PRICING OF MEDICINES

GRATA INTERNATIONAL

PRICING REGULATION IN HEALTHCARE IN BELARUS: DRUGS

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To date, the basis for regulation of prices for drugs in Belarus is represented by an extensive list of regulatory legal acts and explanations of state bodies.

The main legal acts in this sphere are:

1. Edict of the President of the Republic of Belarus of August 11, 2005 No. 366 "On Formation of prices of drugs, medical devices and medical equipment", hereinafter – Edict No. 366.
2. Edict of the President of the Republic of Belarus of August 22, 2018 No. 345 "On registration of prices of drugs".
3. Resolution of the Council of Ministers of the Republic of Belarus of October 31, 2018 No. 776 "On registration of manufacturers' maximum selling prices of drugs".
4. Instruction on the methodology of calculation of manufacturers' maximum selling prices of drugs approved by Resolution of the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus of July 11, 2023 No. 45 "On approval of the Instruction on the methodology of calculation of manufacturers' maximum selling prices of drugs", hereinafter – the Instruction.

The basis for control of the price growth of drugs sold in Belarus by the retailers and wholesalers is the establishment of maximum wholesale and retail markups for drugs.

Amounts of maximum wholesale and retail markups for drugs:

Selling price of the Belarusian manufacturer or estimated selling price per unit of goods, in basic units	Wholesale markup to the selling price of the Belarusian manufacturer or the estimated selling price, in percent	Retail markup to the selling price of the Belarusian manufacturer or the estimated selling price, in percent
1. Up to and including 0.5	9	30
2. Over 0.5 and up to 1 inclusive	8	25
3. Over 1 to 1.5 inclusive	7	14
4. Over 1.5 to 3 inclusive	7	12
5. Over 3 to 5 inclusive	6	10
6. Over 5 to 10 inclusive	4	5
7. Over 10	2	1

There is a different regulation for the manufacturers of drugs from the List of drugs, the maximum selling prices for which are subject to registration (hereinafter referred to as the List). Example of drugs from the List: amoxicillin + clavulanic acid; valsartan; ibuprofen; nimesulide; lactulose; omeprazole; rivaroxaban etc.

The Instruction determines the methodology of calculating manufacturers' maximum selling prices for drugs, defining it as an average value calculated from the weighted average of the actual selling (contract) price, adjusted for the forecasted consumer price index and the average arithmetic value calculated based on manufacturers' minimum selling prices in reference countries and the country of the dosage form.

Note: the list of reference countries includes Belgium, Bulgaria, Hungary, Greece, Kazakhstan, Latvia, Lithuania, Poland, Russian Federation, Romania, Slovakia, France, and the Czech Republic.

The possibility to determine independently the maximum selling price of a drug is provided for new drugs in the absence of sales on the domestic and foreign market, absence of information on the manufacturer's price of a drug on the Internet, including the manufacturer's price of a drug having the nearest adjacent amounts and (or) dosages.

There is a requirement to register manufacturers' maximum selling prices for drugs. The registration of the maximum selling price is based on the fact that the drug is included in the List.

Registration is carried out by the Ministry of Health. The body authorized to receive and review documents is the Republican Unitary Enterprise "Center for Expertise and Testing in Healthcare" and the Ministry of Antimonopoly Regulation and Trade is authorized to conduct economic analysis of the maximum selling price.

The state register of manufacturers' maximum selling prices for drugs is available on the website of the Republican Unitary Enterprise "Center for Expertise and Testing in Healthcare" at the following link: https://www.rceth.by/Refbank/reestr_drugregpricenew/results.

The maximum selling prices are registered in Belarusian rubles.

Note that the holder of the registration certificate (or authorized person) may specify the currency of the contract when applying, if the drug is sold in the territory of Belarus based on a contract in which the amount of payment is expressed in foreign currency.

Some price registration issues:

more than one participant is involved in the manufacturing of a drug	one maximum selling price shall be registered regardless of the number of such participants
the drug is available in the same dosage form and in various doses, prepackaging, primary packaging	maximum selling prices are registered for each variant of dose, prepackaging, primary packaging
the drug may be produced with different combinations of the number of units in the primary packaging and the number of primary packaging in the secondary package	one maximum selling price is registered for all combinations

The registered maximum selling price may be changed. Economic inexpediency could be a reason to change the already registered maximum selling price. Among the cases considered while calculating the new maximum selling price: changes in commodity prices, materials, overhead expenses.

REFERENCE PRICING FOR PHARMACEUTICALS IN GEORGIA

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Under the Law of Georgia on Medicines and Pharmaceutical Activities (the Law) the Government of Georgia (GoG) defined the methodology, rules and conditions for the state regulation of prices for relevant pharmaceutical products approved by its Ordinance #593 from 27 December 2020. The Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia (the Ministry) maintains the reference retail and wholesale prices' catalog and ensures its publicity.

Under the Law the reference retail or wholesale price is defined as the maximum limited retail sale price of a pharmaceutical product in GEL, including pharmacy's charges.

Under the Ordinance #593 of GoG The reference price is set at two levels: for the original pharmaceutical product (including the original biological medicinal product) and for the generic and remanufactured pharmaceutical product (including the biosimilar medicinal product). Reference prices do not represent actual prices, they determine the upper limit of the maximum allowable price, at which the sale or issuance of the product at a higher price will lead to the imposition of liability established by the Law.

Regarding the reference price, an exception can be allowed only for a pharmaceutical product that does not have a substitute therapeutic alternative on the market of Georgia.

For patent-protected expensive original pharmaceutical products, where external reference pricing methodology is not relevant, the state uses the mechanism of Managed Entry Agreement (MEA).

For international price comparison in order to determine the reference prices, the reference prices of four reference countries are used. Those countries are Latvia, Montenegro, Bulgaria and North Macedonia. The reference wholesale price of a pharmaceutical product is determined by the arithmetic average of the average wholesale prices (without VAT) of comparable products in the reference countries.

