

**KARADENİZ İHRACATÇI BİRLİKLERİ
GENEL SEKRETERLİĞİ**



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**KARADENİZ İHRACATÇI BİRLİKLERİ ÜYELERİNE SİRKÜLER
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Sayın üyemiz,

T.C. Ticaret Bakanlığın bir yazısına atfen Türkiye İhracatçılar Meclisinden alınan 20/01/2022 tarih 52-193 sayılı yazıda;

İlaç ihracatına ilişkin olarak, 17 Ocak 2022 tarihli ve 13 sayılı Gürcistan Hükümeti Kararı ile Türkiye'nin, aralarında ABD, AB ülkeleri, Kanada, Japonya, Yeni Zelanda ve Avustralya'nın da yer aldığı izin süreçlerinde kolaylık sağlanan ülkeler listesine eklendiği belirtilmekte olup, anılan kararın aynı tarihte Gürcistan Resmi Gazetesinde yayımlanarak yürürlüğe girdiği ifade edilmektedir.

Bilgilerinize sunarız.

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Sertaç Ş. TORAMANOĞLU
Genel Sekreter a.
Şube Müdürü

Ek: Gürcistan İlaç Sektörü - Basın Haberleri (Gayri Resmi) (11 sayfa)

Karadeniz İhracatçı Birlikleri Genel Sekreterliği
Atatürk Bulvarı No:19/E PK.51 28200 GİRESUN
Telefon: 0.454.2162426 (PBX)
Faks: 0.454.2164842-2168890
e-posta: kib@kib.org.tr Web : www.kib.org.tr

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EK: GÜRCİSTAN İLAÇ SEKTÖRÜ -BASIN HABERLERİ (GAYRİ RESMİ)

<https://bm.ge/ka/article/ra-weria-turgetidan-medikamentebis-shemotanis-shesaxe-b-mtavrobis-dadgenilebashi/99824>

17.January.2022 14:40 _

WHAT IS WRITTEN IN THE GOVERNMENT DECREE ON THE IMPORT OF MEDICINES FROM TURKEY



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Back

From today, pharmaceutical products recognized by the Turkish pharmaceutical regulator will be automatically recognized in Georgia. The relevant [resolution](#) was adopted by the government. The "opening of the market" in Turkey meant this regulatory change. As a result of the change, the pharmaceuticals that are accredited in the Turkish market, including those of Turkish and non-Turkish production, will be automatically recognized in the Georgian market.

The rule of recognizing medicines was adopted by the government in 2009, new countries were gradually added to the list and it now includes more than 20 countries, namely:

"Define the" list of state regulatory bodies for other countries or interstate pharmaceutical

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Ayrıntılı bilgi için: Hüseyin GÖK - Uzman Yardımcısı

Dış Ticaret Kompleksi Çobançeşme Mevkii Sanayi Cd. B Blok Kat:9 (34196) Yenibosna - İstanbul / TÜRKİYE

T +90 212 454 04 90 / +90 212 454 04 91 F +90 212 454 04 13 / +90 212 454 04 83 E tim@tim.org.tr

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products "(in accordance with the Annex) for the recognition of pharmaceutical products registered by them."

Medic European Medicines Agency (EMA).

- United States;
- როზა Commonwealth of Australia;
- Republic of Austria
- New Zealand;
- სამეფო Kingdom of Belgium;
- რესპუბლიკი Republic of Bulgaria;
- ფედერ Federal Republic of Germany;
- სამეფო Kingdom of Denmark;
- სამეფო United Kingdom of Great Britain and Northern Ireland;
- რესპუბლიკი Republic of Estonia;
- სამეფო Kingdom of Spain;
- Ireland;
- რესპუბლიკი Republic of Italy;
- Japan;
- რესპუბლიკი Republic of Iceland;
- Canada;
- კა Republic of Cyprus;
- რესპუბლიკი Republic of Korea;
- დიდი Grand Duchy of Luxembourg;
- რესპუბლიკი Republic of Latvia;
- რესპუბლიკი Republic of Lithuania;
- Republic of Malta;
- სამეფო Kingdom of Norway;
- სამეფო Kingdom of the Netherlands;
- რესპუბლიკი Republic of Portugal;
- რესპუბლიკი Republic of Poland;
- უმ Romania;
- French Republic;
- რესპუბლიკი Republic of Greece;
- Republic of Slovenia;
- რესპუბლიკი Slovak Republic;
- რესპუბლიკი Republic of Hungary;
- რესპუბლიკი Republic of Finland;
- სამეფო Kingdom of Sweden;
- კონ Swiss Confederation;
- რესპუბლიკი Czech Republic;
- რესპუბლიკი Republic of Turkey.**



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<https://bm.ge/ka/article/turgetidan-wamlebis-importi-mosaxleobas-200-mde-medikamentze-xarjs-sheumcirebs---ministri/99809>

17.January.2022 12:42 _

"IMPORTING MEDICINES FROM TURKEY WILL REDUCE THE COST OF UP TO 200 MEDICINES FOR THE POPULATION," THE MINISTER SAID



AUTHOR: VICTORIA MGHEBRISHVILI

Today, the Head of the Government of Georgia Irakli Gharibashvili signed a resolution amending the Government of Georgia №188 of October 22, 2009 "On Defining the List of Regulatory Bodies of Other Countries or Interstate Pharmaceutical Products". The Prime Minister said this before the government session and noted that this decision will increase the population's access to low-quality high-quality medicines.

