ANALYSIS OF THE TUBERCULOSIS MEDICATIONS MARKET IN UKRAINE AND DEVELOPMENT OF INFORMATIONAL SUPPORT FOR THE IT PROGRAM ON IMPORT SUBSTITUTION

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INTRODUCTION

The need to implement Import Substitution Programs for pharmaceuticals can arise very acutely for any country's government and citizens due to various processes: environmental threats, pandemics, socio-economic problems, and armed conflicts. One of the key challenges for the sustainable development of countries worldwide is the management of their own resources. The revitalization of the issue of domestic pharmaceutical production is a matter of societal importance in this century for every country. Environmental tragedies, the COVID-19 pandemic, and armed conflicts on ¹different continents have shown that humanity must understand modern threats and learn to balance them to ensure its existence.

After the invasion of the Russian Federation into Ukrainian territory, all countries of the world, especially EU countries, began actively providing assistance to our country, including pharmaceuticals and medical supplies. However, this process and the goodwill of people worldwide cannot continue indefinitely. It is the realization of this, as well as a clear understanding of the inability of the entire world to cope with local military actions, even if they occur in the center of Europe, that leads us to consider the necessity of implementing a Program for Import Substitution of medicines and medical products in Ukraine.

In order to create an IT program as a resource support for the Import Substitution Program, we have analyzed legislative acts regulating the circulation of pharmaceuticals in Ukraine. The research material consisted of data from the State Register of Medicinal Products of Ukraine¹ and the

¹Державний Реєстр лікарських засобів України (2023) Retrieved from http://www.drlz.com.ua/

²Національний Перелік основних лікарських засобів (2023) Retrieved from https://zakon.rada.gov.ua/laws/show/333-2009-% D0% BF#n15

National List of Essential² Medicines. Analysis and processing of these existing legislative acts were conducted regarding the group of antituberculosis medications. The methods utilized in the work included: systems approach, observation, synthesis, abstraction, analysis, and generalization.

The pharmacological group of anti-tuberculosis medications was studied by us as a model range to determine the list of drugs for import substitution and to create an IT Program, given that Ukraine is classified by the World Health Organization as a high-priority country due to the high burden of drugresistant tuberculosis and ranks fourth in the rate of spread of this disease in the European region³. ²According to the Public Health Center, in 2023, there were 19,851 registered cases of active tuberculosis in our country, with 639 cases among children under 14 years old and 196 cases among adolescents aged 15-17 years old⁴. As of April 2023, there were 1,735 cases of tuberculosis registered in Ukraine: 1,337 new cases of the disease; 309 patients with relapse; 38 patients who resumed treatment after interruption; 35 patients who started re-treatment after failure; 13 other cases; 3 patients with unknown previous treatment history; and 2 patients diagnosed with COVID-19 as well. Overall, in April 2023, 12,584 individuals were undergoing treatment for tuberculosis⁵. The full-scale war waged by the Russian Federation against Ukraine, the dire situation on military positions concerning material-technical and domestic support, a significant number of prisoners of war, and internal displacement of citizens within the country may contribute to an even greater number of tuberculosis infections and the spread of the disease. Therefore, as an analogue for developing a search IT program⁶, we chose the pharmacotherapeutic group of anti-tuberculosis medications. The results regarding the obtained list of anti-tuberculosis drugs subject to import substitution were previously presented by us, and the monographm elucidated the approach to developing an IT program for pharmaceutical

³Tuberculosis – World Health Organization (2023). Retrieved from https://www.who.int/news-room/fact-sheets/detail/tuberculosis

⁴Профілактика, вакцинація та система раннього виявлення туберкульозу на рівні країни дозволять знизити рівень захворюваності серед населення (2024). Retrieved from https://moz.gov.ua/article/news/profilaktika-vakcinacija-ta-sistema-rannogo-vijavlennja-tuberkulozu-na-rivni-kraini-dozvoljat-zniziti-riven-zahvorjuvanosti-sered-naselennja

⁵КОРОНАВІРУСНА ІНФЕКЦІЯ COVID-19 — Центр громадського здоровя МОЗ України (2024). Retrieved from https://phc.org.ua/kontrol-zakhvoryuvan/inshi-infekciyni-zakhvoryuvannya/koronavirusna-infekciya-covid-19

⁶Плеш Н. Т., Венгрин Н. М., Паращин Ж. Д., Кричковська А. М. Опрацювання інтернет програми пошуку переліку лікарських препаратів для імпортозаміщення в Україні // Фармацевтична освіта, наука та практика: стан, проблеми, перспективи розвитку : матеріали науково-практичної конференції з міжнародною участю, присвяченої 25-річчю фармацевтичного факультету Національного медичного університету імені О. О. Богомольця, 19–20 грудня 2023 року, м. Київ. – 2023. – С. 271–272.

import substitution by groups of drugs, precisely through the analysis of legislative acts regarding anti-tuberculosis medications.

