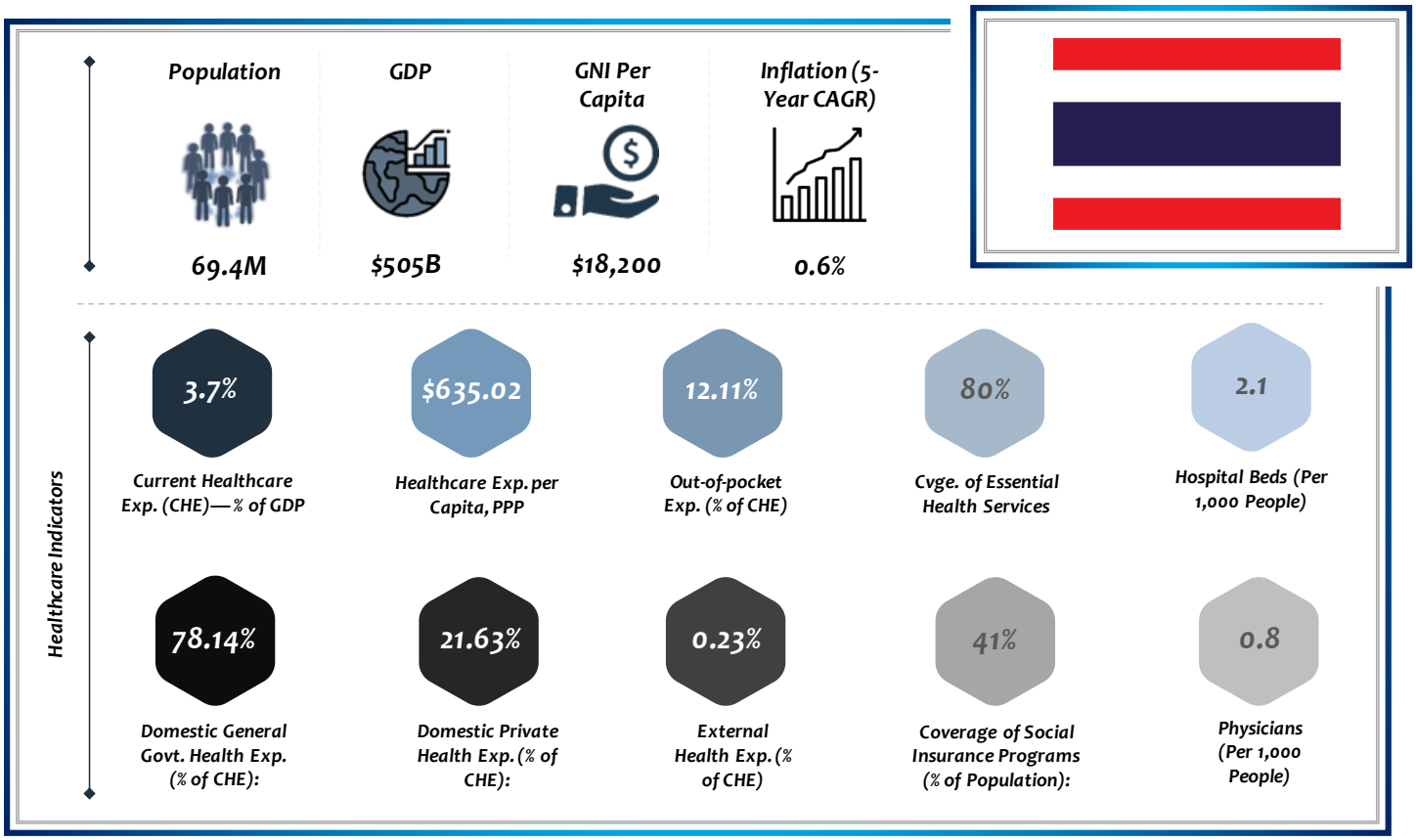
Bibliography

- "Market Review on Priority Sector Under Competition Act 2010— Pharmaceutical Sector", Suruhanjaya Persaingan Malaysia— Malaysia Competition Commission, *Accessed February 2020*
- "Guide of Pharmaceutical Industry in Malaysia", Malaysian Investment Development Authority, *2018*
- "Regulatory, Pricing and Reimbursement", Pharmaboardroom.com (Extracts from Pharma Legal Handbook: Malaysia), *October 2019*
- "Overview of the National Pharmaceutical Regulatory Agency (NPRA)", npra.gov.my, *October 2018*
- "About the Drug Control Authority (DCA)", npra.gov.my, *January 2020*
- "Should drug prices be regulated or decided by competition?", thestar.com.my, *June 2019*
- "Medicine Prices Monitoring in Malaysia— Survey Report 2017", pharmacy.gov.my, *Accessed February 2020*
- "A Price Control Headache", thestar.com.my, *May 2019*
- "What Drug Price Controls in Malaysia Mean for the Pharmaceutical Industry", lek.com, *May 2019*
- "Medicines price control will have negative repercussions", malaysiakini.com, *October 2019*
- "All-Round Opposition to Drug Price Controls", codeblue.galencentre.org, *May 2019*
- "Drug Price Controls in Malaysia: Implications & Considerations (No. 5, June 2019)", codeblue.galencentre.org, *July 2019*
- "Cabinet approves drug price controls", Malaymail.com, *May 2019*
- "Association between medicine Price declaration by pharmaceutical industries and retail prices in Malaysia's private healthcare sector", joppp.biomedcentral.com, *July 2019*
- "Affordability of Medicines in Malaysia— Consumer Perceptions", apps.who.int, *Accessed February 2020*
- "Welcome the Federal Cabinet's decision to introduce a drug price regulation", dapmalaysia.org, *Accessed February 2020*
- "Govt plans to set ceiling prices on medicine", themalaysianreserve.com, *November 2018*
- "Health Ministry Hoping to Impose Medicine Price Controls this Year", malaymail.com, *April 2019*
- "Malaysia May Lose Medicine Access with Price Controls, Hospital Warns", codeblue.galencentre.org, *July 2019*
- "Revisiting the Costs of Medicine Price Controls", codeblue.galencentre.org, *December 2019*
- "Different mechanisms to contain the cost of pharmaceuticals in Malaysia", ieeexplore.ieee.org, *Accessed February 2020*
- "Report: Medicine price controls for private healthcare could affect medical tourism industry", malaymail.com, *November 2019*
- "Control on medicine prices will affect M'sia's medical tourism", themalaysianreserve.com, *November 2019*
- "Urgent need to regulate medicine prices", freemalaysiatoday.com, *December 2019*
- "Round Table on Examining the Interface between the Objectives of Competition Policy and Intellectual Property— Contribution by Malaysia", unctad.org, *October 2016*
- "Seven Malaysian pharmaceutical firms under probe by MyCC and MOH", today.mims.com, *October 2016*

- "Public hospitals don't stock every kind of medicine — here's why", malaymail.com, *March 2017*
- "Official Portal of Pharmaceutical Services Programme, — Ministry of Heath Malaysia", pharmacy.gov.my, *Accessed February 2020*
- "Govt still studying drug price control for private sector, says minister", freemalaysiatoday.com, *November 2019*
- "Free medicine to stay, says minister", thestar.com.my, *August 2018*
- "Price Controls Not for Medicine", thestar.com.my, *September 2018*
- "Health Care Financing: National Health Insurance or Tax-Based System?", codeblue.galecentre.org, *March 2019*

Country in Focus: Thailand

Country Overview



Source: World Bank Data, Accessed February 2020

Healthcare Overview

Thailand has a national healthcare system which consists of three main schemes:

- Social Security Scheme (SSS): This scheme is administered by the Social Security Office and financed by contributions from the government, employers, and employees. It covers employees, and employers with one or more employees. This scheme is not applicable to those covered by the Civil Servant Medical Benefit Scheme or to employees of foreign entities.
- Civil Servant Medical Benefit Scheme (CSMBS): This scheme is administered by the Social Security Office and provides health care benefits to government officials and their dependents (spouse, parents, and up to three children).
- Universal Health Coverage Scheme (UCS): This scheme is administered by the MOPH and covers the remaining population not covered under either the SSS or the CSMBS.

Some challenges that Thailand faces in providing universal health care include fiscal sustainability in the long term, maintaining healthcare service quality and the shortage of healthcare professionals to meet the demands of universal health coverage. Additionally, the urban-rural divide in terms of the provision and quality of healthcare poses a challenge to universal coverage. The innovative use of technologies could address some issues, but significant buy-in and commitment from the policy makers and public sector are needed in order to successfully address the aforementioned issues.

In general, private healthcare is not subsidized by the government. However, some private hospitals may be partially subsidized by the government if they cooperate with the SSS—these hospitals are able to provide healthcare services for patients who are registered at their hospital under the SSS.

The government's contribution to total healthcare spending is one of the highest in the region—at 77%—yet private sector spending is on the rise. In 2008, the Thai government spent $247M on health care while the private sector spent $78M. By 2015, the government was spending $376M, while the private sector spent $120M, implying CAGRs of 6.2% and 6.3% for the public and private sectors respectively. Due to widespread government efforts to provide universal health care, with several public hospitals experiencing sharp increases in patient numbers, patients with the financial means seek treatment at private hospitals.

According to the Ministry of Public Health, there were 353 private hospitals operating in Thailand in 2019, up from 321 in 2011, ~40% of which are in the Bangkok metropolitan area. Private hospitals play a critical role in driving Thailand's medical tourism industry is largely driven by private hospitals. The Thai government intends to shift public policy to improve medical tourists' access to the country's services. Measures taken include loosening of visa restrictions and the creation of smart visas, extending visas from 30 days to 90 days for citizens of China along with those of Cambodia, Laos, Myanmar and Vietnam (CLMV).

Pricing Policy Overview

Governance Framework

In Thailand, drugs, biologics, and medical devices are regulated by the Thai Food and Drug Administration (Thai FDA), under the supervision of the Ministry of Public Health (MOPH).

The Drug Act, B.E. 2510 (1967), as amended, provides the regulatory framework for the marketing authorization and post-marketing surveillance of drugs and biologics in Thailand. The Medical Device Act, B.E. 2551 (2008), as amended, provides legislation governing the marketing authorization and post-marketing surveillance of medical devices in Thailand.

Current Policy

The prices of medicines are only controlled when they are listed in the National List of Essential Drugs (NLED), a list of medications used by public hospitals and public health services. Under the control of the Ministry of Commerce, drugs on the NLED are subject to a median price policy. However, these pricing regulations only apply to drugs that are listed on the NLED and are prescribed in public hospitals.

Private hospitals and drug stores are free to set their own prices for the drugs they sell, but the price must not exceed the sticker price—the maximum price set by the distributor.

The cost of drugs and medical devices on the NLED can be reimbursed by the government. Government hospitals generally provide drugs and medical devices from the NLED to civil servants and other persons under the universal coverage. Public hospitals will be reimbursed in full by the government for the cost of the drugs and medical devices used in these cases.

The Ministry of Commerce began taking measures promote transparency of drug prices in May 2019 after discovering that some private hospitals overcharged patients for drugs. 353 private hospitals were mandated to display the prices of 3,000 drugs—10% of the 30,103 drugs on the Thai Medicine Terminology list, mainly those used in emergencies—as well as the fees

for medical supplies and services to allow consumers to make better-informed decisions prior to receiving treatment. The stipulation is part of the Universal Coverage for Emergency Patients (UCEP) program, which also requires that hospitals give patients an opportunity to buy drugs from pharmacies outside the hospital system by giving them prescriptions.

An Internal Trade Department analysis of the cost structure of 3,892 widely used medicines found that 353 private hospitals charged markups ranging from 300% to 900% on top of production costs.