After the government session, the Minister of Health Zurab Azarashvili clarified that the decision made by the Prime Minister is important and as a result will reduce the cost of 200 medicines for the population. The Minister did not clearly explain the principle (quantity of consumption, price) of this quantity of medicines.

"The important decision of the Prime Minister to include Turkey in the list of drug recognition will facilitate the import of high-quality, competitively priced medicines from Turkey to Georgia, which will reduce the cost of up to 200 medicines for our population. The Ministry of Health is actively involved in verifying and controlling the quality of medicines from these and other importing countries and related certificates or documentation. "We are fully responsible for the sale of high quality medicines at competitive prices in Georgia," said the Minister of Health.

Update:

To find out the details of the principle of selecting 200 types of medicines, which, according to the Minister, will reduce costs for the population, BM.GE contacted the press service of the Ministry, where it was clarified that 200 types of medicines were studied to decide to open the Turkish market. The Turkish market is open for Georgia to import any type of medicine.



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<https://bm.ge/ka/article/gankargulebas-xeli-movaweret-turgetis--bazari-gaixsna-rac-saqartveloshi-wamlebs-gaaiafebs---premeri/99798>

WE SIGNED THE DECREE ... TURKISH MARKET OPENED, WHICH WILL REDUCE THE PRICE OF MEDICINES IN GEORGIA - PRIME MINISTER



AUTHOR: VICTORIA MGHEBRISHVILI

According to the Prime Minister of Georgia Irakli Gharibashvili, from today the importing companies will be able to import low-cost medicines from Turkey in accordance with the GMP standard. The head of government said this before the government session and called on importers to import high quality medicines from Turkey.

"As promised, we signed the government decree today, accordingly, the Turkish market was opened and medicines in accordance with the high quality GMP standard will be imported from Turkey. There is a big difference between the prices, if the most demanded medicines with us cost 10 GEL, in Turkey they cost 1-2 GEL. There is no argument as to why the Turkish market should not have been opened, I could not hear it and so we decided to open the market to Turkey. "I hope importers will import high-quality medicines from Turkey, which will reduce the prices of medicines in Georgia," said the Prime Minister.

Irakli Gharibashvili addressed the Minister of Health Zurab Azarashvili and instructed the Competition Agency to set up a working group to investigate the pharmaceutical market.

"The Competition Agency has completed its work on the research of the pharmaceutical market and sent the relevant recommendations to the Parliament. I would like to ask the Minister of Health to set up a working group, to ask the representatives of the relevant committees of the Parliament and to start working together. Changes to several laws will be needed to make medicines cheaper in our expectation. On the one hand, our task is to monitor the prices of medicines, and on the other hand, to control the quality, this is the number one requirement. "We will start active work and Mr. Minister - Azarashvili will start working on this issue and we will have results in the next few weeks," - said the head of the government.



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Mevzuat İlk Versiyon:

<https://matsne.gov.ge/ka/document/view/4606?publication=0>

Government of Georgia

Resolution №188

October 22, 2009

ğ. Tbilisi

On determining the list of state bodies regulating other countries or interstate pharmaceutical products

Article 1

The Bill "On Changes and Amendments to the Law" On In accordance with Articles 4 and 11 7 , a list of "State regulatory bodies for pharmaceutical products of other countries or interstate countries" (in accordance with the Annex) shall be established for the purpose of recognizing pharmaceutical products registered by them.

Article 2

The resolution shall enter into force upon publication.

Prime Minister N. Gilauri

Appendix

List of state regulatory bodies for other countries or interstate pharmaceutical products

1. State regulatory body for interstate pharmaceutical products - European Medicines Agency (EMA).

2. State regulatory bodies for pharmaceutical products of the following countries:

- A) the United States;
- B) the Commonwealth of Australia;
- C) the Republic of Austria;
- D) New Zealand;
- E) the Kingdom of Belgium;
- F) the Republic of Bulgaria;
- G) the Federal Republic of Germany;
- H) Kingdom of Denmark;
- I) the United Kingdom of Great Britain and Northern Ireland;
- J) the Republic of Estonia;
- K) the Kingdom of Spain;
- M) Ireland;
- M) the Republic of Italy;
- N) Japan;
- O) the Republic of Iceland;
- P) Canada;
- Q) the Republic of Cyprus;
- S) the Republic of Korea;
- S) the Grand Duchy of Luxembourg;
- T) the Republic of Latvia;
- U) the Republic of Lithuania;
- V) the Republic of Malta;
- W) Kingdom of Norway;