Planned revision of reference prices is carried out once a year and is published in November by the Ministry.

Information on reference wholesale and reference retail prices is public and is published in the form of a price catalog on the official website of the Ministry https://www.moh.gov.ge/. The prices published in the price catalog take effect 1 month after publication.

The most recent catalog of the reference prices include pharmaceutical substances under 2079 International Nonproprietary Names.

The penalty for failure to comply with the reference prices defined for pharmaceutical products varies from GEL 5 000 to GEL 30 000.

GOVERNMENT REGULATION OF PRICES FOR MEDICINES AND MEDICAL DEVICES IN THE REPUBLIC OF KAZAKHSTAN

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In the Republic of Kazakhstan, as in many other countries worldwide, regulating prices for medicines and medical devices (MD) is one essential tool for monitoring the medicines market.

State regulation of prices for medicines and medical devices in Kazakhstan are regulated by the *Code of the Republic of Kazakhstan dated July 7, 2020, No. 360-VI ЗРК "On Public Health and Healthcare System" (Healthcare Code) and the Rules for the regulation, formation of maximum prices and markups for medicines, as well as medical devices within the guaranteed volume of free medical care and (or) in the compulsory social health insurance system, approved by Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 11, 2020, No. ҚР ДСМ-247/2020 (Price Regulation Rules).*

The authorized body determines the procedure for state price regulation and affects only those registered and in circulation in Kazakhstan, sold wholesale and retail, and included in special lists of medicines whose prices are regulated. The state also regulates prices for registered medicines and MD included in the guaranteed volume of free medical care and (or) in the compulsory social health insurance system.

In Kazakhstan, as part of the state healthcare system, for example, as in France, Italy, Great Britain, Canada, and other countries, citizens are provided with medicines and MD free of charge when providing emergency medical care, inpatient, hospital-replacement medical care and sanatorium-resort treatment. Also, specific categories of citizens with certain diseases (conditions) within the guaranteed volume of free medical care are guaranteed free and (or) preferential provision of more than 600 types of medicines and MD purchased from budget funds.

In Kazakhstan, several mechanisms regulate prices for medicines and MD, including setting maximum prices, controlling manufacturer prices, and limiting trade markups.

When setting maximum prices for medicines and MD, the costs of production, transportation, insurance, storage, and the profit margin shall be considered. Relevant documents shall confirm the costs.

Markups on medicines and MD, including under special procedures, are differentiated by a regressive scale of markups depending on the cost of the medicines and MD; the more expensive the drug or medical device, the lower the markup.

The list of medicines for wholesale and retail sale, whose prices are regulated by the state, is approved by the authorized body no more than once every six months in agreement with the antimonopoly authority. At the same time, the authorized body approves the manufacturer's maximum prices and retail/wholesale prices for the medicine's trade name.

Compliance with pricing rules is controlled by an authorized body, namely the Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan and its territorial divisions.

All healthcare entities, including manufacturers, distributors, and pharmacies, must comply with maximum medicines and MD prices. Fines and other penalties are provided for violations of established standards. Exceeding the established price limits can lead to serious consequences, including administrative liability. According to Article 426 of the Code of the Republic of Kazakhstan on Administrative Offences, exceeding the established maximum prices for medicines entails the imposition of an administrative fine on individuals in the amount of 70 monthly calculation indices (MCI), on officials in the amount of 100 MCI, on legal entities - up to 1,000 MCI. Repeated violation within a year after the imposition of an administrative penalty entails suspension of the license and (or) annex to the license for pharmaceutical activities for up to six months.

Even though state price regulation aims to ensure the availability and quality of medicines and MD for the population and maintain a balance between the interests of manufacturers, suppliers, and consumers, since 2021, the Agency for the Protection and Development of Competition (APDC), together with the Ministry of Healthcare, has been working on the gradual abandonment of state medicine price regulation.

Above all, medicines that will remain under state regulation were identified. These are medications purchased for the treatment of:

- within the framework of the guaranteed volume of free medical care and (or) in the compulsory social health insurance system,
- socially significant diseases,
- cancer patients,
- orphan diseases,
- coronavirus infection (special order).

The remaining medicines are planned to be removed from state regulation in three stages, from 2022 to 2026.

At stage 1 – 2022–2023 – 2551 medicines. These are homeopathic remedies, dietary supplements, vitamins, and medications to treat simple diseases. They are all over the counter and available for sale.

At stage 2 – 2023–2025 – prescription medicines and antibiotics.

At stage 3 – 2025–2026 – the remaining medicines, except those that will remain under state regulation.

This process aims to reduce the number of medicines subject to government price regulation. It is expected that this will increase competition in the market, which, in turn, should lead to lower prices for consumers, improved quality of services provided, innovation, and the development of more effective medicines.

The gradual deregulation of medicines has already begun, but no active dynamics have been observed so far. Thus, on November 16, 2023, on the Open Legal Entities portal was published a draft order to amend the order of the acting Minister of Healthcare of the RoK, dated August 27, 2021, No. ҚР ДСМ-94 "On approval of manufacturer's maximum prices for the trade name of a medicinal product, maximum prices for the trade name of a medicinal product for retail and wholesale sales". The document contains 4913 names of prescription medicines, excluding over-the-counter medicines. This project complies with the Roadmap for developing competition in the healthcare sector, created by the Ministry of Healthcare and the APDC and approved on December 29, 2022.

However, the draft order published on December 7, 2023, already includes 6,953 names of medicines, including over-the-counter ones. Based on this, we assume the deregulation process can be suspended or modified.