- Private hospitals must display the price lists of drugs either on its website or via QR codes within 45 days after the effective date.
- Those who do not comply will be subjected to a fine not more than 10,000 baht and/or imprisonment not more than one year
- For prescriptions, private hospitals are required to first give them to all emergency patients and to all types of patients at a later stage
- The prescriptions must give both trade and scientific names of the medicines. Failure to comply with the rule results in a five-year jail term and/or a fine of up to 100,000 baht.
- Private hospitals are also required to inform the Internal Trade Department of the raised prices 15 days before the prices would be raised.

In May 2019, the Department of Internal Trade issued Notification No. 52 on the Price Reporting of Drugs, Devices, and Healthcare Services, that requires distributors to set reasonable prices and to report the price of any and all drugs sold to government and private hospitals. Further, government and private hospitals must also report the selling price of medicinal product and medical devices.

Future Policy

In December 2018, Thailand's Ministry of Commerce announced plans to put medical-related fees, including drugs, supplies and service charges, on the price control list of the government's central committee on prices of goods and services

In January 2019, the plan was approved, and the Thai government added medicine, medical supplies and medical services to its price control lists, which was announced by Minister of Commerce Sontirat Sontijirawong.

A subcommittee was formed to identify measures to control prices, consisting of representatives from the ministries of commerce and public health, insurance associations, the Private Hospital Association, the Foundation for Consumers and the National Health Security Office.

Merits

A Focus on the Majority of Population Treated in Public Sector

The prices of medicines on the National List of Essential Drugs (NLED) are controlled when are prescribed in public hospitals. As universal healthcare is offered to over 98% of the Thai population, it follows that price controls should be placed in the public sector as opposed to the private sector.

Thailand has not placed price controls yet on drugs purchased privately but has mandated transparency of prices across all private hospitals to regulate malpractice.

Considering Input from all Stakeholders in Private Sector Pricing Policy

After the plan to put drugs on the price control list was approved in January 2019, the Ministry of Commerce formed a subcommittee to identify measures to control prices. The subcommittee is intended to consider the interests of all stakeholders and consists of representatives from the ministries of commerce and public health, insurance associations, the Private Hospital Association, the Foundation for Consumers and the National Health Security Office.

Demerits

Proposed Price Controls May Limit Healthcare Investment and Innovation

As private hospitals are concerned about price controls limiting investments in healthcare innovation and reduce the country's competitiveness. The Private Hospital Association noted that this may pose a threat to Thailand's goal to promote medical tourism.

As private hospitals generally have higher medical prices for drugs and services due to investments in medical infrastructure and maintaining standards,

In January 2019, the Private Hospital Association called for the state to bring all public hospitals under the jurisdiction of the Medical Facilities Act of 1988, in response to the government's proposed price controls. This would put all hospitals under the same regulatory framework, requiring each to provide a minimum number of physicians, paramedics and pharmacists, a costly regulation applying to private but not public hospitals.

The association is calling for the related state agencies to consider and bring all public hospitals to be under the control of this Act as it wants all public hospitals to recognize their actual operation costs

Thai Patients at Private Hospitals Do Not Need Price Controls

As all Thais are entitled to free medical treatment in the universal healthcare scheme, coupled with the fact that in life-threatening emergency cases, free treatment for 72 hours at any medical facility in the country is provided, price control opponents say that patients are going to private hospitals voluntarily, possibly because they like the services there.

Several private hospital stakeholders have said that they would fully support price controls if there were no free-treatment options. "Given that services by private hospitals are now an alternative service, we should focus on improving such alternatives. Do not make any move that will only destroy people's choices,"

Bibliography

- "Medical Price Controls to Shake Up Thai Healthcare", International Medical Travel Journal, April 2019
- "Thailand's rising pharmaceutical price pressures hamper multinational drugmakers' opportunities", Healthcare Asia Magazine, January 2019
- "Medical price control plan looms over private hospitals", The Nation, January 2019
- "Price controls 'will hit healthcare", Bangkok Post, January 2019
- "Medical supplies, services, drugs now under price control", Bangkok Post, January 2019
- "The Kingdom of Thailand health system review", WHO, 2015
- "Regulatory, Pricing and Reimbursement Overview", Tilleke & Gibbins, September 2019
- "Medicine prices in Thailand: A result of no medicine pricing policy", Mahidol University, Thailand, Ministry of Public Health, Thailand, January 2009

Country in Focus: UAE

Country Overview

Population	GDP	GNI Per Capita	Inflation (5-Year CAGR)
9.6M	$441B	$75,440	2.6%

Healthcare Indicators					
3.5%	$2,546	18.57%	76%	1.2	
Current Healthcare Exp. (CHE)—% of GDP	Healthcare Exp. per Capita, PPP	Out-of-pocket Exp. (% of CHE)	Cvge. of Essential Health Services	Hospital Beds (Per 1,000 People)	
72.48%	27.52%	0.00%	N/A	2.4	
Domestic General Govt. Health Exp. (% of CHE):	Domestic Private Health Exp. (% of CHE):	External Health Exp. (% of CHE)	Coverage of Social Insurance Programs (% of Population):	Physicians (Per 1,000 People)	

Source: World Bank Data, Accessed February 2020

Healthcare Overview

With a comprehensive, government-funded health service and a rapidly developing private health sector that delivers a high standard of health care to the population, the UAE is regarded as one of the region's leaders in healthcare with regard to quality and standards.

- Experiencing a tremendous expansion over the past four decades, UAE's healthcare industry, which at the time of the country's founding in 1971 consisted of merely 7 hospitals and 12 medical centers, had grown to over 126 public and private hospitals with a combined capacity of over 12,000 bed by 2015.
- With regard to costs, healthcare services in the country are relatively high but for UAE nationals, public hospitals and clinics offer medical services for free. Non-Emirati residents however, do not have access to any free health services, although, in 2013, the Ministry of Health and Prevention (MOHOP) introduced a series of health cards available to expatriates at an annual fee, which gives them access to subsidized consultation and treatment charges and government hospitals and clinics.

- Certain Emirates such as Dubai and Abu Dhabi have already implemented regulations enforcing all nationals and expatriates to obtain healthcare insurance. The federal government is

Pricing Policy Overview

Governance Framework

The UAE's healthcare and pharmaceutical sector is regulated at both the Federal and Emirate level.

- The Ministry of Health & Prevention (MOHOP), a primary authority responsible in regulating and implementing healthcare policies while also regulating the licensing of pharmaceutical companies, using key federal legislation, for the northern emirates of the UAE— Sharjah, Ajman, Umm Al Quwain, Ras Al Khaimah and Fujairah.
  - The Federal Law, Number 4 of 1983, which is the leading piece of legislation by the government concerning the pharmaceutical profession and related institutions, governs the import, manufacture, and distribution of pharmaceutical products.
  - Federal Law Number 14 of 1995 regarding countermeasures against narcotic drugs and psychotropic substances regulate the import of pharmaceutical and other medicines to the UAE
  - Federal Law Number 5 of 1984, governs the licensing and registration requirements of physicians, pharmacists, and other professionals with the pharmaceutical sector.
  - Federal Laws Number 7 or 1975 and Number 2 of 1996 has laid down specific requirements for the establishment and licensing of public and private medical laboratories, clinics and hospitals in the country.
  - Federal Law Number of 1 of 1979 on the Organization of Industry Affairs affect pharmaceutical companies located in the mainland as a local Emirati agent must be appointed, and their shares in the company's capital should not fall below a certain percentage.
- The Dubai Health Authority (DHA), established in June 2007, through Law No. 13 with an aim to provide an accessible, effective, and integrated healthcare system, protect public health, and improve the quality of life in the emirate.
  - The Dubai Pharmacy Licensure and Pharmaceutical Practices Guide (Feb 2013) issued by the Health Regulation Department of the DHA primarily focuses on the licensing and protocol of institutions a professional. The guide offers detailed instructions and information with regard to setting up a pharmaceutical company whilst offering instructions on purchasing, storing, dispensing, and prescribing of medicinal drugs.
- The Department of Health— Abu Dhabi, established in 2007, is responsible for providing healthcare services to its citizens and residents, regulating both the public and private healthcare sectors through policies, laws, regulations, inspections, and audits.
  - As part of the jurisdiction in Abu Dhabi, the Department of Health monitors and regulates the licensing of pharmacies and pharmacists, the registration of pharmaceuticals, and advertising guidelines for medicinal drugs and medication.

Current Policies

Consumers in the UAE, being of high income, generally exhibit strong preferences for branded pharmaceutical products. This Inclination for branded products is high to such an extent, resulting in demand for them continuing even following the expiry of their patents, and the availability of generic substitutes.

- Key attributes influencing such preferences include the influence of multinational manufacturing establishments on physicians, many of whom are expatriates, and thus more familiar with branded medicine, and general perceptions among the populace that high priced and imported branded medicinal products are far superior to locally manufactured generic drugs.
- While drug dispensing in the country is under strict regulation and purchases require valid prescriptions, medical practitioners in the UAE have a large say in the pharmaceutical retail segment, and thus, their familiarity with leading brands have benefitted the multinational branded pharmaceutical product manufacturers.
- With prescription medicine accounting for ~80% of all sales in the pharmaceutical market and being largely imported, combined with a high preference for such imports by the general public, pharmaceutical prices in the UAE are among the highest in the Middle Eastern region.

In the UAE, pricing legislation for pharmaceutical drugs and medicine are currently in place providing fixed margins for pharmacies and distributors with regard to registered pharmaceutical products sold to consumers.

- In accordance with Article 65 of the Federal Law No. 4 of 1983 of the UAE, all imported pharmaceutical products into the country are required to be registered with the Ministry of Health and Prevention.
- In the past, legislation in the country relating to the pricing of pharmaceutical drugs (particularly, Articles 2, 3, and 4 of the Ministry Resolution No. 834 for the year 2008), made a distinction between products used for chronic diseases and non-chronic diseases.
  - **Drugs of chronic diseases:** Selling price to the public = CIF Cost X Exchange Rate + Profit Margin to the Agent (15% of the Cost, Insurance and Freight in AED) + Profit Margin of the Pharmacy (18% of CIF in AED).
  - **Concerning Drugs not stated in Category 1 (Non-chronic and Non-antiviral):** Selling price to the public = (CIF Cost X Currency Exchange Rate) minus 10% + Profit Margin to the Agent (20% of the Cost, Insurance and Freight in AED) + Profit Margin of the Pharmacy (24% of CIF in AED)
  - **Sale of local medicinal drugs to the public**: Selling price to the public = Ex-factory Price + Profit Margin of the Agent (20% of the Ex-factory Price) + Profit Margin of the Pharmacy (24% of the Ex-Factory Price)
- Replacing the 2008 legislation, new price controls resolutions were enacted by the government, which included an External Reference Pricing (ERP) model, incorporated for all imported drugs. The prices of in-patent pharmaceuticals are set according to the lowest price based on a set of criteria which include ex-factory price of the product in the country of origin, import price proposed by the company including the freight & insurance costs until delivery at the port of the destination country, and the median of the approved CIF price of the product in the list of reference countries.
  - The revised pricing controls enacted were viewed by the UAE authorities to support their desire to find a balance between affordable healthcare and international obligations to sustain patent and product quality standards.
- Further, specific additional criteria are also taken into account when determining the prices of such in-patient pharmaceutical products including therapeutic significance of the drugs in question, prices of similarly registered or therapeutically equivalent/ alternative drugs, pharmaco-economic studies, factory price, wholesale price, and public price in the country of origin in $, price proposed by the manufacturer in $ or AED, including CIF inside the ports of the country, export price to reference countries, and guidance on the price of countries that the product is marketed.
- Under the new resolutions, at the time of registration, a committee selected by the Ministry is tasked with reviewing the product in focus and determining the 'CIF' (cost, insurance and freight) price for the particular pharmaceutical product.