1. History and current state of tuberculosis morbidity. Analysis of the Register of Medicinal Products in Ukraine regarding the list of anti-tuberculosis drugs

Currently³, one-third of the world's population is infected with tuberculosis mycobacteria. Every year, between 7 to 10 million people worldwide become ill with tuberculosis. The total number of patients worldwide reaches between 50 to 60 million. This is somewhat more than the entire population of Ukraine or France.

The history of humanity's struggle with tuberculosis is well known and widely researched by scientists today⁷. In 1887, our compatriot from Galicia, Ivan Puluj, discovered X-rays, and later in 1895, they were discovered by the German scientist Wilhelm Conrad Röntgen, for which he received the Nobel Prize. This initiated the development of radiology and improved tuberculosis diagnostics. In 1919, French scientists Albert Calmette and Camille Guérin developed the BCG vaccine, which consists of live attenuated (avirulent) tuberculosis mycobacteria. This discovery initiated tuberculosis vaccination. In 1944, American bacteriologist Selman Waksman obtained streptomycin, an antibiotic that proved effective against tuberculosis. Thus, with the end of the pre-antibacterial era, the antibacterial era of combating tuberculosis began. In 1954, such anti-tuberculosis drugs as PAS, Thiozone, and drugs of the HIN group – slow-acting drugs (Isoniazid) entered medical practice. Since 1965, the most effective anti-mycobacterial drug to date, Rifampicin, has been used. Last year, the Verkhovna Rada of Ukraine supported the Law "On Overcoming Tuberculosis in Ukraine", which takes into account the legal aspects of regulation in accordance with Ukraine's international legal obligations in the sphere of European integration and key recommendations of the World Health Organization.

At the regional levels over the past year, efforts have been made to strengthen cooperation between healthcare facilities and establish a system for detecting new cases of tuberculosis, ensuring timely treatment and continuation of therapy, especially for patients who, due to the war, have been forced to leave their homes and relocate to other regions.

Despite the full-scale war, the Ukrainian healthcare system ensures patients' access to free diagnosis and treatment of tuberculosis. Within the framework of cooperation between the committees of the National Council on Tuberculosis and HIV/AIDS, this year a series of programmatic measures

⁷ Aelita, K., Roksolana, K., Liliia, B., & Oksana, L. (2022). Vaccine Prevention of Tuberculosis in Children: Outstanding Issues Family Medicine Systems in Ukraine. Archives of Pharmacy Practice, 13(4).

have been updated and planned at national and regional levels. Specifically, improvements have been made to the system for detecting and monitoring new cases of the disease while working with internally displaced persons to ensure access to tuberculosis services⁸⁴. Providing medical-psychosocial support services has become particularly important in conditions of martial law, where tuberculosis patients face issues such as internal displacement, loss of employment, decreased quality of life, and increased psychological stress. These services allow for comprehensive support during treatment. Patients receiving such services are more likely to complete the full course of treatment and adhere to anti-tuberculosis medication regimens. Currently, in Ukraine, with support from the Global Fund to Fight AIDS, Tuberculosis, and Malaria, medical-psychosocial support services are provided by regional nongovernmental organizations under conditions of confidentiality and tolerance towards tuberculosis patients. Patients can contact their physician or, if they have changed their place of residence, the nearest facility providing tuberculosis treatment services, to learn about support programs from nongovernmental organizations. Additionally, in six regions of the country, there are state-supported medical-social support programs. It is worth noting that for tuberculosis diagnosis, the family doctor conducts screening and questioning, assesses the risk of disease. Based on the results (if necessary), the patient is referred for radiological examination and examination of sputum or other biological material using molecular-genetic systems. The family doctor may also prescribe necessary additional examinations by a phthisiologist, as it is the phthisiologist who establishes the tuberculosis diagnosis.

Understanding the threat posed by this particular disease, we began our search IT program for pharmaceutical import substitution by studying and analyzing this group of medications. We processed the State Register of Medicinal Products in Ukraine (Table 1) to establish a list of all antituberculosis drugs available on the country's pharmaceutical market as of 2023.