PRICING OF MEDICINES IN MONGOLIA

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In Mongolia, the regulation of medicine prices is a crucial aspect of healthcare policy, impacting access to essential treatments and the overall functioning of the healthcare system. With a rapidly evolving healthcare landscape and increasing demands for quality healthcare services, the Mongolian government has implemented various measures to ensure the affordability and accessibility of medicines for its citizens. The pricing policy for medicines in Mongolia is designed to strike a balance between promoting innovation in pharmaceuticals, ensuring fair competition among manufacturers and distributors, and safeguarding the affordability of medicines for all segments of society. This dynamic policy framework reflects Mongolia's commitment to enhancing public health outcomes while navigating the complexities of the global pharmaceutical market.

Within the framework of the National Medicine Policy (2014), Mongolia aims to supply the population with a diverse range of highly effective, safe, and quality medicines. In terms of price, the following strategies are implemented:

1. **Promote the use of generic medicines and implement a strategy to substitute brand-name medicines with generic ones;**
2. **Establish a price database and disseminate impartial and accurate information on medicines costs to healthcare professionals and consumers;**
3. **Impose price control or limit on the price of essential medicines;**
4. **Enhance the licensing system for pharmaceutical supply entities to foster competition and lower medicines prices.**

The Policy's implementation span extends from 2014 to 2018; nevertheless, it continues to be effective, with no additional policies currently enacted.

Further as outlined under the Law of Mongolia on Medicines and Medical Devices (2010), the Government of Mongolia establishes the maximum prices for medications that are listed as essential medicines and orphan drugs. According to the most recent list of "Types of essential medicines, their price ceilings, and discount rates to be provided from the Health Insurance Fund", there are 590 types of medications priced between MNT 40 and MNT 123,000, with discounts ranging from MNT 12 to MNT 86,100.

A temporary inspection committee has been established under the Resolution No. 60 of the State Great Khural of Mongolia (the Parliament), dated June 30, 2023, to scrutinize the factors contributing to the rise in medicines prices. The Committee is undertaken to investigate the price, availability, purchasing power, and pricing structure of medicines in Mongolia, along with identifying the underlying reasons and conditions leading to the escalation of drug prices. The Committee is currently in operation and conducts inspections within the following frameworks:

1. Approval of the essential drugs list, current status, and challenges.
2. Quality standards, safety measures, and assurance protocols for essential drugs.
3. Investigation into the underlying causes and circumstances driving the price surge of essential medications in the market.
4. Accessibility of essential drugs and associated challenges.
5. Proposals for enhancing Mongolia's drug inspection framework and optimizing inspection procedures for greater efficacy.

According to the Medicines and Medical Devices Regulatory Authority, Mongolia imports over 3,400 types of drugs while domestically producing about 1,000 types. As of March 16 of the previous year (2023), Mongolia has registered a total of 4,204 types of drugs, with imports accounting for approximately 80 percent. Moreover, around 220 organizations with special licenses for drug importation are currently active in the country.

In summary, essential medicines are subject to price control or limit in order to ensure affordability to the general public. In addition to this policy, Mongolia endeavors to sustain lower prices and a wide range of medication options by fostering competition among pharmaceutical suppliers.

References:

1. "The Law of Mongolia on Medicines and Medical Devices"
https://legalinfo.mn/mn/detail/85

2. "The Law on Health"
https://legalinfo.mn/mn/detail/49

3. National Medicine Policy (2014)
https://legalinfo.mn/mn/detail/10736

4. Appendix of Resolution No. 11, dated July 4, 2022, by the National Health Insurance Council, "Types of essential medicines, their price ceilings, and discount rates to be provided from the Health Insurance Fund"

5. Resolution No. 60 of the Great Khural of Mongolia, dated June 30, 2023

SPECIFIC FEATURES OF PHARMACEUTICAL PRICING IN THE RUSSIAN FEDERATION

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The issue of regulation of prices for medicines is one of the most relevant in the context of social policy of the state. Setting prices for medicines requires balancing the interests of the population and pharmaceutical companies aimed at increasing the cost of products. That is why the state often provides for measures to regulate pricing, involving the establishment of marginal selling prices and mark-ups for certain drugs.

Thus, in the Russian Federation, regulation of prices for medicines is carried out in accordance with the provisions of Federal Law No. 61-FZ dated 12.04.2010 "On Circulation of Medicines". To implement state regulation, the List of Vital and Essential Medicines for Medical Use (approved by the Order of the Government of the Russian Federation No. 2406-r dated 12.10.2019) has been approved. Inclusion of drugs in the List of Vital and Essential Drugs for Medical Use (hereinafter - the VED List) is based on the analysis of clinical efficacy, possible consequences of use, as well as the assessment of economic factors. Examples of drugs included in the VED List are: omeprazole, Drotaverine, retinol, loperamide, ascorbic acid and others.

In relation to the medicines included in the List of VEDs, a methodology for calculating manufacturers' maximum selling prices has been approved, and the amounts of wholesale and retail mark-ups to actual selling prices have been established. Manufacturers' maximum selling prices are subject to registration in the State Register of manufacturers' maximum selling prices for medicinal products included in the List of Vital and Essential Medicinal Products for Medical Use. The rules for maintaining the said register are regulated by Resolution of the Government of the Russian Federation No. 865 dated 29.10.2010 "On State Regulation of Prices for Medicinal Products Included in the List of Vital and Essential Medicinal Products".

At the same time, it should be noted that the pricing of drugs not included in the Vital and Essential Drug List is carried out by pharmacies independently on the basis of costs associated with the storage, purchase and sale of drugs. The state does not set maximum selling prices and mark-ups for this category of medicines.

At the same time, the COVID-19 pandemic served as a catalyst for changes in the pricing system for medicines not included in the List of Vital and Essential Drugs. Thus, Resolution of the Government of the Russian Federation No. 1310 dated 29.08.2020 "On Approval of the Rules for Formation of the List of Medicinal Products Not Included in the List of Vital and Essential Medicinal Products, in respect of which the maximum selling prices of manufacturers, maximum

wholesale mark-ups and maximum retail mark-ups to the actual selling prices of manufacturers are established" approved special rules according to which the state authorities of the constituent entities of the Russian Federation shall set the price of medicinal products not included in the List of Vital and Essential Medicinal Products. This state regulation implies the establishment of maximum selling prices, as well as wholesale and retail mark-ups in respect of the drug. At the same time, the maximum wholesale mark-up and the maximum retail mark-up to the manufacturer's actual selling price for a medicinal product are established for each constituent entity of the Russian Federation. A decision on state regulation of the price of a drug not included in the List of VEDs may be made if the Federal Service for Healthcare Supervision reveals an increase in retail prices for the drug by 30 per cent or more.