- Following the setting of the CIF price for the product, all agents/ distributors of the pharmaceutical product, and the pharmacy or private hospitals shall be paid a fixed margin (depending on the 3 CIF pricing categories) of the CIF price as set out below:

	CIF Price Category 1	CIF Price Category 2	CIF Price Category 3
	AED 0-250 (~0-$70)	AED 250-500 (~$70-$140)	Above AED 500 (~$140)
Distributor/ Agent	15%	15%	15%
Pharmacy/ Private Hospital	28%	28%	20%

- Thus, the price of the pharmaceutical product to the end consumer is the CIF price, plus the agent's margin, plus the pharmacy's margin.
- The controls apply to the supply of pharmaceutical products to the private sector which includes private hospitals and pharmacies.
- However, pharmaceutical manufacturers or distributors supplying directly to government authorities such as the DHA or to government owned hospitals etc., are not subject to the pricing regulations, but instead determined as set out in the commercial arrangements entered between the two parties in question.
- Further, certain generic products such as aspirin and paracetamol are not covered under the new pricing regulations.

- As part of the decision-making process for price setting, a data sheet specifying product details, proposed CIF price, calculations and comparisons with the available reference prices based on the prevailing regulation are prepared for each medicinal pack.
  - Internal committees' comparison of the Pricing Unit Supervisor, Registration & Pricing Section Head, and the Registration & Drug Control Department Director screen proposed prices, and the CIF price acceptable for each pack based on the prevailing criteria is noted.
  - However, if the proposed price is not agreed and accepted, applicants are required to reduce the price to an accepted level.
  - If the applicants do not respond positively to the requests by the committee within 2 weeks, the product is taken to the Pricing Committee for decision without further notice to the applicant.
  - If reference prices are not available at the time of first pricing of an essential or lifesaving medicine, the committee will, based on circumstances, approve the price temporarily, in order to make it available for use by the country at the earliest possible time, and then reviewed again once reference prices are available. Parent companies/ distributors are required to furnish such information to the Ministry of Health & Prevention as soon as the information is available.
  - The committee can reject the proposed price or defer product pricing if it deems necessary, and then inform the applicant of the decision. However, an appeals process is available to the pharmaceutical company.
- Furthermore, completely locally manufactured pharmaceutical generic drugs in the UAE are priced at 70% of the innovator, without considering the time order and number of products.
  - Partially manufactured generics in the UAE are priced at 60% for the first generic, 50% for the second generic, and 40% for the third generic of the innovator.

- The government also initiated the Pharmacy Benefit Management (PBM) system in 2013. Under the system, pharmacies have to obtain immediate payment approval from insurance organizations for any medicines that they dispense, instead of charging patients in advance for drugs they believed the insurance firms would cover under their specific schemes. Further, the PBM system also encouraged (but did not enforce) the use of generic drugs over branded medication or originators.
  - The system also provides savings by monitoring the patient's tolerance to any new medication prescribed, reducing the level of medicinal waste. The DHA believes that up to 50% of total spend by patients is generally wasted.
  - In addition, through access to ongoing prescription requirements of patients, the PBM system can also be used to tailor refill policies or step-therapy protocols, ensuring the monitoring of tolerance to new drugs and makings sure patients start treatment with lower cost alternative drugs before moving to higher cost medication options if the more inexpensive medication is deemed ineffective.
- In September 2018, the Emirati governments introduced further regulations mandating pharmacies to dispense generic medication.
  - The new mechanism develops a reference price for all drug categories with an equivalent generic substitute. However, drugs without a generic substitute would not have reference prices listed.
  - Under the new policy, generic drugs will also be expected to be covered under health insurance, and patients who opt for branded drugs/ originators would be required to pay the difference in price.
  - Thus, such moves are expected to further boost the pharmaceutical industry in the UAE while also providing patients with more choice
- Further, since 2011, the Ministry of Health & Prevention of the UAE has been making reductions in various ranges to innovator and generic drugs imported and manufactured in the country.
  - The price reductions by the Ministry is based on regular analysis and amendments of drug prices according to the latest updates in the pharmaceutical sector, including prices of similar drugs, and other economic factors.
  - Initial reductions to medicinal prices took place in June 2011, when the government slashed prices of 565 drugs by ~55%. Further reductions were enacted in November 2011 when the prices of additional 115 generic medicines were reduced by ~35%.
  - In June 2013, 6,632 drugs, which included medicine used for the treatment of hypertension and heart failure, anti-depressants, asthma, and antivirals for HIV, experienced cuts by ~40%. A further 192 vital drugs were reduced again in the latter part of 2013 which included 14 used for the treatment of diabetes.
  - Again, in September 2019, the UAE announced price reductions for ~422 medicine; the fifth overall reduction in the country's history.

Merits

Boosting of Demand for Generic Drugs

- The new policies with regard to pricing controls are considered by experts and most stakeholders to have a positive impact on the growth of the country's pharmaceutical sector, boosting the demand for generic drugs.
  - This is evident by the fact that locally based pharmaceutical establishments such as 'Pharmax Pharmaceuticals' is keen to commence manufacturing of more affordable generic medicines, particularly targeting chronic conditions common in the region including cardiovascular diseases and gastroenterological diseases.

- The general public has also been seen to laud the new regulations and price reductions as it will lead to significant savings without limiting the options available to them— the UAE ranks among the top 5 countries in the world in terms of licensing promising new treatment and cures. In addition to reducing overall healthcare costs, the policy also supports the country's medical tourism industry.

Striking a Balance Between Affordability & Environment for Innovation

- While the industry has faced some difficult adjustments to certain pharmaceutical products in the past, the government has struck a good balance between ensuring affordability for medicinal products and maintaining an environment for innovation and investment.

Diminishing the Prevalence of Healthcare Fraud

- UAE's Pharmaceutical Care Management Association states that the enactment of the Pharmacy Benefit Management system (PBM) will bring about significant longer-term benefits.
  - Since healthcare fraud is relatively high in the UAE, costing ~$1B a year, the PBS system identifies and strives to diminish the number of rogue claims.
  - The system also ensures that all drugs dispensed by prescription are cross-checked with rules set by insurance companies based on medical guidelines in order to reduce inappropriate prescribing by doctors.

Demerits

Opposition for Controls Citing Conflict of Free Market Principles

- Criticism for the price controls are not voiced out by stakeholders in great detail in the UAE. However, drug manufacturers in the country have opposed regulations to reduce profit margins and enforce price caps per medicinal packs claiming that such moves contravene the country's free market principles.