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⁸Туберкульоз — Центр громадського здоровя МОЗ України. Retrieved from https://phc.org.ua/kontrol-zakhvoryuvan/tuberkuloz

Table 1
Anti-tuberculosis medications registered in the State Register of Medicinal Products in Ukraine
(as of October 20, 2023)

No.	INN	ATX	Trade Name	Release form	Composition	Applicant:	Applicant:
		code			(active ingredients)	name in Ukrainian	Country
1	1 Sodium aminosalicy late	J04AA02	SODIUM AMINOSALICYLATE	enteric granules 0.8 g/1 g, 100 g in a bag; 1 packet together with the dosing device in the container	1.0 g of granules contains 0.8 g of sodium aminosalicylate dihydrate	PrAT "Technologist"	Ukraine
			ПАС	enteric granules, 80 g/100 g, 100 g in an aluminum foil pouch enclosed in a plastic bag, complete with a measuring spoon and a silica gel sachet in a plastic container	100 g of granules contain 80 g of sodium aminosalicylate	SCAN BIOTECH LTD	India
			PASK SODIUM SALT	powder for oral solution, 5.52 g; 12.5 g of the drug in a laminate bag; 25 or 300 sachets in a cardboard box	1 sachet contains 5.52 g of para- aminosalicylic acid of the sodium dihydrate salt, which corresponds to 4.00 g of para- aminosalicylic acid	JSC "Olainfarm"	Latvia
2	2 Cycloserine	J04AB01	COXERINE	250 mg capsules No. 100 (10x10): 10 capsules in a strip; 10 strips in a cardboard package; No 90 (10x9): 10 capsules in a blister; 9 blisters in a cardboard box; No. 100 (10x10): 10 capsules in a blister; 10 blisters in a cardboard box	1 capsule contains cycloserine 250 mg	McLeods Pharmaceutic als Limited	India
			HELPOSERIN	250 mg capsules; 10 capsules in a blister; 5 blisters in a pack; 50 capsules in a plastic or glass bottle; 1 bottle in a carton	1 capsule contains 250 mg of cycloserine	Help S.A.	Greece
			CYCLOSERINE	hard capsules 125 mg, 10 capsules in a blister, 3 blisters in a cardboard pack	1 capsule contains cycloserine 125 mg	PrAT "Technologist"	Ukraine
			CYCLOSERINE	hard capsules 125 mg, 10 capsules in a blister, 3 blisters in a cardboard pack	1 capsule contains cycloserine 125 mg	PrAT "Technologist	Ukraine
			CYCLOSERINE	hard capsules 250 mg, 10 capsules in a blister, 3 blisters in a cardboard pack, 60 capsules in a container, 1 container in a cardboard pack	1 capsule contains cycloserine 250 mg	PrAT "Technologist"	Ukraine
			CYCLOSERINE	hard capsules 250 mg, 10 capsules in a blister, 3 blisters in a cardboard pack, 60 capsules in a container, 1 container in a cardboard pack	1 capsule contains cycloserine 250 mg	PrAT "Technologist"	Ukraine
			Cycloserine capsules Ph. Int. 250 mg	250 mg capsules, 10 capsules in a blister, 10 blisters in a cardboard pack	1 capsule contains: cycloserine 250 mg	M.BIOTECH LIMITED	United Kingdom
			CYCLOSERINE CAPSULES USP 125 MG	125 mg capsules, 10 capsules in a blister; 10 blisters in a cardboard box	1 capsule contains: cycloserine 125.00 mg	McLeods Pharmaceutic als Limited	India
3	Rifampicin	J04AB02	MAKOX 150	150 mg capsules, 10 capsules in a blister; 10 blisters in a cardboard box; 10 capsules in a strip; 10 strips in a cardboard box	1 capsule contains rifampicin 150 mg	McLeods Pharmaceutic als Limited	India
			MAKOX 300	300 mg capsules, 10 capsules in a blister; 10 blisters in a cardboard box; 10 capsules in	1 capsule contains rifampicin 300 mg	McLeods Pharmaceutic als Limited	India