Additionally, it should be emphasized that Article 14.4.2 of the Code of Administrative Offences of the Russian Federation No. 195-FZ dated 30.12.2001 provides for administrative liability for the sale of medicinal products in violation of the requirements of the legislation on the circulation of medicines in terms of setting maximum wholesale or retail mark-ups to the actual selling prices set by manufacturers of medicinal products for the said medicinal products. The amount of an administrative fine for a pharmaceutical organization may be set in the amount from 250,000 to 500,000 thousand roubles.

It follows from the above that at the moment with respect to the drugs included in the List of Vital and Essential Medicines for Medical Use in the Russian Federation there is a pricing system that involves the establishment of maximum selling prices, as well as wholesale and retail mark-ups. The maximum selling prices are subject to registration in the relevant Register. These methods of state regulation have a positive effect on the final prices of drugs included in the List of Vital and Essential Drugs. Pricing for medicines not included in the VED List is set by pharmacy organizations depending on their own costs. At the same time, the current legislation provides for the possibility of regulating the pricing of medicinal products not included in the List of VEDs. If the Federal Service for Healthcare Supervision reveals an increase in retail prices for a drug by 30 per cent or more, the drug will be subject to state price regulation measures. This measure prevents unjustified price increases for many imported medicines necessary to maintain the health of the country's citizens. Violation of the current legislation on pricing of medicines may result in the imposition of an administrative fine.

PHARMACEUTICAL PRICING IN TÜRKİYE

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1. Institutional Structure of the Pharmaceutical Sector in Türkiye

The pharmaceutical sector in Türkiye is regulated through various governmental institutions. The Ministry of Health and its affiliated bodies play a main role in overseeing organizations within the pharmaceutical sector and formulating policies relevant to the industry. The Ministry of Health is responsible for regulating activities within the sector, managing licensing processes, and determining policies related to the functioning of the healthcare system in general.

The Turkish Medicines and Medical Devices Agency ("TİTCK") is an organization that ensures compliance with international standards by granting licenses and marketing authorizations to pharmaceutical companies, conducting compliance audits according to regulations, enforcing necessary sanctions, and approving clinical trials. Additionally, TİTCK takes measures to increase accessibility of products and makes relevant regulations.

The Social Security Institution ("SGK") is an institution responsible for the reimbursement of companies for medicines provided free of charge by the state to its citizens and aims to provide effective, fair, accessible and sustainable healthcare services within the scope of general health insurance. The SGK is authorized to determine the pricing and reimbursement terms of pharmaceuticals.

2. Pharmaceutical Pricing System in Türkiye

Pharmaceutical pricing in Türkiye has been a matter of significant discussion over time due to its importance in public health. The pricing of medicinal products is regulated by the Turkish Ministry of Health, which was authorized to make regulations in this field by the Decree on the Pricing of Human Medicinal Products ("Decree") in Turkish Law and the Communiqué on the Pricing of Human Medicinal Products published in the Official Gazette numbered 30195 on 29.09.2017 ("Communiqué").

Pharmaceutical pricing in Türkiye has been conducted according to the "Reference Price System" since 2004. Under this Reference Price System, drug prices are determined by selecting the lowest price among five European Union ("EU") member countries determined by the Ministry of Health and the country from which the drugs are imported, along with the country where "parallel importation" is carried out.

The actual source price is used in determining prices, which is the sales price of the product to the warehouser, and this price is considered as the lowest sales price to the warehouser of the source product that is licensed and sold in the market among the determined countries, excluding discounts. The actual source price is denominated in euros, and calculations are made based on the determination of the value of 1 (one) Euro.

The source countries determined by the Ministry of Health among EU member countries are France, Spain, Italy, Portugal, and Greece. Although the designated source countries are taken into account, countries where the product is manufactured or imported, outside of these reference countries, and if there is a warehouse sales price lower than the reference country prices in those countries, the price in the country with the lower warehouse sales price is accepted as the reference price.

Official or generally accepted databases can be used to determine source country prices. Monitoring of databases allows for the identification of all aspects declared by applicants and explanatory information and documents may be requested from applicants or official institutions regarding all matters declared.

3. Pharmaceutical Pricing Process in Türkiye

a. Price Evaluation Committee

Price Evaluation Committee ("Committee") is formed under the coordination of the Ministry of Health with the participation of representatives, at least at the level of general director or authorized representatives, from the Ministry of Finance, Ministry of Development, Undersecretariat of Treasury, and Presidency of the SGK. The Committee convenes at least once a month during the first six months of each calendar year. However, in the event of extraordinary circumstances, the Committee may also convene upon the invitation of one person.

The Committee makes decisions regarding the increase, decrease, maintenance, or determination of prices for products whose prices cannot be determined according to the provisions of the Decree. Accordingly, increases in drug prices can be made based on rates determined by the Committee. General increase decisions made by the Committee can also be applied to other products upon request by the Ministry of Health.

In order to protect public health and ensure accessibility to medication, it is regulated in Article 3, Paragraph 3 of the Decree that, before the increase in the Euro value used in pricing human medicinal products, specific price increases for products for which price changes have been made, except for changes in the actual source price determined by the Price Evaluation Committee, will not result in additional increases if the specific product price increase rate is higher than the increase rate in the Euro value. However, if the specific product price increase rate is lower than the increase rate in the Euro value, an additional increase can be applied to the product price for the difference rate. However, products for which requests for reaching the source price have been considered appropriate by the Committee will not be subject to offsetting based on the increase in the Euro value.