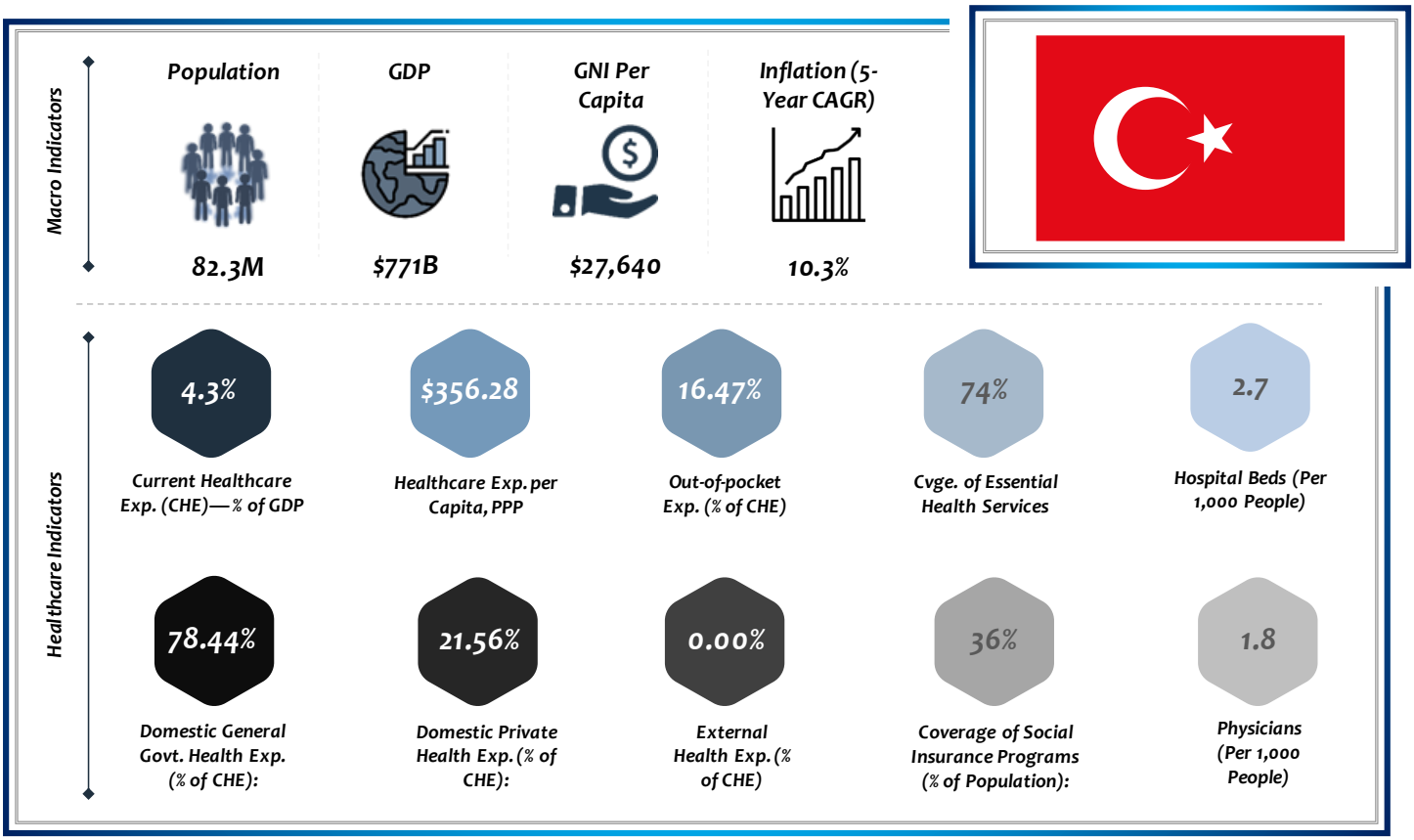
Bibliography

- "Pharma industry in UAE sees robust growth ahead", khaleejtimes.com, *September 2019*
- "UAE pharmaceutical market set to hit $5.7 billion by 2020 as medical tourism grows, says GlobalData", chemdiv.com, *October 2016*
- "UAE's Health and Pharmaceutical Economic Growth & Innovative Capacity", usuaebusiness.org, *2017*
- "UAE's Health and Pharmaceutical Economic Growth & Innovative Capacity", usuaebusiness.org, *January 2017*
- "The U.A.E. Healthcare Sector", usuaebusiness.org, *January 2018*
- "Detailed FAQ on Pharmaceuticals and Medical Devices", stalawfirm.com, *February 2018*
- "GCC Pharmaceutical Industry", static.mubasher.info, *March 2013*
- "UAE Ministry of Health Cuts Prices Of 422 Drugs", gulfbusiness.com, *September 2014*
- "How does the new regulation in Abu Dhabi enhance local healthcare?", pacificprime.ae, *Accessed February 2020*
- "UAE pharma firm begins manufacturing 'affordable' generic medicines in Dubai?", gulfbusiness.com, *August 2018*
- "Prices & Discounts on Drugs", tamimi.com, *Accessed February 2020*
- "Why are medicines so expensive in the UAE?", gulfbusiness.com, *February 2016*
- "Pricing of Pharmaceuticals Products in the United Arab Emirates", clydeco.com, *September 2016*
- "Pharmaceutical pricing and reimbursement in the Middle East and North Africa region", lse.ac.uk, *November 2018*
- "Strategic partnership between Ministry of Health & international pharmaceutical firms results in control of drug prices", mohap.gov.ae, December 2015
- "Understanding the UAE's Pharmacy Benefit Management System", linkedIn.com, *February 2016*
- "Regulatory Aspects of Pharmaceuticals in Gulf Co-operation Council Countries", ijpacr.com, *July 2017*
- "Drug Lists", dha.gov.ae, *Accessed February 2020*
- "UAE Ministry of Health reduces prices of over 400 medicines", gulftoday.ae, *September 2019*
- "Doctors urged to issue generic brand drugs as UAE acts to make healthcare more affordable", thenational.ae, *November 2019*
- "Generics set to transform Abu Dhabi's pharmaceuticals market", oxfordbusinessgroup.com, *September 2018*
- "United Arab Emirates: What International Companies Need to Know to Distribute Pharmaceuticals in the UAE", mondaq.com, *May 2018*
- "Generic drugs rule will keep costs down", khaleejtimes.com, *August 2018*
- "UAE's Health and Pharmaceutical Economic Growth & Innovative Capacity", XX, *Accessed February 2020*
- "U.A.E. Healthcare Sector", usuaebusines.org, *January 2019*
- "Pharmaceutical sector in the UAE is in good health", thenational.ae, *July 2014*
- "3 Regulatory Trends Impacting UAE Healthcare", pharmaboardroom.com, *October 2019*
- "What International Companies Need to Know to Distribute Pharmaceuticals in the UAE", gowlingwlg.com, *May 2018*

- "UAE leading the healthcare sector", home. kpmg, *Accessed February 2020*
- "Legalities Surrounding Pharmaceutical Industry in UAE", stalawfirm.com, *February 2018*
- "Department of Health- Abu Dhabi", haad.ae, *Accessed February 2020*
- "About the Dubai Health Authority", dha.gov.ae, *Accessed February 2020*
- "Health regulatory authorities", government.ae, *Accessed February 2020*
- "Abu Dhabi pharmacies told to dispense generic medicines in new regulation", gulfnews.com, *August 2018*
- "WHO Guideline on Country Pharmaceutical Pricing Policies", apps.who.int, *2015*
- "Dubai Community Pharmacy Licensure & Pharmaceutical Practices Guide", dha.gov.ae, *February 2013*
- "UAE pharma firm begins manufacturing 'affordable' generic medicines in Dubai", gulfbusiness.com, *August 2018*
- "Doctors urged to issue generic brand drugs as UAE acts to make healthcare more affordable", thenational.ae, *November 2019*
- "New Mechanism of Dispensing Generic Medicines introduced by Department of Health Abu Dhabi", healthinsurancearabia.com, *November 2018*
- "Health for all is closer than you think in UAE, say experts", khaleejtimes.com, *April 2018*
- "Health Insurance and the Healthcare System in the UAE Explained", internations.org, *Accessed February 2020*
- "Health Care Around the World: United Arab Emirates", umhs-sk.org, *September 2014*
- "Mandatory health insurance essential for national development, finds UAE University report", thenational.ae, *June 2018*

Country in Focus: Turkey

Country Overview



Source: World Bank Data, Accessed February 2020

Healthcare Overview

The healthcare sector in Turkey has seen significant growth over the past two decades with the Government working towards improving the efficiency and sustainability of the healthcare system. The key objective of the Government is providing all citizens with access to quality services.

Along with the healthcare sector, the Turkish pharmaceutical sector has also seen significant growth, both in terms of sales volume and value. Growing at a CAGR of ~11% during the period of 2010-2019, the sector consists of over 80 manufacturing companies (70 local and 14 multinational). As of 2018, original products account for 68% of the market share in terms of sales value. However, generic drugs account for a majority share in terms of volume. While the country has grown local manufacturing over the last few years, imported drugs still account for ~50% of the total drug value (imports account for ~16% of volume), reaching USD 5B in 2018.

Pricing Policy Overview

Turkey's pharmaceutical pricing is regulated by Cabinet Decree on Pricing Human Medicinal Products and the corresponding Communiqué on Pricing of Human Medicinal Products—these communiqués provide details of the changing requirements of the pricing method.

Turkey had implemented a Cost-Plus mechanism to determine pharmaceutical pricing in 1984 and was operating based on this method for close to two decades. However, Turkey's membership negotiations with the EU and subsequent evaluations brought the Cost-Plus pricing mechanism under scrutiny. A complaint filed by the European Federation of Pharmaceutical Association (EFPIA) led to a Trade Barriers Regulation (TBR) investigation against Turkey. The EFPIA claimed that the existing Cost-Plus pricing approach in Turkey was non-uniform, lacked transparency, and was arbitrary in deciding the ceiling prices. Based on these allegations, the TBR committee evaluated the issues of transparency, discriminatory applications of pharmaceutical imports, sales and marketing system, and discrimination in pricing. This investigation prompted a review of the pricing mechanism and Turkey introduced a new External Reference Price (ERP) pharmaceutical pricing method in 2004—considering Greece, Italy, Portugal, France and Spain as primary reference countries.

The new price control method resulted in reductions in pharmaceutical prices and also provided opportunities to both local and international pharmaceutical companies. However, with ever-increasing expenditure on pharmaceuticals and negative impacts of the global financial crisis led the Government to fix the public pharmaceutical expenditure from 2009-2012. This also involved a revision of the ERP method and resulted in significant reductions in the maximum retail prices of drugs.

- Prior to the revision:
  - Original (Branded) drugs were priced at 100% of the cheapest price available in the pool of reference countries
  - Generic drug indexed to an Original drug was allowed to be priced up to 80% of the Original drug's price
- Following the revision:
  - Original drugs without generic equivalents (due to patent protection) were allowed to price at 100% of reference price
  - Original drugs with generic equivalents were allowed to charge 66% of reference price
  - Generics drugs were allowed to charge 66% of the cheapest reference price

Additionally, due to the depreciation of the Turkish Lira, the Government also enforced restrictions on price revisions generated by exchange rate fluctuations. The previous method allowed price revisions if the exchange rate fluctuations exceeded the fixed exchange rate (Euro Term Value) by more than 5% (considering a period of 30 days). However, post restrictions, price revisions were only allowed if the average exchange rate fluctuations over a period of 90 days exceeded the Euro Term Value by over 15%.

These changes created numerous issues within the pharmaceutical sector including drug shortages, international companies removing innovative products from the market, use of cheaper raw material, and deterioration in quality control measures.

Governance Framework

With a population of over 80 million, Turkey is the second largest pharmaceutical market in Central/ Eastern Europe. With the aim of improving access to healthcare, Turkey introduced Universal Healthcare in 2004 and expenditure on healthcare and pharmaceuticals has been on the rise. Along with this growth, a number of regulations on drug pricing, registration, reimbursements, and promotion have been introduced to tightly control the pharmaceutical sector.

The primary regulation governing the marketing, authorization, and pricing of pharmaceuticals is the Law on Pharmaceuticals and Medical Preparations, Number 1262, dating from 1928. Additionally, the 1987 Law on Medical Services (Number 3359) also plays a key role in Turkey's overall pharmaceutical policy framework. At present, these regulations provide the broader regulatory structure and secondary regulations separately cover different subject matters.

Secondary Regulation Governing Subject Areas

- Law on the Pharmacists and Pharmacies – 1953
- Regulation on the Licensing of Human Medicinal Products – 2005
- Regulation on the Surveillance and Examination of Human Medicinal Products – 2005
- Regulation on Traditional Herbal Medical Products – 2010
- Regulation on Medical Devices – 2011
- Regulation on Clinical Research for Medication and Biological Products – 2013
- Regulation on Sales, Advertisement and Promotion of Medicinal Devices – 2014
- Regulation on the Safety of Medicinal Product – 2014
- Regulation on Pharmacists and Pharmacies – 2014
- Regulation on Manufacturing Plants for Human Medicinal Products – 2014
- Regulation on Clinical Research for Medical Devices – 2014
- Regulation on Promotion of Medicinal Products for Human Use – 2015
- Regulation on Test, Control and Calibration of Medical Devices – 2015
- Council of Ministers Decree on the Pricing of Human Medicinal Products – 2017
- Communiqué on the Pricing of Human Medicinal Products – 2017
- Implementing Regulation for Labelling, Package Leaflet and Tracing of Human Medicinal Products – 2017
- Guidelines for the Labelling, Instructions and Tracing of Human Medicinal Products

Objectives of the Pharmaceutical Regulations

The key objectives of the regulations are to provide affordable access to healthcare while improving the efficiency and sustainability of healthcare sector.

Regulatory Authorities

There are several authorities that play a critical role in Turkey's healthcare and pharmaceutical regulations.

Ministry of Health

Turkey's Ministry of Health is the main regulatory body responsible for drugs, biological and medical devices. The ministry exercises its powers to develop policies for the healthcare sector, implement national health strategies, and set regulations for the pharmaceutical industry—to ensure drugs and medical products are available for consumers and establish a more efficient and sustainable healthcare system in Turkey.

Turkish Medicines and Medical Devices Agency ("TİTCK")

The Turkish Medicines and Medical Devices Agency is a sub-unit within the Ministry of Health and is the authority responsible for the regulation of medicinal products, medical devices, cosmetics, traditional herbal medicinal products, as well as other products that are marketed with a health claim. The primary duties of the TITCK include:

- Providing marketing authorizations.
- Establishing standards for the authorization, pricing, manufacturing, storing, sales, import, export, marketing, distribution, promotion, monitoring of medicinal products.
- Monitor legal compliance and take necessary action including enforcing sanctions for non-compliance

- Regulating, approving and controlling clinical trials relating to the products falling under its authority.
- Maintain accessibility of pharmaceuticals, medical devices and other products that are of vital importance.

Price Evaluation Commission

Housed within the TITCK, the price evaluation committee plays a key role in determining the drug prices and consists of representatives from Ministries of Health, Finance, Development, Treasury, and Social Security Institution. The commission is required to meet once a month for the first six months of the year, unless required to conduct extraordinary meetings based on the invitation of other regulatory institutions. The operational procedures of the commission are governed by the directive prepared by the Authority, taking into account the feedback of institutions that provide representatives to the commission.

Specifically, the commission:

- Takes decisions to increase/ decrease prices of referenced drugs or decide on prices for products for which prices cannot be determined based on the guidelines provided in the communiqué. Applications to the commission for price revisions can be made once a year.
- Re-evaluate the prices of drugs that were previously increased—to decide whether to reduce or maintain the price or to withdraw the drug
- Determine the Euro exchange rate for the year
- Evaluate the pricing of products that are mandatory to be on the market for public health reasons and those products that provide savings in terms of public finance

Current Policies

As a remedy for the issues encountered from the previous revisions, Turkey introduced new rules for Pricing Human Medical Products by way of a Cabinet Decision in February 2017. The corresponding Communiqué on Pricing Human Medical Product (Journal Number 30195) outlining detailed principles on implementing the cabinet decision was released on September 2017.

Source Countries

- According to the document, the primary source countries selected for the ERP system are France, Spain, Italy, Portugal, and Greece
- When determining prices of the source country, information can be gathered from official institutions or generally accepted databases. The price evaluation committee has the authority to request for explanatory information and documents pertaining to the information provided by the applicant/ institutions
- In a situation where a product is offered for sale by a company other than a company that has an economic integrity with an applicant, has an active commercial activity or has a sales authority, such products are not considered as source products.
  - In this situation, price reference is made according to the cost card of the reference product for which the price could not be determined. However, this reference price cannot be higher than the highest priced identical product in the market that is not included source list.