				a strip; 10 strips in a			
			R-CIN	cardboard box 150 mg capsules, 100 or	1 capsule contains	Lupin	India
			R-CIN	1000 capsules in jars capsules of 300 mg, 100 or	rifampicin 150 mg 1 capsule contains	Limited Lupin	India
			RIFAMPIN	1000 capsules in jars powder for solution for injection 600 mg, 600 mg powder in a 20 ml vial; 1 bottle in a cardboard box	rifampicin 300 mg 1 vial contains: rifampicin 600 mg	Limited Mylan Laboratories Limited	India
			RIFAMPIN	Lyophilized powder for the preparation of solution for infusion 600 mg, 1 vial of powder in a cardboard box	1 vial contains rifampicin 600 mg	M.BIOTECH LIMITED	United Kingdom
			RIFAMPICIN	150 mg capsules, 10 capsules in a blister, 2 blisters in a pack, 1000 capsules in a container, 90 capsules in a container, 90 capsules in a plastic container with a lid with first closure control, 1 container in a pack	1 capsule contains 150 mg of rifampicin (on a 100% dry matter basis)	Public Joint Stock Company "Research and Production Center "Borshchahiv skiy Chemical and Pharmaceutic al Plant"	Ukraine
4	Rifabutin	J04AB04	RIFABOUTIN	150 mg capsules, 10 capsules in a blister, 3 blisters in a cardboard package	1 capsule contains rifabutin 150 mg	Lupin Limited	India
			RIFABOUTIN 150	150 mg capsules No. 100 in a plastic jar	1 capsule contains rifabutin 150 mg	Lupin Limited	India
5	Capreomycin	J04AB30	CAPREOMYCIN	powder for solution for injection, 1.0 g in vials	1 vial contains sterile capreomycin sulfate equivalent to 1 g of capreomycin.	Pat "Kisovmedpr eparation"	Ukraine
6	Isoniazid	J04AC01	БІТУБ®	solution for injection, 100 mg/ml, 5 ml in a vial; 10 or 30 bottles in a pack; 5 ml in an ampoule; 5 ampoules in a blister pack; 2 blister packs per pack	1 ml of solution contains 100 mg of isoniazid	LLC "Yuria- Pharm"	Ukraine
			ISONIAZID	syrup, 100 mg/5 ml; 200 ml in bottles; 200 ml in a bottle; 1 bottle in a cardboard pack	5 ml of syrup contains 100 mg of isoniazid	LLC "Yuria- Pharm"	Ukraine
			ISONIAZID	100 mg tablets, 10 tablets in a blister, 10 blisters in a cardboard box	1 tablet contains: isoniazid 100 mg	Micro Labs Limited	India
			ISONIAZID	100 mg tablets, 10 tablets in a blister, 3, 9 or 10 blisters in a cardboard package; 28 tablets in a blister, 3 or 24 blisters in a cardboard package; 1000 tablets in a plastic bag, 1 package in a plastic container	1 tablet contains isoniazid 100 mg	McLeods Pharmaceutic als Limited	India
			ISONIAZID	100 mg tablets, 10 tablets in a blister; 5 blisters per pack	1 tablet contains 100 mg of isoniazid (on a dry matter basis)	Public Joint Stock Company "Research and Production Center "Borshchahiv skiy Chemical and Pharmaceutic al Plant"	Ukraine
			ISONIAZID	200 mg tablets, 10 tablets in a blister, 5 blisters per pack	1 tablet contains isoniazid (in terms of dry matter) 200 mg	Public Joint Stock Company "Research and Production Center "Borshchahiv skiy	Ukraine