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K) the Kingdom of the Netherlands;
Y) the Republic of Portugal;
Z) the Republic of Poland;
C) Romania;
D) the French Republic;
S) the Hellenic Republic;
J) the Republic of Slovenia;
H) the Slovak Republic;
C) the Republic of Hungary;
H) the Republic of Finland;
Z1) Kingdom of Sweden ;
Z2) the Swiss Confederation;
H3) Czech Republic.

Mevzuat Değişikliği: Türkiye'nin Listeye Eklenmesi

<https://matsne.gov.ge/ka/document/view/5355246?publication=0>

Government of Georgia

Resolution №13

January 17, 2022

ğ. Tbilisi

Amendment to the Resolution №188 of the Government of Georgia of October 22, 2009 on Determining the List of State Bodies Regulating Other Countries or Interstate Pharmaceutical Products

Article 1

Pursuant to paragraph 4 of Article 20 of the Organic Law of Georgia on Normative Acts, in the Resolution of the Government of Georgia №188 of October 22, 2009 “On Determining the List of State Bodies Regulating Other Countries or Interstate Pharmaceutical Products” (SSM, №129, 22/10 / 2009) to be amended and the following sub-paragraph “L1” shall be added to the second paragraph of the Annex defined by the Resolution (“List of State Regulatory Bodies of Other Countries or Interstate Pharmaceutical Products ”):
"L1) Republic of Turkey".

Article 2

The resolution shall enter into force upon publication.

Prime Minister

İrakli Garibashvili



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<https://www.bpn.ge/article/90588-ra-gaaiapebs-camlebs>

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What makes medicines cheaper ?!



According to the Prime Minister of Georgia, the market with Turkey will be opened and medicines will flow. As the Prime Minister said at the government session, higher quality medicines will flow and the price will be reduced as well.

Some met this story with hope, some with suspicion. What does this initiative do for the community and the local pharmaceutical business? - "Kviris Palitra" contacted healthcare specialists to talk about this topic.

Kakha Jakeli, Professor, Health Economist: - The use of Turkish drugs in the pharmaceutical market can not solve the problem of cost. The main problem is the monopolies that reign in the market. By their structure, they are a kind of cartels that seek to impose high prices on the market through illegal agreements. Even if the drug is imported cheaply, it will be sold at a high price. The market is divided between three pharmacological giants. It should be well studied what market shares they have and the antitrust or competition service should force them to disintegrate into many competing entities. Only competition allows us to make medicines cheaper. In Georgia, the previous government facilitated the creation of monopolies in the pharmaceutical market. These monopolies or oligopolies today own not only the pharmaceutical market but also the market of medical service providers. They own hospitals, insurance companies ... therefore, they can set prices in different markets, and the most important thing is that they can agree and offer high, rising



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prices to the population. As a result, the price of many drugs has increased by 250-300% in the last four years.

The previous government was, in fact, fed up with monopolies in the pharmaceutical market. They were still created when the pharmaceutical, insurance and medical companies merged. Such associations help to raise prices, set high prices or lower quality ... Cheap Turkish medicines can be of high or low quality. But if the medicine is of poor quality, eventually the treatment becomes more expensive. Treatment with less effective cheap drugs will not end effectively and the disease will get worse. It is known that cheap and substitute medicines do not make treatment cheaper, they make it more expensive. This is checked at the formula level. "We will import Turkish medicine," the government said. Turkish medicines should not be imported by the government, but Turkish, Indian, German or Arabic medicines should be imported by those structures, Who are professional traders in pharmaceuticals and they have to have constant competition. The winner in this competition is the one who imports the drug cheaply and sells it with less profit because it will sell more.

- Why do you expect an increase in the cost of treatment with Turkish medicine?

- There is a well-known formula: if German drugs have a 100% effect, the effect of Turkish drugs is only 30%. When we treat any chronic disease with, say, Turkish drugs, even if this disease is not eliminated, it is delayed. So I do not advise anyone to use cheap drugs.

The second issue: when the government says that medicines are expensive and that we should lower the prices by importing Turkish medicines, it is a manifestation of unprofessionalism. There seems to be ignorance of the pharmacological market, which is very sensitive and governed by supply-demand laws. The more expensive the medicine, the less it has to be sold, but if the monopolists agree that everyone will have expensive drugs, patients will be forced to buy anyway.

- Even cheap expensive?