Determining the Real Source Price

Real Source Price: The sale price of the product licensed and available in the source country to the warehouse declared in the price list as Euro

Prior to establishing the reference prices for manufactured and imported products, the "Real Source Price" of these reference drugs have to be determined. The communiqué provides detailed approaches for determining real source prices for the following type of products:

- Imported reference products
- Manufactured reference products
- Imported equivalent products
- Manufactured equivalent products

Real source price of the imported reference products

- The lowest sale price of the product to the warehouse in the source countries and countries where the series is released / imported
- If the product does not have a source product in the countries where the series is released / imported, the lowest sales price of the product to the EU warehouse in the EU countries
- The sale price of the product in any country to the warehouse if it is not available in the EU countries

Real source price of a manufactured reference products

- The lowest sale price to the warehouse in the source countries
- The lowest sale price to the warehouse in the EU countries, if the product does not have the source product in the source countries
- The sales price to the warehouse in any country, if not in the EU countries

Real source price of an imported equivalent products

- (1) The reference product in the price list has the actual source price, or the lowest price of the reference product in the source countries to the warehouse
- (2) While conducting the price research of the imported equivalent product:
  - The lowest sale price of the product to the warehouse in the source countries and in the countries where the series is released / imported / took the form of pharmaceuticals
  - If above is not available, the lowest selling price of the product in the EU countries
  - If not available in the EU, The sale price of the product in any country to the warehouse
- For the 1st method, 60% of the value is taken as the real source price and for the 2nd method, 80% in price protected products and 100% of the real source price of the imported equivalent is taken. The lower value of the two methods are used for real source price determination.
- If the price of the reference product cannot be compared in Turkey and in the source countries, 100% of the real source price of the imported equivalent product is taken into consideration

Real source price of the manufactured equivalent products

- Real source price of the reference product in the price list
- The lowest selling price of the reference product in the source countries to the warehouse
- The real source price of the highest priced equivalent product in the price list
- The real source price of the pharmaceutical reference product, which is on the price list
- The price stated in the cost card

Real source price of products priced by cost card

- For products that are priced according to the cost card, 100% of the total price declared in the cost card is determined as the sale price to the warehouse. The sale price to the warehouse is divided by the periodic euro value and the real source price is found.

General guidelines when determining real source prices:

- In the period of real source price change of manufactured products, which have lost their actual source price due to legislative changes or other reasons, they should conduct real source price research based on guidelines given in "*Real source price of a manufactured reference products*" and "*Real source price of the manufactured equivalent products*".
- Discount practices that cause temporary price changes in the source countries, and special practices and special taxation practices related to product classification are not taken into account in the real source price calculation.
- When determining the real source price, the price of the product in the countries where the product is withdrawn is not taken into consideration.
- A reference or equivalent product that has received a price with a cost card cannot be shown as a source product to another product. For this reason, for products that do not have a real source price product, a price application is made with a cost card. The sales price of the product to which the price is demanded by the cost card cannot exceed the sales price of the one-to-one identical product, which does not constitute the source in the price list and is the highest priced identical product in the market.
- The prices of the products, whose real source price cannot be determined by the above procedures, are determined by the Commission.

Determining the Source Price

Source Price: The price, which is taken as the basis for calculating the sales price of the products to the warehouse in Turkey

Imported or manufactured reference products

- Products that are not price protected:
  - If an equivalent product is not available, source price of the manufactured or imported reference product will be 100% of the real source price
  - If there is a one-to-one or an equivalent product, source price will be 60% of the real source price
- Products that are price protected:
  - Regardless of the equivalence, source price of manufactured or imported reference products will be 80% of real source price

Imported equivalent products

- If the actual price of the product is considered when determining the real source price:
  - Products that are not price protected – source price is 60% of real source price
  - Products that are price protected – source price is 80% of real source price
- If the lowest sale price to the warehouse was considered when determining the real source price:
  - Source price is 100% of the real source price

Manufactured equivalent products

- Products that are not price protected:
  - Source price will be 60% of real source price

- Products that are price protected:
  - Source price will be 80% of real source price

Products priced based on cost card

For products where real source price is determined based on the cost card, 100% of the real source price is considered as the source price.

General Pricing Principles

In addition to the specific rules on determining source prices for defined product types, the communiqué also includes general pricing principles providing additional clarity on specific scenarios that could arise when determining the real source price of reference products and source price of products. These principles are included in the appendix section.

Application and Evaluation Process for Pricing

- Applicants should apply to the Authority with the price declaration form for the first quotation request and for requests regarding changing source price or source country
- Applicants are responsible for the accuracy of submitted information
- Applicants should submit the price declaration document, price declaration form, and application letters received from the company HQ or official authority in the source country for reference and import equivalent products
- Manufactured equivalent products do not require a price declaration document
- If the application date and the institution's price confirmation date are different, sale price to the warehouse will be determined based on the Euro on the approval date
- There is no obligation to submit a price declaration form if changes to the Euro value is to be made by the decision of the commission
- The Authority has the right to request additional information from the applicant
- Applications for the first quotation will be completed within ninety days
- The current price declaration from is valid from the date the first equivalent product is entered into the market
- Following information should be clearly stated in the price declaration document:
  - *Trade name of the product in Turkey and related countries, amount of active substance, packaging size, whether it is only a hospital product*
  - *Ex-factory prices in the relevant countries specified in the real source pricing section, in accordance with the condition of the product*
  - *Ex-factory prices, as specified in the general pricing principles section*
  - *In the countries defined in the above two bullets, whether the products are licensed, whether they are in the market, whether they are reimbursed or not, and their prices,*
  - *Prices of countries with a currency other than Euro, where the source product can be found, in their own currency*
- If the price declaration document is more than one page, the applicant must ensure document integrity

Specially Stipulated Products

Apart from general drugs, the communiqué outlines the approach and pricing mechanism for drugs without real source price tracking, blood products, medical foods / enteral nutrition products, radiopharmaceutical products, allergy products, orphan products, traditional herbal medicinal products, biosimilar products, hospital products, serums, non-refundable / non-prescription products and vaccines.

Further, it states vaccines to be determined by the Commission and products of critical importance for public health are priced should be priced as below:

- For these products, the pricing commission can establish a price higher than the price determined by general pricing principles
- These products that are manufactured in Turkey may receive prices based on the cost card

Further details are included in the appendix section.

Profit Rates

Once the sale price to the warehouse is established, the predefined profit rates are applied to determine the retail prices.

Sale Price to the Warehouse	Storage Profit (%)	Pharmacist Profit (%)
For the part up to 10 TL (including 10 TL)	9	25
For the part between 10-50 TL (including 50 TL)	8	25
For the part between 50-100 TL (including 100 TL)	7	25
For the part between 100-200 TL (including 200 TL)	4	16
For the part above 200 TL	2	12

Framework for Price Revisions

Turkey's pricing mechanism allows for changes in prices in defined circumstances. The communiqué specifically outlines the potential price changes available for real source prices and exceptional real source prices.

Real Source Price Changes

- Applicants can make requests to increase the sale price warehouse as a result of an increase of real source price increase. These requests are evaluated as:
  - In a situation where there is a change in source country, increases up to 20% of the sale price to the current warehouse price is evaluated by the Authority
  - If there is no change in source country, increases up to 50% of the sale price to the current warehouse price is evaluated by the Authority
  - Requests exceeding those stated above will be evaluated by the commission
- For products that received the sales price to the warehouse below the source price to the warehouse, the rate of increase can amount up to rate of increase of the source price
- For products that are currently in the price list and are price tracked, real source price research is carried out based on general pricing principles and required changes are applied in the relevant period

- Notifications regarding the changes to real source pricing or source pricing are made in following periods:

Reference	Period
Application period of reference products that are connected to the real source price or have a price card and manufactured / imported equivalent products without reference products in Turkey	August 15 - September 1 (until finishing work)
Application evaluation period and publication of 1st Interim List	September 2 - September 30
Acceptance of objections to the interim list	October 1 - October 7 (until finishing work)
Publication of the final 1st intermediate list	October 21
Application period of equivalent products with a price card, equivalent products that are reference products in Turkey and other products	October 22 - October 30 (until finishing work)
Application evaluation period and publication of the second interim list	October 31-November 21
Admission to object list 2	November 22 - November 28 (until finishing work)
Appeal evaluation period and publication of the final list	November 29 - December 15

Additional scenarios for real source price changes and exceptional real source price increases are included in the appendix section.

Revisions to the Euro Exchange Rate

Based on the on Pricing of Human Medicinal Products published in 2017, the Euro exchange rate is determined based on the average Euro foreign exchange selling rate for the previous year adopted at 70% coefficient. The price evaluation committee is required to declare the Euro exchange to be used for the year, within the first 45 days of the year.

If the declared Euro value is an increase compared to the previous year, it will come into effect 5 days after the announcement of the decision. If the declared Euro value is a decrease compared to previous year, it will come into effect 45 days after the announcement.

However, there has been criticisms regarding this adoption, especially from pharmaceutical companies, over the past two years. The key issue highlighted was that this coefficient does not cover the significant exchange rate fluctuations over the past year. Due to continued pressure from the industry, the Turkish Government change the coefficient to 60% in 2019— increasing the exchange rate by 26.4%.

Demerits

Drug Shortages

While the Government has implemented the price control mechanism as a means of creating affordability, the continuation of strict policies has resulted in shortages in certain types of drugs as pharmaceutical companies stopped supplying to the market. Most recently in February 2019, Turkey faced a shortage of ~150 types of drugs including those for cardiovascular diseases, high blood pressure and diabetes. As a means of addressing this issue, the Government authorized selling 41 drugs at a higher price than that was decided by the price control mechanism.

Inability to Align with Current Market Conditions

There have been severe criticisms of Turkey's approach to maintain drug prices artificially low—by applying additional discounts and fixing the exchange rate. This has also led to the policy having to be adjusted through the years to ensure drug availability. The most recent change has been the adjustment to the Euro exchange rate coefficient where it was reduced from 70% to 60% with the aim of aligning it more to actual exchange rate fluctuations. As Turkey imports ~50% of its drug needs and a majority of raw material for domestic manufacture are also imported, fixed Euro exchange rate has created significant stress on pharmaceutical companies.

Companies Withholding Innovative Drugs

Due to reduced prices and resulting decline in profitability, multinational companies have withheld their innovative drugs from the market. Additionally, these price controls have also discouraged multinational companies to launch innovative drugs in Turkey and could result in these companies moving to countries that provide higher prices.