						Chemical and	
						Pharmaceutic al Plant"	
			ISONIAZID	300 mg tablets, 28 tablets in a blister, 24 blisters in a cardboard box	1 tablet contains: isoniazid 300 mg	Micro Labs Limited	India
			ISONIAZID	300 mg tablets, 10 tablets in a blister, 3, 9 or 10 blisters in a cardboard package; 28 tablets in a blister, 3 or 24 blisters in a cardboard package; 1000 tablets in a plastic bag, 1 package in a plastic container	1 tablet contains isoniazid 300 mg	McLeods Pharmaceutic als Limited	India
			ISONIAZID- DARNITSA	solution for injection, 100 mg/ml; 5 ml in an ampoule; 5 ampoules in a blister pack; 2 blister packs per pack	1 ml of solution contains isoniazid 100 mg	PrJSC "Pharmaceuti cal Firm "Darnitsa"	Ukraine
			ISONIAZID- DARNITSA	300 mg tablets, 10 tablets in a blister pack; 5 blister packs per pack; 1000 or 1500 or 2500 tablets in containers	1 tablet contains isoniazid 300 mg	PrJSC "Pharmaceuti cal Firm "Damitsa"	Ukraine
7	Protionamide	J04AD01	PROTEKH	film-coated tablets 250 mg; 10 tablets in a blister, 5 or 10 blisters in a cardboard pack; 10 tablets in a blister, 50 or 100 blisters in a cardboard box	1 tablet contains 250 mg of prothionamide	PrAT "Technologist"	Ukraine
			PROTHIONAMIDE	film-coated tablets, 250 mg, 10 tablets in a blister; 10 blisters in a cardboard box	1 tablet contains: prothionamide 250 mg	Micro Labs Limited	India
			PROTHIONAMIDE	film-coated tablets, 250 mg; 10 tablets in an 10 tablets in an 11 tablets in are ardboard box or 10 tablets in an 11 tablets in an ardboard box; 28 tablets in an 11 tablets in an 11 tablets in an al. /PVC/Aclar blister; 10 blisters in a cardboard box; 50 tablets in a plastic jar	1 film-coated tablet contains 250 mg of prothionamide	Lupin Limited	India
			PROTHIONAMIDE TABLETS 250 MG	film-coated tablets, 250 mg; 10 tablets in a blister, 10 blisters in a cardboard package	1 tablet contains: prothionamide 250 mg	Lupin Limited	India
			PROTOMIDE	250 mg film-coated tablets, 10 tablets per strip, 5 strips per carton	1 tablet contains prothionamide 250 mg	McLeods Pharmaceutic als Limited	India
8	Ethionamide	J04AD03	ETHIONAMIDE	dispersible tablets, 125 mg, 10 tablets in a blister; 10 blisters in a cardboard box	1 tablet contains: ethionamide 125 mg	Micro Labs Limited	India
			ETHIONAMIDE DISPERSIBLE TABLETS 125 MG	dispersible tablets of 125 mg; 10 tablets in a strip; 10 strips in a cardboard box	1 tablet contains: ethionamide 125 mg	McLeods Pharmaceutic als Limited	India
			ETHOMIDE	film-coated tablets 250 mg; 10 tablets in a strip; 5 or 10 strips in a carton	1 tablet contains ethionamide 250 mg	McLeods Pharmaceutic als Limited	India
9	Pyrazinamide	J04AK01	MACROSIDE 500	500 mg tablets, 10 tablets in a blister, 10 blisters in a cardboard box	1 tablet contains pyrazinamide 500 mg	McLeods Pharmaceutic als Limited	India
			PAIZINA	500 mg tablets of 100 or 1000 tablets in jars	1 tablet contains pyrazinamide 500 mg	Lupin Limited	India
			PYRAZINAMIDE	500 mg tablets, 10 tablets in a blister; 5 blisters per pack	1 tablet contains pyrazinamide 500 mg equivalent to 100% anhydrous substance	Public Joint Stock Company "Research and Production Center "Borshchahiv skiy Chemical and Pharmaceutic al Plant"	Ukraine