As an exception, the Committee may determine drug prices and/or profit margins differently or use different pricing models, such as differentiating prices or paying box-based service fees to warehouses/free pharmacies, for drugs subject to purchases made using alternative reimbursement models under Article 73 of Law No. 5510 dated 31/5/2006 on Social Insurance and General Health Insurance ("Law No. 5510"), without adhering to the provisions of the Decree and the Communiqué.

b. Determination of the Value of 1 (One) Euro

As per current legislation and explicitly regulated in the Decree, the value of 1 (one) Euro in Turkish Lira to be used in pricing human medicinal products is determined by multiplying the annual average Euro value calculated based on the daily Euro exchange sales rate announced by the Central Bank of the Republic of Türkiye, which is indicative and published in the Official Gazette of the previous year, by the adjustment coefficient set at 60%.

The Committee convened within the first 45 days of each year to announce the value of 1 (one) Euro to be used in pricing human medicinal products, in accordance with the aforementioned procedures.

The value of 1 (one) Euro in Turkish Lira to be used in pricing human medicinal products was increased by 25% in December 2023, and the new periodic Euro value was determined as 17.5483 TRY. It has been decided to continue applying this amount for the year 2024, and a new valuation of 1 (one) Euro has not been made for the year 2024. In the current economic situation in Türkiye, the average Euro selling rate for 2023 was 26.025 TRY, and the average Euro selling rate for 2024 is currently 33.844 TRY.

In the case of countries with different currencies;
- For currencies for which the Central Bank of the Republic of Türkiye officially announces the foreign exchange selling rate, the foreign exchange selling rate on 13/2/2009,
- For currencies for which the Central Bank of the Republic of Türkiye has not officially announced a foreign exchange selling rate, the conversion rate on the relevant date from the official representative office of that country in our country or from the website of the central bank of that country or from the website of the European Central Bank based on the Euro equivalent.

c. Profit Margins

The profit margins for warehousers and pharmacists are applied as indicated in the table below when determining the retail selling price of products other than drugs subject to purchases made using alternative reimbursement models specified in Law No. 5510 and mentioned above.

Sale Price to Warehouser;	Warehouse Profit (%)	Pharmacist Profit (%)
Up to 10 TL (including 10 TL)	9	25
For the remaining part between 10-50 TL (including 50 TL)	8	25
For the remaining part between 50-100 TL (including 100 TL)	7	25
For the remaining part between 100-200 TL (including 200 TL)	4	16
For the part over 200 TL	2	12

d. Price Applications

License or applicants submit an application to the Ministry of Health along with the Price Declaration Form for initial price acquisition and real source price change requests. These price applications are finalized within 90 (ninety) days.

e. Pharmaceutical Reimbursement System in Türkiye

In Türkiye, pharmaceutical companies apply to the SGK for reimbursement after obtaining product licensing approval. Accepted applications are evaluated clinically, technically, and financially by the Medical and Economic Evaluation Committee ("MEEC"). Based on the evaluations conducted by the Pharmaceutical Reimbursement Committee, reimbursement applications are decided upon and submitted to the SGK Presidency. Upon approval by the SGK President, the decisions deemed appropriate are published in the Official Gazette. Pharmaceuticals licensed and reimbursed in Türkiye are published in the Health Implementation Communique ("SUT") List 4/A [1].

4. Implementation of Regulations and Current Situation in Türkiye

Pharmaceutical pricing in Türkiye has been a contentious issue due to both economic fluctuations and meeting the public's healthcare needs. Consequently, it has been subject to frequent revisions over time. As a result of Türkiye's economic characteristics, the basis for pricing, which is 1 (one) Euro, has fluctuated over the years, ultimately being increased by 25% in December 2023, with the new periodic Euro value set at 17.5483 TRY. It has been decided to continue applying this amount for the year 2024, and this value is used in calculations. All these processes have widened the gap in the sector even further.

The current implications of pharmaceutical pricing made in line with all these regulations manifest as medication shortages and supply issues. As briefly mentioned above, although the determination of the value of 1 (one) Euro is made under certain conditions, these criteria do not meet the needs of current economic conditions.

4.1. Regarding Pharmaceutical Imports

The rapid rise in the Euro exchange rate compared to the Euro rate set for pharmaceutical pricing has led to significant difficulties in the supply of imported drugs. As a result of pharmaceutical pricing in Türkiye, the determined amounts cannot cover the cost of imported drugs, causing financial strain on foreign drug manufacturers, and ultimately leading foreign drug suppliers to withdraw from the Turkish market. It is alleged that foreign drug manufacturers find the pharmaceutical pricing system in Türkiye income-restrictive, leading to their withdrawal from the Turkish market to prevent Türkiye from setting an example to other countries and to prevent parallel exports [2].

As a result, patients are directed to equivalent drugs for drugs that cannot be imported. In cases where equivalent drugs are not available, patients experience significant hardships. Given that the difficulties in the pharmaceutical sector threaten public health, it is evident that pharmaceutical pricing is becoming increasingly important every day.

4.2. Regarding Pharmaceutical Exports

The problems in the pharmaceutical pricing system in Türkiye also have a significant impact on domestic trade. The stability of pharmaceutical prices amid rapid and substantial changes in foreign exchange makes it difficult for some drugs to be manufactured in Türkiye. Turkish companies producing equivalent drugs for drugs that cannot be imported state that the cost exceeds profit due to the procurement of many technologies from abroad.

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[1] IQVIA - Turkish Pharmaceutical Industry Report, 2023, p. 40
[2] Parallel Exports: This refers to buying products from low-priced countries and selling them to high-priced countries.

Due to the increase in costs of items such as glass bottles, aluminum foil, and paper used in pharmaceutical packaging, Turkish pharmaceutical manufacturers suffer losses. It is crucial for Türkiye to reduce its dependency on imports in pharmaceutical production and produce both drugs and the by-products used in drug production domestically to reduce production costs.