Appendix

Appendix – General Pricing Principles

- *When determining the real source price, the sale price to the warehouse is taken, excluding discounts and special discounts in the relevant source country.*
- *Euro is used as the real source price currency. If the country does not use Euro, exchange rate stated by the Central Bank of Turkey on 02/13/2009 will be used as currency sales rate.*
- *When determining the real source price of a product:*
  - *In each row, the same active substance in the same pharmaceutical form:*
    1. *Products with the same packaging size containing the same amount of active substance, which are identical products*
    2. *Products with the closest small packaging size containing the same amount of active substance, if not equivalent*
    3. *Products with the closest large packaging size containing the same amount of active substance, if not equivalent*
    4. *Other products with the same packaging size with the closest low active ingredient containing a different amount of active substance, which is a close identical product*
    5. *Products with the nearest low active ingredient quantity and the closest small packaging size containing a different amount of active substance, which is a close identical product*
    6. *Products with the nearest low active ingredient quantity and the closest large packaging size containing a different amount of active substance, which is a close identical product*
    7. *Products with the same packaging size with the closest high active ingredient amount containing a different amount of active substance, which is a close identical product*
    8. *Products with the nearest high active ingredient quantity and the closest small packaging size containing a different amount of active ingredient, which is a close identical product*
    9. *Products with the nearest high active ingredient quantity and the closest large packaging size containing a different amount of active ingredient, which is a close identical product*
  - *For the same pharmaceutical form of the same active substance in Turkey or in the source countries, if there is no reference product that complies with the above, the price can be determined according to the order the equivalent manufactured products.*
- *When determining the real source price of products in liquid form, price is determined by comparing the amount of active substance it includes, irrespective of the volume of liquid*
- *The sale price of a product priced for the first time to the warehouse is proportional to the Turkish Lira equivalent of the real source price of the product of the same company with the same trade name and the same pharmaceutical form.*
  - *Steps used in proportioning are:*
    1. *From the smallest packaging size in different packaging sizes with the same amount of active substance, or the closest large packaging size*

2. *If products with different amounts of active substance are available, the same packaging size of the lowest quantity of active substance, if not the smallest packaging size, or the closest large packaging size*
3. *If the product with lower active ingredient quantity is not available in the market, the same packaging size of the closest high active ingredient product, otherwise the smallest packaging size, or the closest large packaging size*

– *Once this is done, below prices are compared and the lower price is taken the sale price to the warehouse:*

1. *Turkish Lira equivalent of the source price of the product*
2. *Price derived based on the proportion calculation*

– *Products without source price tracking are not considered in the rate of packaging*

– *If there is no proportional product of the same company with the same commercial name and pharmaceutical form exists, unit price of the product is taken as sales price*

– *Products of the same active substance used in different therapeutic areas will not have any proportionality between prices.*

- *All values in the price list are written considering the first two digits of the last value calculated after the comma.*
- *For all equivalent products, the decrease in the real source price of the reference product, which was reduced to 60% with the introduction of the first equivalent product is not reflected in the sale price until the real source price falls below the 60% limit. When it falls below this limit, the sale price to the warehouse can be taken up to 100% of the new real source price.*
- *If the real source price of a reference product whose real source price falls below the 60% limit increases between 60% and 100% of the first base value used in the calculation, the source price cannot exceed 60% of the first real source price. If the real source price of a reference product, whose real source price is below the 60% limit, increases above the first base value used in the calculation, the source price is calculated to be 60% of the new real source price formed. The base value to be used next is the real resource price value used last. This method applies equally to all equivalent products of reference products.*
- *From the publication of the first equivalent product in the price list to the date on which the product is placed on the market, if there is a change in the actual source price of the reference product, 60% of the real source price of the reference product at the date of entry of the equivalent product, and 80% of the price protected products are considered as source prices. In this process, changes in the real source price are also reflected in the price of the reference product.*
- *The real source price decreases that will occur after the price determined in price protected products are not reflected in the sales price to the warehouse until the 80% limit is below the limit. When the real source price drops below the 80% limit, the sale price to the warehouse can be taken up to 100% of the new real source price. This procedure applies equally to all equivalent products.*
- *If the real source price of the price protected reference product, the real source price of which falls below the 80% limit, increases between 80% and 100% of the first base value used in the calculation, the source price will be 80% of the first real source price. If the real source price of the protected price of the reference product, whose real source price is below the 80% limit, increases above the first base value used in the calculation, the source price is calculated to be 80% of the new real source price formed. The base value to be used next is the real resource price value used last. This procedure applies equally to all equivalent products of price protected reference products.*
- *Requests of products with prices below the source price equivalent to the source price reserve are evaluated by the Commission.*

- *In addition to the release of the existing series, in addition to the new release place and the product arrives in Turkey; this country price is taken into account in the real source price calculation. The same is true for the country in which it is imported.*
- *The place of release of the series of products with special import permit or the country from which it is imported is not taken into account in the real resource price determination.*
- *If a product's price protected product status changes, this applies ex officio to all other equivalent products.*
- *Discounts that applicants will request for any form of a product are not applied to other forms of this product without their own application.*
- *Applications made to obtain a unit price lower than 50% of the unit price arithmetic average of the one-to-one product and peer products that are included in the price list or new to the market, by maintaining the competition and market balances. It is evaluated by the Commission in order to ensure its availability in the market.*
- *In co-marketed products, the low-priced source product is taken into account in the actual source price calculation.*
- *If the reference product received a sale price to the warehouse lower than the TL equivalent of the source price, this does not affect the sale price of the equivalent product to the warehouse.*
- *While giving the price protected product status, the evaluation regarding the definition of the "product" stated in the expression "the product that came to the market before 1/8/1987 for the first time in the world" is made independently from the trade name of the product that came to the market for the first time and the license holder company.*
- *In the event that the product containing a newly discovered active substance (s) is produced and licensed in Turkey for the first time in the world, pricing is made by considering the company declaration.*

Appendix – Specially Stipulated Products

In the initial pricing of the products for which the real source price is not followed:

  - *Reference products produced in Turkey country get a source price of 100% of the real source price. If there is no real source price, it can take a price with a cost card. The equivalent products produced in Turkey; According to the ranking in the third point in the general pricing principles, or the equivalent price of the one-to-one product / co-product / close product in Turkey, or the reference product in the source countries, 100% of the real source price of the pharmaceutical-like reference product in Turkey up to the source price. If the real source price cannot be found, it takes the price with the cost card.*
  - *Imported reference products get a source price of 100% of the real source price. Imported equivalent products; It gets a source price of 100% of the real source price of the reference product in Turkey, or the real product / equivalent product / close product in Turkey. Otherwise, the reference product in the source countries is 100% of the lowest sale price to the warehouse, or 100% of the lowest sale price in the source countries and in the countries where the series is released / imported / pharmaceutical, or the lowest store in the EU countries. It gets a source price of 100% of its price, or 100% of the sale price of the product in any country to the warehouse.*

- *Blood products produced by plasma or recombinant method get a source price of 100% of the real source price. Upon the request of the applicants, the sale price can be given to the warehouse up to TL equivalent of 10% more than the source price. In order to ensure the availability of these products in the market, it can be decided by the Commission to determine the price of those deemed necessary, according to the current exchange rate, to be updated every two weeks, taking into account the Euro sales rate announced by the Central Bank of the Republic of Turkey.*
- *Medical foods and enteral nutrition products; The source with the lowest sales price to the warehouse and the reimbursement from the pharmacy gets a source price of 100% of the real source price of the product. When the real source price cannot be found according to the order in the third paragraph of the article 7, the lowest real source price*

can be taken from the different flavored products of the same product as the source product. For products produced in Turkey, the price can be given according to the cost card. Up to 15% more than the price requested in the cost card, the sale price can be given to the warehouse. Requests more than 15% are evaluated by the Commission.

- *Radiopharmaceutical products receive a source price of 100% of the real source price determined. These evaluations are made according to the lowest sale price to the warehouse and the lowest sale price to the hospital. The lowest price found is taken into account. These products are given ex-factory price excluding VAT and ex-factory price including VAT. For products produced in Turkey, the price can be given according to the cost card. Up to 15% more than the price requested in the cost card, the sale price can be given to the warehouse. Requests more than 15% are evaluated by the Commission.*
- *Allergy products receive a source price of 100% of the real source price. These products are given ex-factory price excluding VAT and ex-factory price including VAT. For products produced in Turkey, the price can be given according to the cost card. Up to 15% more than the price requested in the cost card, the sale price can be given to the warehouse. Requests more than 15% are evaluated by the Commission.*
- *Orphan products receive a source price of 100% of the real source price. For products produced in Turkey, the price can be given according to the cost card. Up to 15% more than the price requested in the cost card, the sale price can be given to the warehouse. Requests more than 15% are evaluated by the Commission.*
- *Imported traditional herbal medicinal products receive a source price of 100% of the actual source price found as a result of the evaluation made according to the highest sale prices to the warehouse. For the production of traditional herbal medicinal products, prices can be given according to the applicants' declaration. If these products fall within the scope of reimbursement, the general aspects of this Communiqué are applied.*
- *Biosimilar products receive a source price of 100% of the real source price of their own product, or the real source price of the product in Turkey. In the case of the biosimilar, the actual source price of the biotechnological product is not changed.*
- *In pricing of hospital products and serums:*
  - *These products get a source price of 100% of the real source price. By adding the existing VAT rate to the warehouse sales price excluding VAT for hospital products, the warehouse sales price including VAT is determined, but the retail price is not determined.*
  - *Imported reference hospital products and imported serums get a source price of 100% of the real source price. Imported equivalent hospital products and imported serums get a source price of 100% of their actual source price. These evaluations are made according to the lowest sale price to the warehouse and the lowest sale price to the hospital. The lowest price found is taken into account.*
  - *In case the real source price of manufactured hospital products and manufactured serums cannot be found, they can get the price of the highest priced product from the one-to-one product / co-product / close-co-products, respectively, according to the cost card. Up to 15% more than the price requested in the cost card, the sale price can be given to the warehouse. Requests more than 15% are evaluated by the Commission.*
- *Imported non-refundable / imported non-prescription products receive a source price of 100% of the actual source price found as a result of the evaluation made according to the highest sale prices to the warehouse. Non-refundable / manufactured non-prescription products can be priced according to the applicant's declaration. If these products fall within the scope of reimbursement, the general aspects of this Communiqué are applied. There is no proportion between the sales prices of non-refundable products to the warehouse on TL basis.*
- *For vaccines to be determined by the Commission and products of critical importance for public health; A price higher than the price determined by considering the general principles regulated in article 7 may be given by the commission. Products that are in this scope and produced in Turkey may also receive prices according to the cost card.*

Appendix – Real Source Price Changes

- *For reference products that are connected to a real source price or have a price card and the manufactured/ imported equivalent products that do not have a reference product in Turkey, the actual source price as of 1st of July in the relevant calendar year is taken into consideration*
- *In the real source price change period, the price decrease of the equivalent products, the price of the source product, is ex officio*
- *The final list published in the real resource price change period will be effective on the first Tuesday after the publication date*
- *In the products that have or should be priced according to the cost card, if the company offers a new cost card, price update should be according to the changing costs. Except for the Euro update and general price increases not specific to the product made by the Commission, it is made in a way not to exceed the cumulative PPI calculated since the last price change date. If the calculated increase rate of these products is higher than the increase in the Euro value, the price increase is given as much as the difference between the calculated increase rate and the Euro value increase rate. If the calculated increase rate of these products is less than the increase in Euro value, no further increase in the price of these products.*
- *Products without real source price tracking:*
  - *If they apply with real source price, the sale price to the warehouse can be updated.*
  - *Manufactured equivalent products without reference products in Turkey can update the sales prices to the warehouse by presenting the real source price of the reference product in the source countries.*
- *Equivalent products, the reference product of which is not available in the market for three years in Turkey, may update their prices by presenting the real source price of the reference product available in the market in the countries determined in general pricing principles*
- *Products with license transfer, product trade name change, product barcode change, applicant's title change and license manufacture or import status change are traded at the current price. However, if a request for a decrease in the sale price to the optional warehouse is made together with the request for the changes to be published in the price list for these products, this request is evaluated simultaneously only if the company undertakes that pharmacy and warehouse stock losses will be covered. Requests for updating the real source price and sale prices to the warehouse are made during the real source price change period.*
- *Firms may receive a price below the sale price to the warehouse specified in the cost card, but then the increases requested until the sale price to the warehouse specified in the cost card are evaluated by the Commission*
- *Before the increase in the value of Euro, except for the real source price change by the Commission, if the product-specific price increase is higher than the increase rate in the Euro value, no additional increase is made in the price of this product. In case the product-specific price increase rate is less than the increase in Euro value, an additional increase is made in the price difference of this product. However, no offsetting arising from the increase in the value of Euro is made for the products whose appraisal requests up to the source price allowance are evaluated by the Commission*
- *Optional decreases to be made in the price list will be valid 60 (sixty) days after the announcement. But;*
  - *This period is not expected when the product is not on the market or if it is committed by the relevant applicants that pharmacy and warehouse stock losses will be covered.*
  - *This period is not expected for new products added to the price list and products with a price increase by the Commission, price corrections made by the Authority and other changes not related to the price change.*