- of course. 90% of the market is owned by three or four giant companies. They can import cheap medicines and sell expensive ones. We need to set up a competition, antitrust, anti-cartel service. He should study the situation and if it turns out that pharmaceutical companies are suffocating the market, the state will have a legal basis that not three companies will be on the market, but - 30. Today there are 68 universities in Georgia. Public universities and private universities deprive students of each other. The cost of tuition has been reduced by



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almost everyone. Many universities have equated it with tuition fees at Lama State University. Why? Because there is competition in this market.

- So, why is the introduction of Turkish medicines on the agenda?

- This is a manifestation of unprofessionalism. Thorough market research is needed. Do not operating companies import drugs from Turkey? Obviously, they bring in, but they also sell at a high price.

Georgia should review its antitrust legislation. This is a very serious part of any socially oriented market state, such as Germany, Sweden, Norway, Denmark, USA. Maybe the government does not want to dismantle the monopolies, because there are interests there, so the people, non-governmental organizations should be active, the government should develop healthy antitrust legislation, so that we do not have such a monopoly. This is what makes drugs more expensive, and ultimately it all leads to impoverishment of the population. We need to develop an antitrust office that will work effectively to dismantle monopolies.

- Or the initiative of the Prime Minister can not poison the impoverished population?

- This will be the staging of the threat in the vegetable garden, which has long been eaten by crows.

Akaki Zoidze, Public Health Specialist: - Two years ago, when you were the Chairman of the Health Committee, we conducted a serious study of the pharmaceutical market. Recommendations have been developed and are now being circulated. Opening the Turkish market was one of the recommendations, but the problem is really complex and other recommendations should be worked out consistently. At that time, the group included all stakeholders - pharmaceutical companies and patients' advocates, NGOs, experts, etc. If you really want to solve the problem, several steps must be taken at once.

- Concern was expressed, medicines in Turkey are of low quality ...

- Therefore, there was a specific reference in the recommendation. We have a recognition regime, i.e. parallel imports are allowed from countries that we know have strict or credible regulators. Let no one deceive you as if our controller has any leverage to control the quality of the market. Even when registering a drug, one sample may be presented and then another imported, so it is futile to worry as if the country would be destroyed if we imported the drug from Turkey. If someone wanted to import counterfeit and substandard medicine, they have already imported it, however, unlike many other countries, with us it is not large-scale.



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How does a counterfeit party get into the market? Maybe someone registers a company in Turkey and then pretends to import medicine from there. Countries where control is weak can bring in such a falsified party on behalf of Turkey. That is why the recommendation clearly states that an agreement should be signed with the Turkish Ministry of Health in parallel - our regulator should have real-time access to the Turkish Drug Market Regulator databases to check whether a particular batch is coming from Turkey.

The Turkish market is large, with more than 80 million people, and pharmaceutical companies are offering big discounts. The state also promotes local production and partially covers the cost of medicine for a large part of the citizens. That is why the manufacturers or importers there can offer many names of medicines to their citizens at a low price. If medicines become available to our citizens as well so that we do not suffer from counterfeiting, it will only be welcome.

In addition, any administrative barriers that prevent parallel imports from other countries should be removed. The most important thing is the so-called Unethical marketing used by too many companies in our market. Most of them are registered abroad - be it Azerbaijan, Turkey or other countries, but there are such Georgian companies, legal entities ...

- What does unethical marketing mean?

- involves prescribing a drug by a doctor only under the name the company produces, and by law a doctor must prescribe a drug under a generic name, for example, not Bayer aspirin but acetylsalicylic acid. They even prescribe the medicine to a specific company and as a result receive a commission. They are registered as consultants and are officially paid. This is not explicitly prohibited by law. It is true that the health law prohibits medical staff from prescribing treatment for the purpose of self-employment, but there is no mechanism in the law to prove that it was done with self-interest. The doctor can always prove that he thinks a particular medication is best and therefore prescribes it to the patient.

We have a lot of decent doctors and they think that prescribing medicine should not harm the patient, and some of them are right, it means the medicine that the patient really needs, but he also prescribes three or four other medicines that he may only theoretically need. In fact, it is not recommended to prescribe more than two or three medications for one disease, with rare exceptions. In the neighborhood-friendship we have seen prescriptions with 7-8 medicines. Two of them can be used to treat a specific disease, while the rest are bioactive substances that neither hurt nor irritate the patient.



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Turkey was the fourth recommendation in our plan. The first was the maximum accounting of who's how much and what means to the patient. The doctor should know that his prescription will be public. The second is to increase the state subsidy program. Elderly, socially vulnerable - at a symbolic price for more than a million people, 23 of the five most common chronic diseases are being subsidized. That's a bit, the number has to increase to 100 denominations.

As for setting threshold prices, for citizens who are not subject to subsidies, threshold prices should be set for the above 100 medicines and this will help us to open the Turkish market. We will only win and we will not lose anything. Only unscrupulous companies will lose.

"The Kviris Palitra magazine"