The increase in foreign exchange rates in the Turkish economy and the determination of a fixed Euro value for pharmaceutical pricing in Türkiye have a chain effect deeply impacting the pharmaceutical sector and public health.

In light of all these explanations, it is necessary to align the value of 1 (one) Euro with the current Euro exchange rate to resolve the economic difficulties in the pharmaceutical sector and protect public health. Currently, medication supply shortages have been increasing since 2021, posing a chronic threat to public health.

PRICING OF MEDICINES IN THE UAE

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The United Arab Emirates (UAE) is rapidly establishing itself as a leading hub for healthcare investment, driven by ambitious economic agendas like the Dubai Industrial Strategy 2030 and the Abu Dhabi Vision 2030. These strategic initiatives highlight the pharmaceutical industry as a pivotal subsector primed for growth, owing to its promising expansion opportunities, export potential, and substantial long-term economic influence.

As part of the market-oriented approach endorsed by the GCC (Gulf Cooperation Council) states, such as the UAE, Health Ministers have implemented a range of legislative and regulatory changes. These reforms are designed to oversee medication pricing and guarantee the provision of safe and efficient medicines.

Through an examination of relevant laws, penalties, and services provided by the relevant authorities, this article aims to provide a comprehensive understanding of medicine pricing regulations in the context of the United Arab Emirates (UAE).

Codified Laws Governing Medicine Pricing

In the UAE, the Ministry of Health and Prevention ("MOHAP" or the "Ministry") serves as the regulatory body for pharmaceuticals. In recent years, the UAE has undergone significant legislative changes aimed at ensuring the accessibility, safety, and fairness of medical products within its borders. Central to these changes is the repeal of Federal Law No. 4 of 1983 on the Pharmacy Professional and Pharmaceutical Establishments and the subsequent enactment of Federal Law No. 8 of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments (the "New Law").

Part II of the New Law outlines crucial provisions related to the regulation and circulation of medical products. Article 3 (Marketing Authorization) (Article 3) of the law mandates that no medical product may be circulated in the UAE without obtaining marketing authorization or exclusive marketing approval from MOHAP. This authorization is subject to specific rules, conditions, and procedures set forth by the Minister. Further Article 5 (Product Pricing) clearly states "For the circulation of a medical product that has obtained the marketing authorization, it must have a price..."

Article (8) titled 'Sale of Priced Medical Product' discusses regulations pertaining to the sale of medical products with established prices. It stipulates that such products cannot be sold at prices exceeding those set by the Ministry. To quote "8(1) The priced medical product may not be sold at

a price higher than that set by the Ministry" Additionally, Article 8 (2) prohibits granting discounts from the Ministry-set prices, except under specific circumstances outlined in the executive regulations of the law. These regulations aim to ensure fair pricing practices and prevent price manipulation in the pharmaceutical sector.

More emphasis has been paid to prohibition on quoting higher prices other than the one set by the Ministry under the New Law vide Article 48 which addresses the responsibilities and prohibitions imposed on pharmacy licensees regarding pricing practices. It emphasizes that pharmacy licensees must adhere to professional standards of integrity, honesty, and duty. Specifically, the article prohibits pharmacy licensees from engaging in actions such as withholding or concealing medical products or selling them at prices higher than those established by the Ministry. These regulations aim to uphold ethical conduct and ensure transparency in pricing within the pharmaceutical industry. To quote "Licensee's Prohibitions: Pharmacy licensee may not carry out any act involving a breach of the professional duties, honor or honesty, and, in particular, the following acts shall be prohibited sub clause 4. Withholding or hiding medical products or selling them at a price other than the one set by the Ministry."

The Ministry has clearly outlined measures which aim to enforce adherence to pricing standards, enhance consumer transparency, and prevent any discrepancies in medicine pricing as apparent under Article (73) 'Affixing Price Label' "The Medical Warehouse shall affix the Ministry-approved price label on the outer cover of the medical product in a clear way before the same is sold and delivered. The Authorized Marketer, pharmacists in charge at pharmaceutical establishments and their owners shall all be held jointly liable for affixing the Ministry-approved price label on the outer cover of the medical product."

Legal Consequences for Violations

Notably, the article outlines penalties for individuals found violating the Ministry's set prices for medical products. Art. 109 explicitly states "a fine not exceeding (AED 100,000 – One Hundred Thousand Dirhams) shall be imposed on whoever:...acts in violation of the Ministry-set price of medical products; and the penalty shall be doubled in case of recidivism." These penalties serve as a deterrent to ensure compliance with pricing regulations and protect consumer interests. Additionally, the provision for doubling penalties upon recurrence of violations underscores the Ministry's proactive stance in maintaining integrity in medicine pricing.

MOHAP's Services for Medicine Pricing

Pricing And Repricing Proposals: The Ministry of Health and Prevention (MOHAP) in the UAE offers a comprehensive online portal for submitting pricing proposals for medical products. This portal serves as a centralized platform for healthcare providers and pharmaceutical companies to submit their pricing proposals conveniently. Through the portal, users can access regulatory guidance, submit documentation, and track the progress of their pricing submissions. This online platform streamlines the price approval process, enhancing efficiency and transparency. Users can also find relevant information, updates, and resources related to pricing regulations on the MOHAP website, facilitating compliance with regulatory requirements. MOHAP additionally facilitates the process for pharmaceutical companies registered to import and market their products within the UAE to request a re-pricing of a specific medicine.