  - *In these cases, the price list is announced every Friday, in case Friday is a public holiday, the previous business day is announced and valid on the next Tuesday.*

- *Inventory losses to be incurred in accordance with subparagraph (a) of the fourteenth paragraph are paid to the pharmacy warehouses by the applicants and to the pharmacies by the warehouses. In this context, the notifications made by the pharmacists to the Pharmaceutical Track and Trace System are based on. The total amount of the difference in the cost of drugs to the pharmacy stocks registered in the Pharmaceutical Track and Trace System and affected by the price arrangements, within 15 (fifteen) days at the latest after the announcement of the price change by the license holders, to the pharmacies no later than 15 (ten). five) is paid within days.*
- *For the products decided by the commission where it may threaten public health or public finance due to its absence in the market; When a company regarding production of products that do not have a licensed reference or equivalent product in the market takes the decision to produce in Turkey, the price is determined by the Commission considering the price stated in the list of Social Security Institution of the imported product with the permission given by the Ministry or the price of the imported product. If the second manufactured product enters the market, its price cannot exceed the price of the current product. If the third product enters the market, no exceptional case applies to all products listed. The reference or equivalent product that is not available in the market is passive in the drug price list in line with the Commission's decision.*

Exceptional Real Source Price Increases

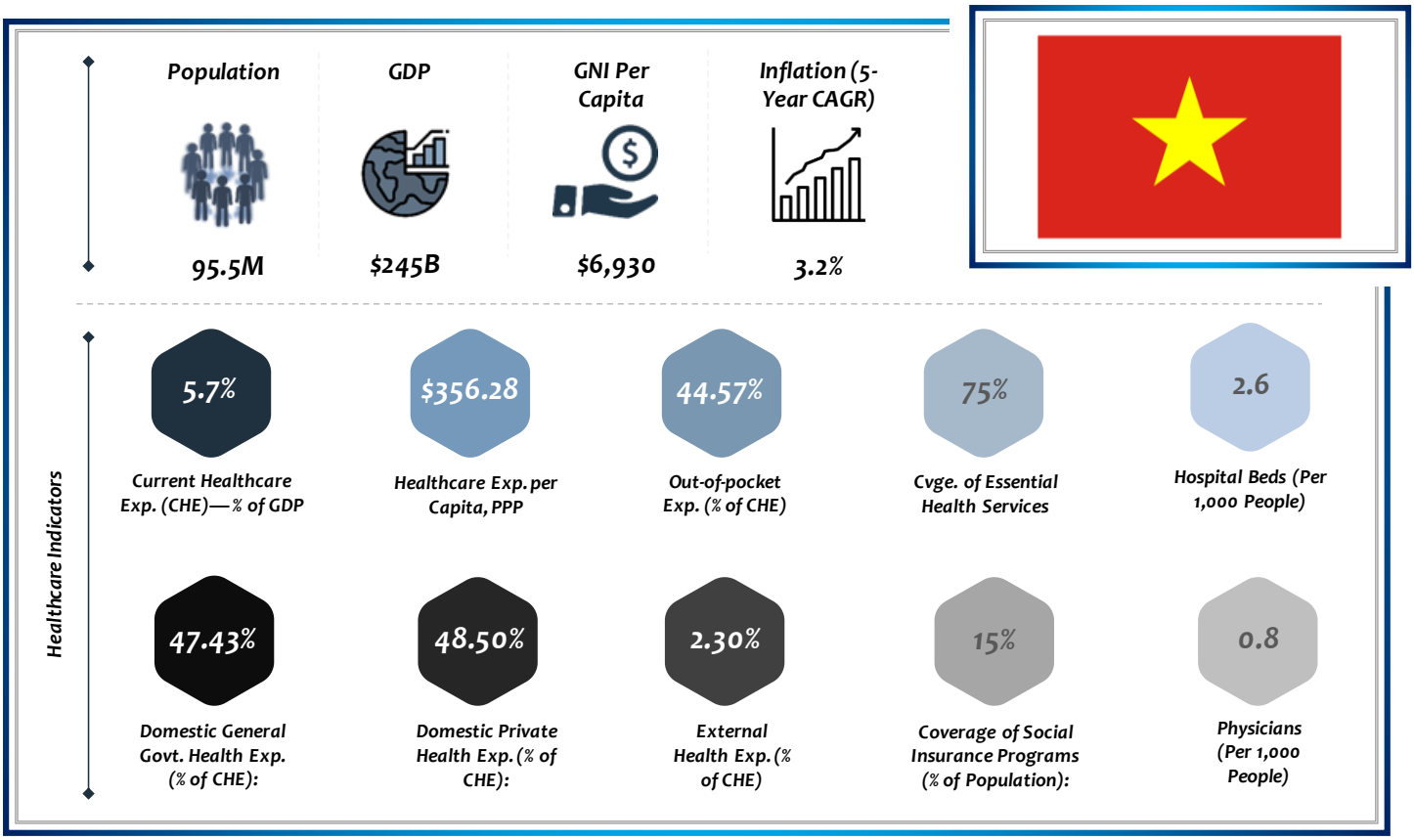
- *Manufacturing traditional herbal medicinal products, manufactured non-prescription products and manufactured non-refundable products may apply for an increase in the price with the price they request in the price declaration form during the real source price change period*
- *Imported traditional herbal medicinal products, imported non-prescription products and imported non-refundable products may apply for a price change by presenting their real source prices during the real source price change period. The products in this scope, which have received the sale price to the warehouse under the source price, can receive the price up to the sale price to the warehouse in return for the source price*

Bibliography

- "Turkish Pharmaceutical Industry", Presidency of the Republic of Turkey Investment Office, September 2019
- "General Overview of Health Sector in Turkey", Harmoni July 2017
- "Turkey: Transforming Health Care for All", The World Bank, April 2018
- "Ethical Overview of Pharmaceutical Industry Policies in Turkey from Various Perspectives", Murat ORAL*, Gülbin ÖZÇELİKAY, 2017
- "Pharmaceutical Antitrust in Turkey", Lexology, April 2019
- "The Turkish Medicines and Medical Devices Agency: Comparison of Its Registration Process with Australia, Canada, Saudi Arabia, and Singapore", Emel Mashaki Ceyhan, Hakki Gürsöz, Ali Alkan, Hacer Coşkun, Oğuzhan Koyuncu, and Stuart Walker, 2018
- "Communique on Pricing Human Medical Products - Official Journal Number: 30195", Turkish Medicines and Medical Devices Agency, September 2017
- "Pharmaceutical and Medical Preparations Law – Law No: 1262", Turkish Medicines and Medical Devices Agency, Accessed February 2020
- "An Analysis of Public Pharmaceutical Policy, Pricing and Spending in Turkey", Türkiye'de Kamu İlaç Politikaları, İlaç Fiyatlaması ve İlaç Harcamasının Analizi, 2016
- "Results of reference pricing and reimbursement discount rate schemes of Turkey", Guvenc Kockaya 1, Kagan Atikeler, Esin Tuna, Pelin Kılıc, Pelin Tanyeri, Nurcan Umman, İsmail Mert Vural, Omer Altun, Akif Akbulat, Guven Artiran, Ercan Simsek, Hakkı Gursoz, Saim Kerman, 2013
- "Pharmaceutical Prices in the 21st Century", Ipek Eren Vural, 2015
- "Interim Evaluation of the European Union's Trade Barrier Regulation (TBR)", Crowell & Moring, June 2005
- "Pharmacy stocks run low as Turkey's drug price policy hits supplies", Reuters, February 2019
- "Current Problems on the Pricing of Pharmaceuticals for Human Use in Turkey", Serap Zuvin Law Offices, Accessed February 2020
- "Turkish Medicines and Medical Devices Agency Announces Draft Regulation on Sales, Advertising and Promotion of Medical Devices", Mondaq, May 2019
- "Increase in Euro Exchange Rate Set for Pharmaceuticals", Mondaq, August 2020
- "Turkey to increase drug prices by over 25 percent", Ahval, February 2019

Country in Focus: Vietnam

Country Overview



Source: World Bank Data, Accessed February 2020

Healthcare Overview

Vietnam's healthcare landscape is an evolution from separately established systems in the North and South, with the former having established an extensive network of primary healthcare facilities during the country's war period from 1945 to 1975 to achieve universal healthcare coverage. The South comprised of a strong private healthcare sector early on, up until the country's unification in 1975, following which private enterprises were banned.

- With the country suffering financial pressures, which included considerable post war reconstruction, and economic blockade by the US, withdrawal of aid from the USSR, increasing inflation across the country, as well as inclusion of the South to the network of free public health services added a severe strain to the already struggling economy.
  - This led to poor maintenance of healthcare facilities and a lack of basic equipment and medicinal drugs in many hospitals and healthcare establishments.
- The country's economic reform process, referred to as the 'Đổi Mới', led to important policy shifts in Vietnam's healthcare system in the late 1980s to early 1990s.

  - This period brought about several market-oriented measures, including the introduction of user fees at public health facilities, legalization of private pharmacy and medical practices, and the liberalization of the production and sale of pharmaceutical medicine.
  - In addition, free access to healthcare services in the country transformed to a system which included direct payments by patients and the provision of free drugs dispensed through the public healthcare system was completely discontinued. Thus, Vietnam's near universal and publicly funded healthcare system was converted into an unregulated public-private mix.
- With the establishment of pharmaceutical policies and governing practices, the sector has been heavily dependent on imports in recent times—accounting for ~50% of the share, focusing specifically on specialized drugs.
  - Domestic production of pharmaceutical drugs accounted for an increasingly growing share, rising from 36% in 2001 to ~50% in 2008. However, this segment continued to face difficulties due to limited R&D facilities, insufficient financial capacity and poor management, and a high usage of imported raw materials.

Pricing Policy Overview

Governance Framework

- Prior to the enaction of Đổi Mới economic liberalization policies, pharmaceutical products were being manufactured & distributed based on a central planning system, consisting of a monopoly of state-run organizations.
  - Prices of medicinal drugs were determined by the State Pricing Commission and the Ministry of Health. At the time, a majority of the drugs were imported from the USSR, using medicinal aid.
  - With aid from the Soviet Union drying up, there were severe shortages of pharmaceutical drugs amidst rising demand by the Vietnamese public, resulting in black markets, smuggling, counterfeits, & theft.
  - Average medicinal drug expenditure per capita was ~$0.5- 1 per year and quality was not a key concern at the time.
- Following the economic reforms, several market-oriented measures were implemented by the government, including introducing user fees at public health facilities, legalization of private medical practices/ pharmacies, and the liberalization of the production and sale of pharmaceuticals, resulting in an unregulated public-private mix.
  - During the period, free access to healthcare was also replaced by a system of direct payments by patients.
  - The Central Resolution 4 (14/01/93) and Decision 58/QD-TTG (03/02/94) which opened up the pharmaceutical sector, led to a 300% increase in production, while importation rose tenfold.
- In 1996, Vietnam's government issued Resolution No. 37/CP, approving key policies such as the 'Strategic Orientation on People's Healthcare to 2000 and vision to 2020', as well as the 'Vietnam National Drug Policy'.
  - The resolutions aimed to ensure adequate supply of high-quality drugs at affordable prices, while also ensuring a rational use of medicines by patients.
  - However, the rapid shift to free market regulations made medicinal drug prices highly unaffordable to many of the general public.
- 2005 saw the enactment of the first 'Pharmaceutical Law', which was initially drafted in 1997 by the MOH. A key aim of the law was to ensure that ~60% of the needs were met by local producers by 2015. This target was unachieved due to issues with raw material availability on the local market & inadequate human resources.