Tatmeen: The Ministry of Health and Prevention (MOHAP), in collaboration with EVOTEQ, has introduced Tatmeen, a groundbreaking initiative aimed at enhancing pharmaceutical traceability in the UAE. Tatmeen leverages serialization technology aligned with the GS1 standard to facilitate the tracking of medications from manufacturer to end-user. This initiative is designed to combat

counterfeit drugs, enable efficient recalls of expired products, and improve visibility across the pharmaceutical supply chain. Through Tatmeen, MOHAP seeks to strengthen regulatory compliance, enhance patient safety, and protect public health in the UAE. With Tatmeen, authorities can better regulate pricing by accessing detailed information on the origin, distribution, and handling of pharmaceuticals, thereby facilitating fair pricing practices, and minimizing discrepancies. Tatmeen's capabilities contribute to combating counterfeit medications, which can distort market prices and endanger public health. Overall, Tatmeen plays a crucial role in promoting transparency, regulatory compliance, and fairness in medicine pricing within the UAE.

WhatsApp Service: Residents of the UAE have convenient access to medication prices and details through a recently launched WhatsApp service available 24/7. This initiative, spearheaded by the Ministry of Health and Prevention, introduces a Registered Medical Product Directory accessible via the Ministry's website. Subscribing to this service is simple: users can add the number 0097142301221 to their WhatsApp contacts and initiate engagement with a welcoming message in English, such as "Hi." This collaborative effort between the Ministry and health authorities underscores the UAE government's dedication to bolstering patient rights and providing vital services to foster individual empowerment and societal inclusion.

DHA's Involvement in Medicine Pricing

In addition to the Ministry, the Dubai Health Authority (DHA) is a governmental body in Dubai, United Arab Emirates, tasked with the supervision of healthcare services and the formulation of healthcare policies. Here are some essential elements concerning the DHA and its involvement in medicine pricing.

The DHA exerts an indirect influence on medicine pricing through its regulatory framework and policy directives. Pricing strategies for pharmaceuticals may differ depending on factors such as patent status, availability of generic alternatives, and local manufacturing capacity. The Healthcare providers operating in Dubai are required to seek approval from the DHA prior to implementing any adjustments to their gross prices.

Dubai Health Authority (DHA) follows MOHAP in listing the medications in use in UAE, which contain:

- Narcotic, Controlled & Semi-controlled Medications,
- Prescription only Medications (POM)
- Pharmacist only Medications
- Over the Counter Medications (OTC)

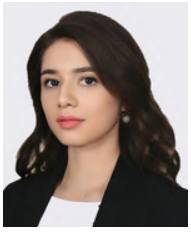
On January 11, 2024, the Dubai Health Authority (DHA) made a significant announcement regarding the coding of over 14,000 medicines across the UAE using the Dubai Drug Code (DDC). This initiative, which was launched by the Authority three years ago, represents a milestone in aligning with cutting-edge international technologies and standards. The implementation of the DDC is integral to the DHA's ongoing endeavors to ensure optimal health sustainability in the region. The DDC List serves as a comprehensive inventory of all drugs registered with the DHA's Pharmacy Services department. Each drug on the list is assigned a unique DDC code, facilitating differentiation based on various parameters such as route of administration, dosage, form, pack size, price, manufacturer, registered owner, and source. By employing this system, patients gain improved access to their prescribed medications, while also mitigating the risk of counterfeit drugs infiltrating the local pharmaceutical market.

The guidelines provided by the Dubai Health Authority (DHA) for pharmacies, as per Version 1 of the Pharmacy Guidelines, are detailed under Clause 12, specifically Subclause 12.1.5 for the mandate not to exceed the selling price indicated by MOHAP on medication packaging. Subclause 12.1.6 addresses the prohibition on offering discounts beyond those set by MOHAP. Additionally, Subclause 12.1.7 outlines the requirement for medications to be retailed in their original packaging, with provisions for partial packs or strips as described.

In the past year, Abu Dhabi initiated the distribution of "generic" prescription medications, aiming to optimize value for money. Medical professionals and insurers, as reported by a leading official gazette, advocate for the broader implementation of this policy, recognizing its potential for significant cost savings. They stress the importance of physicians reducing unnecessary prescriptions. With mandatory private medical insurance in Dubai and Abu Dhabi for all residents, prescription medication coverage is often comprehensive, with some basic packages requiring patients to contribute approximately 20 percent of the cost.

The UAE is expected to experience a significant population surge, with projections from the World Bank indicating an increase from 9.4 million in mid-2017 to nearly 11.1 million by 2030. Moreover, the Joint Commission International (JCI), a renowned US organization responsible for accrediting healthcare institutions and programs, has recognized the UAE as the global pioneer in healthcare, boasting over 200 accredited health facilities. These encompass a wide array of establishments, ranging from hospitals and medical laboratories to specialized centres, primary health centres, and home health facilities. Therefore, maintaining fair and transparent pricing practices in the pharmaceutical sector is vital for promoting economic stability and ensuring the health and welfare of the population.

PRICING OF MEDICINES AND MEDICAL PRODUCTS IN UZBEKISTAN



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Pricing medicines and medical products is one of the key issues in today's medical industry. The issues of access to medicines for patients, including the fairness in the prices of medical goods are at the forefront of the public debate. This article will discuss the main aspects of pricing in medicine, including the changes that have occurred in the related legislation of Uzbekistan.

Over the past year, there have been some notable changes in Uzbekistan in connection with the practice of price regulation, which is carried out by the government in accordance with the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On measures to further improve the formation and application of prices (tariffs) for goods, prices for which should be regulated by the state" No.722 dated December 29, 2023 (the "Resolution No.722").

In accordance with the Resolution No.722, the government regulates the prices of goods in the following ways:

- **establishment of fixed or limited prices (tariffs) for socially significant and strategically important goods, the prices for which are subject to regulation by the government, the price regulation authority, and local self-government authorities within the framework of their powers;**
- **regulation of prices (tariffs) for products produced and sold by economic entities of social or strategic importance. Prices for such goods are set by the state using regulated profitability ratios, markups, or limited profitability, which is called "declaration of prices (tariffs) for goods";**
- **approval by the price regulator of coefficients, markups, or marginal profitability that regulate prices (tariffs) or their limited levels for goods produced and sold by natural monopoly entities. This process is called "price (tariff) approval";**
- **coordination with the price regulation authority or establishment of fixed or limited prices (tariffs) and markups for certain goods in accordance with the decisions of the President of the Republic of Uzbekistan.**

In addition to the above methods, in accordance with current legislation, other methods of state regulation of prices (tariffs) may be used.

For certain types of goods, state authorities, within their competence provided for by law, in agreement with the price regulation authorities, may establish fixed or maximum prices (tariffs) and markups.

It should be noted that in order to increase the level of provision of the population and medical institutions with affordable, high-quality medical products, introduce a flexible and transparent mechanism for their pricing, suppress unjustified price increases and the practice of prescribing expensive imported drugs in the presence of more affordable and high-quality domestic analogs, Presidential Decree "On measures to improve further the provision of the population with medicines and medical products" No.2647, dated October 31, 2016 (the "Decree No.2647") was enacted. According to Decree No.2647, social pharmacies were required to sell socially significant medicines and medical products at a 10% markup of the purchase price or wholesale price. However, this requirement is no longer valid.

Following Regulations on the procedure for wholesale sale of medicines and medical products (Appendix No.1 to Resolution of the Cabinet of Ministers No.185 dated April 6, 2017), wholesale and retail sales of medicines and medical devices imported or purchased from domestic manufacturers shall be conducted with the application of maximum trade markups. These markups are determined irrespective of the number of intermediaries involved in supply. For wholesale sales, the maximum trade markup should not exceed 15% of the purchase price, and for retail sales - no more than 20% of the wholesale price.

Territorial health care authorities exercise control over the pricing of medicines in pharmacies, while the Antimonopoly Committee of the Republic of Uzbekistan conducts periodic selective inspections to ensure that wholesale entities supplying these products to pharmacies adhere to the protocols for state regulation of prices for medicines and medical products.

The Ministry of Foreign Trade of the Republic of Uzbekistan is responsible for analyzing global price trends and submitting quarterly proposals to the Republican Commission. These proposals include recommendations for establishing the maximum permissible contract price for medicines and medical products. The Department for Combating Economic Crimes under the General Prosecutor's Office of the Republic of Uzbekistan is responsible for ensuring that wholesale and retail organizations selling medicines and medical products comply with the established procedure for state regulation of prices for them. If violations are identified, the Department is authorized to submit relevant materials to the licensing authority to take measures in accordance with the law.

In accordance with the Resolution "On additional measures to deepen reforms in the pharmaceutical industry of the Republic of Uzbekistan" No.4554 dated December 30, 2019 (the "Decree No.4554"), from July 1, 2020, a system of reference pricing for medicines is gradually introduced in Uzbekistan, the main requirements of which are:

- selection of at least 10 reference countries belonging to the group of countries with high, above-average or below-average income per capita.

The list included:

1. Hungary.
2. Russian Federation.
3. Ukraine.
4. Republic of Poland.
5. Republic of Tajikistan.
6. Republic of Slovenia.
7. Republic of Kazakhstan.
8. Republic of Bulgaria.
9. Republic of Belarus.
10. Kyrgyz Republic.

- submission to the registration authority by the holder of the registration certificate or his authorized representative of the manufacturer's selling price in the country of origin, reference countries and the Uzbekistan of a medicinal product of the same manufacturer with the same active substance, taking into account the dosage form, number of units in the package, dosage, concentration, volume and packaging;

- registration of maximum prices for each trade name of a medicinal product, taking into account the pharmaceutical form, quantity per package, dosage, concentration, volume, and packaging, above which it is supplied to Uzbekistan (for imported medicinal products) and released by domestic manufacturers (for domestic medicinal products) cannot be carried out.

Furthermore, in compliance with Resolution No.4554, the Minister of Health of the Republic of Uzbekistan issued Order No.3242 dated July 10, 2020, "On the Approval of the Regulation on the Procedure for Registering Prices for Medicinal Products in the Reference Pricing System", according to which the Procedure for Registering Prices for Medicinal Products was approved. This regulation defined the procedure for registering maximum prices, the procedure for determining the purchase cost of imported drugs, including the above mentioned reference list of countries.

Moreover, it should be noted that this provision applies only to medicines authorized for use in medical practice in Uzbekistan. According to the Regulations on the Procedure for Registration of Prices for Medicines, within the framework of the reference pricing system, price registration does not apply to medicines included in the list of medicinal substances, Orphan medicines intended for the treatment of rare diseases, and for medicines certified before the establishment of price limits.

The Pharmaceutical Industry Development Agency has developed an online platform [1] through which manufacturers operating in the Uzbekistan market must provide the Agency with the selling prices of their medicines in 10 reference countries. Their average value is the maximum cost above which medicines cannot be imported or sold to distributors in Uzbekistan.

In addition, one of the main innovations in the legislation is that in accordance with the Presidential Decree of the Republic of Uzbekistan "On additional measures to provide the population with quality medicines and medical devices" No.411 dated October 26, 2022 (the "Decree No.411"), from May 1, 2023, an automatic system will be introduced in Uzbekistan to detect cases of overpriced medicines sales. If, during the analysis process, the system detects overpricing compared to established retail prices, the system will automatically send a message to the state authority responsible for consumer protection to take appropriate action.

After verification based on such notification, if it is determined that the price of the drug on the receipt is actually higher than the retail reference price, a fine will be imposed in accordance with the established rules. In addition, indicating an incomplete amount of purchased medicines and medical products on the purchase receipt will be considered a violation of the laws on trade or the provision of services.

The pricing of medicines and medical products remains a complex issue that requires the attention of governments, manufacturers, and consumers. In order to ensure better health and well-being for all members of society, transparency, fairness, and affordability must be the core principles guiding the healthcare pricing process.

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[1] https://uzpharminfo.uz/login.html

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> 15
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