- In 2007, following its entry into the WTO, the country opened its economy to foreign businesses and reduced tariffs on 37 pharmaceutical products from 10-15% in 2006 to 2.5% in 2012.
    - Initially foreign companies could Import drugs into the country but were not allowed to distribute them to the end-users. Such limitations have since been removed.
    - Domestic producers were required to achieve the standard equivalent to Good Manufacturing Practice (GMP— ASEAN), and GMP—WHO, PIC/S, and EU—GMP etc., helping companies integrate better to the global market. As a result, domestic manufacturers certified by the DAV for reaching the GMP—WHO standard increased to ~150 by 2015.
- In 2013 & 2014, laws were established to further support achievement of the country's 5-year health sector plan, while proposing a national strategy for development of the country's pharmaceutical industry to 2020 and its vision to 2030.
    - When evaluated in 2016, the plan was viewed to be generally successful with access to medicines further strengthened and targets set out achieved before their deadlines.
- In August 2019, the Drug Administration of Vietnam, under the Ministry of Health launched the country's first online drug bank (www.drugbank.vn) with the objective of offering a database to support drug management in Vietnam.
    - The drug bank facilitates the development of pharmaceutical companies in the country, while also raising public awareness regarding overall healthcare and drug use habits. The platform currently offers information on over 10K drugs and ~41k pharmaceutical manufacturing/ distribution facilities located throughout the country, including pharmacists.
    - Using the bank, physicians are able to access a complete database of all medicinal drugs in circulation, obtaining updates to the latest information on drugs to support them in providing treatment to the public.
    - The platform provides the public with information regarding safe, effective and, economical use of medicine, while also informing on origin of medicine, prices, and pharmacies meeting Good Production Practices (GPP).

Current Policies

Vietnam currently lacks a cohesive pharmaceutical pricing policy. The current controls have been introduced pre-dominantly through ad-hoc regulations—including numerous decrees & circulars.

- The legal instruments and policies introduced are classed into three focus areas, namely the general management of pricing of most goods including pharmaceutical medicine, the state management of medicinal prices, and the state management of medicinal prices in public health facilities.
    - Decree 120/2004/ND-CP proposed by the Ministry of Finance, aimed to prescribe the management of human-use preventive & curative medicine, stabilize fluctuations, and outline a process to inspect, examine, and handle any violations.
    - Decree 79/2006/ND-CP (Ministry of Health) outlined the state policies for pharmacies, the control of drug prices, and defined the conditions for the drug trade, while managing medicines under special controls, and maintaining drug quality.
    - Decree 54/2017/ND-CP, also proposed by the Ministry of Health, detailed out some articles and guided implementation practices of law on Pharmacy. The decree included areas such as revised drug price management mechanism.

  - Circular 06/2013/TT-BYT (Ministry of Health) provided guidance on the experiment in drug price management by maximum whole surpluses in a cycle, applicable to the drugs covered by the State budget and health insurance.
  - Circular 11/2016/TT-BYT, proposed by the Ministry of Finance, in association with the Ministry of Health, involved stating out the details required for bidding for the supply of drugs for public health facilities.

- Decree 120, Decree 79, and Circular 11 established External Reference Pricing (ERP) as a key control for pharmaceutical products pricing and stabilization.
  - In 2008, the MOH proposed Thailand, Malaysia, Indonesia, The Philippines, and Cambodia as the comparator countries for Vietnam's ERP mechanism.
  - Decree 120 specified that comparator countries are those having similar medical and commercial conditions as Vietnam.
  - At the same time, Decree 79 nominated specific criteria to determine countries with statistical indices similar to that of Vietnam, which included indicators such as GDP per Capita, GDP per Capita (PPP), networks of providing services for preventing medicine, medical examination/ treatment, functional rehabilitation, and health improvement & medicine supply.
  - Circular 11 stated the use of average price standard, employing a medicine to medicine (i.e. identical bioactive ingredients) comparison base.
  - The Circular also established that the declared price of a medicine imported into the country should not be higher than the average CIF (Cost, Insurance, and Freight) price of the medicine sold in comparator countries.
  - Thus, the imported medicines are to be compared to identical products in comparator countries to ensure that the price in Vietnam was the average level in comparator countries.
  - The country also attempted to apply ERP pricing to all medicines and not just on-patent products similar to EU countries.
- In addition to ERP, Circulars 11 and 50 incorporated Cost-Plus Pricing techniques to ensure reasonableness or fairness of declared prices.
  - The circulars established that authorities in charge of pricing use importation or production and distribution costs, and changes in factors that determine price, including active ingredients costs or exchange rates, to determine if the declared prices were of a reasonable level.
- Decree 120 issued maximum distribution margins to ensure reasonableness of wholesale and retail prices.
  - The formula stipulated for retail price included the following: Retail Price = buying price + retail margin percent (%) x buying price.
  - In addition, the maximum retail margins (%) applied to drug retailers in health facilities were as follows:
    - If the buying price is not exceeding VND 1K per smallest pack: *15%*
    - If the buying price is exceeding VND 1K but not exceeding VND 5K per smallest pack: *10%*
    - If the buying price is exceeding VND 5K but not exceeding VND 100K per smallest pack: *7%*
    - If the buying price is exceeding VND 100K but not exceeding VND 1M per smallest pack: *5%*
    - If the buying price is exceeding VND 1M per smallest pack: *2%*
  - Moreover, the decree provided details regarding the definitions of the smallest pack:

- If the dosage form is tablets, pills or capsules, the smallest pack is a tablet, pill or capsule.
- If the dosage form is liquid, the smallest pack is a pre-filled tube, bottle, jar or syringe.
- If the dosage form is powder for solution for injection, the smallest pack is a pre-filled tube, bottle, jar, bag, or syringe.
- If the dosage form is orally administered powder or granules, the smallest pack is a bag, bottle.
- If the dosage form is cream, salve or gel for topical administration, the smallest pack is a tube or jar.
- If the dosage form is transdermal patch, the smallest pack is a patch.
- IF the dosage form is aerosol, the smallest pack is a bottle.
- If the dosage form is a kit, the smallest pack is a kit.

- Circular "06/2013/TT-BYT" applied price control ceilings to wholesale markups. However, results showed that it was difficult to enforce such maximum prices as most critical medicines were imported or produced from imported raw materials.
  - This included only medicines reimbursed through the government budget & the social health insurance fund
  - The exercise included medicines with large consumption value and large price difference between items with the same active pharmaceutical ingredient, strength & dosage— including amoxicillin, cefoperazone, & oxaliplatin.
- Decree No. 54 stipulated that pharmaceutical suppliers are not allowed to sell their products at a price higher than the published price by manufacturers/ importers, enabling the published price to a be a ceiling to control the actual sales price.
  - The wholesale & retail (if applicable) prices have to be declared or re-declared by drug manufacturers or entities ordering the drug-processing or drug-importing entities on the Web Portal of the MOH, with such declarations done prior to introducing the first batch of drugs to the market.
  - There were also stricter requirements in case of increasing the drug price with manufacturers/ importers/ distributors required to provide justification on drug efficacy, a comparison between cost and effectiveness, and technology evidence & a cost breakdown of the drug price.
- Furthermore, prior to marketing pharmaceutical products in Vietnam, such medicine must be registered with the MOH with a declared price nominated by the registrant company.
  - The MOH then issues a marketing authorization, usually valid for 5 years, after which the product must be re-registered.

Merits

Maintaining of Drugs below Consumer Price Inflation

- Even though implementation & enforcement has been inconsistent, Vietnam has been able to keep the Consumer Price Index (CPI) for drugs and medical services controlled at a level below general consumer price inflation.

Minimizing Price Discrimination & Eliminating Price Gouging

- As manufacturers & importers are required to disclose prices through the Ministry of Health's website, this creates greater visibility for the public, while minimizing price discrimination & also eliminating price gouging.

Demerits

Lack of Definition of Prices for International Comparisons

- Implementing the ERP mechanism in Vietnam was found to be relatively challenging as regulations did not explicitly define the type of prices for international comparisons (i.e., ex-factory price, retail or wholesale price, before or after taxes)
  - The Decrees, namely 120 & 79, used non-specific language, particularly around the requirement of the price of a medicine sold in the country ("to be not higher than" prices of medicines of "the same categories" sold in comparable countries), thus creating confusion among pharmaceutical manufacturers and distributors as such statements could be interpreted in such a way that the price in Vietnam could be as high as the highest price among the comparator countries.
  - Further, due to difficulties in policy implementation and enforcement, Vietnam's ERP pricing system was included in legislation, but not applied in practice.

Lack of Formula for Calculating the Declared Price

- While a 'Cost-Plus' pricing mechanism was introduced under Circulars 11 & 50, no specific formula for calculating the declared price from costs were stated in the legislation, making compliance difficult for suppliers.

Unclear Implementation of Retail & Wholesale Price Margins

- Under Decree 120 which specified maximum distribution margins, the Ministry of Finance was specified to be the authority responsible for specifying the maximum wholesale/ retail mark-ups. However, no circulars were issued by this Ministry for implementation and thus, wholesale & retail margins were not clearly regulated.

Inflated Prices

- No pricing regulations explicitly stipulate that the prices declared to the MOH should be the price to publish for customers reference resulting in the lack of a mechanism to ensure a fair or reasonable published price.
  - As a counteract to this limitation, Circulars 11 and 50 required producers & importers to declare the final wholesale price of medicines and wholesalers were not permitted to sell medicines to retailers at higher prices
  - While pharmaceutical companies declare higher prices at the time of authorization, so as to avoid having to declare again for an increase, studies conducted suggested that the declared prices were sometimes ~200% more than the selling prices.
  - Further, the regulation also failed to consider economic circumstances such as adjustments for inflation over the life of the license. Additionally, the shortage of personnel & resources for assessing the reasonableness of declared prices meant that most of the information on drug prices declared by pharmaceutical companies were not validated.

Bibliography

- "Distribution and marketing of drugs in Vietnam", Tilleke & Gibbins, December 2019
- "Pharmacy Law Guidance Scheduled for July Implementation in Vietnam", Vietnam Briefing, June 2017
- "Medicine prices and pricing policies in Vietnam", School of Public Health & Community Medicine, April 2011
- "Corruption practices in drug prescribing in Vietnam", BMC Health Services Research, July 2018
- "Medicine pricing policies: Lessons from Vietnam", Southern Med Review, October 2010
- "Inflated medicine prices in Vietnam", Oxford University Press, February 2017
- "Pharmaceutical Industry in Vietnam: Sluggish Sector in a Growing Market", International Journal of Environmental Research & Public Health, August 2017
- "Healthcare Market Access: Vietnam", Phamax, January 2015

This report has been privately commissioned for the perusal of Sri Lanka Chamber of the Pharmaceutical Industry (SLCPI) and its stakeholders. The policy review herein is based on secondary research carried out by Stax on seven reference countries, namely India, Bangladesh, Malaysia, Thailand, UAE, Turkey and Vietnam, as proposed by SLCPI.

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