			PYRAZINAMIDE	500 mg tablets, 28 tablets in	1 tablet contains:	Micro Labs	India
				a blister, 24 blisters in a cardboard box	pyrazinamide 500 mg	Limited	
			PYRAZINAMIDE	dispersible tablets of 150 mg, 10 tablets in an aluminum strip; 10 strips in a cardboard box	1 tablet contains: pyrazinamide 150 mg	Micro Labs Limited	India
			PYRAZINAMIDE- DARNITSA	500 mg tablets, 10 tablets in a blister pack, 5 blister packs in a pack; 1000 tablets in containers	1 tablet contains pyrazinamide 500 mg	PrJSC "Pharmaceuti cal Firm "Darnitsa"	Ukraine
10	Ethambutol	J04AK02	ECOKS 400	film-coated tablets, 400 mg, 10 tablets in a blister, 10 blisters in a carton	1 tablet contains ethambutol hydrochloride 400 mg	McLeods Pharmaceutic als Limited	India
			ETAMBUTOL	400 mg tablets, 10 tablets in a blister, 5 blisters in a pack; 120 tablets in a plastic container; 1 container in a pack; 1000 tablets in a plastic container	1 tablet contains ethambutol hydrochloride (in terms of 100% dry substance) – 400 mg	Public Joint Stock Company "Research and Production Center "Borshchahiv skiy Chemical and Pharmaceutic al Plant"	Ukraine
			ETAMBUTOL	400 mg tablets, 10 tablets in a blister pack; 5 blister packs per pack; 1000 tablets in containers	1 tablet contains ethambutol hydrochloride 400 mg	PrJSC "Pharmaceuti cal Firm "Darnitsa"	Ukraine
			ETAMBUTOL	film-coated tablets, 400 mg, 1000 tablets in a plastic jar	1 film-coated tablet contains: 400 mg ethambutol hydrochloride compliant with the requirements of the British Pharmacopoeia	Svisera Europe B.V.	Netherlands
			ETHAMBUTOL DISPERSIBLE TABLETS 100 MG	dispersible tablets of 100 mg, 10 tablets in a blister; 10 blisters in a cardboard box; 6 tablets in a strip; 10 strips in a cardboard package; 10 tablets in a strip; 8 strips in a cardboard box	1 tablet contains ethambutol hydrochloride 100.00 mg	McLeods Pharmaceutic als Limited	India
			ETHAMBUTOL DISPERSIBLE TABLETS 100 MG	100 mg dispersible tablets, 10 tablets in a blister, 10 blisters in a cardboard package	1 tablet contains ethambutol hydrochloride - 100.00 mg	McLeods Pharmaceutic als Limited	India
			Ethambutol Hydrochloride 400 mg tablets	400 mg film-coated tablets, 10 tablets in a blister, 10 blisters in a cardboard box; 28 tablets in a blister; 24 blisters in a cardboard box	1 tablet contains: ethambutol hydrochloride - 400 mg	Cadilla Pharmaceutic als Limited	India
			INBUTOL®	concentrate for solution for infusion, 100 mg/ml, 10 ml in glass vials; 20 ml in glass bottles	1 ml of solution contains 100 mg of ethambutol hydrochloride	LLC "Yuria- Pharm"	Ukraine
			INBUTOL®	solution for injection, 100 mg/ml in 10 ml or 20 ml vials	1 ml of solution contains 100 mg of ethambutol hydrochloride	LLC "Yuria- Pharm"	Ukraine
11	Terizidon	J04AK03	TERISIDON	hard capsules 250 mg, 10 capsules in a blister, 1 blister in a cardboard pack	1 capsule contains terizidone 250 mg	PrAT "Technologist"	Ukraine
			TERIZ	250 mg capsules, 10 capsules in a strip, 10 strips in a carton	1 capsule contains terizidone 250 mg	McLeods Pharmaceutic als Limited	India
12	Bedaquiline	J04AK05	SIRTURO	100 mg tablets; 188 tablets in a bottle, 1 bottle in a cardboard box; 6 tablets in a blister, 4 blisters in a cardboard package	1 tablet contains 120.89 mg of bedaquiline fumarate (corresponds to 100 mg of bedaquiline)	Johnson & Johnson Ukraine LLC	Ukraine

			SIRTURO	20 mg tablets; 60 tablets in a white opaque high-density polyethylene bottle with a polypropylene cap with an aluminum crimp to protect against opening by children; 1 vial together with silica gel desiccant in a cardboard box	1 tablet contains 24.18 mg of bedaquiline fumarate, which corresponds to 20 mg of bedaquiline	Johnson & Johnson Ukraine LLC	Ukraine
13	Delamanid	J04AK06	DELTABA®	50 mg film-coated tablets; 48 tablets per pack: 8 tablets in a blister; 6 blisters in a cardboard box	1 film-coated tablet contains 50 mg of delamanid	R-Pharm Germani GmbH	Germany
14	Blackmanid	J04AK08	DOVPRELA	200 mg tablets, 14 tablets in a blister; 1 or 13 blisters in a cardboard box, 26 or 182 tablets in a bottle; 1 bottle in a cardboard box	1 tablet contains pretomanida 200 mg	Mylan Laboratories Limited	India
			PRETOMANID TABLETS	200 mg tablets, 26 tablets in a bottle in a cardboard box	1 tablet contains: pretomanida – 200.0 mg	Mylan Laboratories Limited	India
15	Comb drug	J04AM	COMBITUB-NEO	film-coated tablets, 10 tablets in a strip, 4, 6 or 10 strips in a carton	I tablet contains lomefloxacin (as lomefloxacin hydrochloride) 200 mg, prothionamide 188 mg, pyrazinamide 400 mg, ethambutol hydrochloride 360 mg/	Simex Pharma Pvt. LTD.	India
			PAS ISO	enteric granules, 100 g granules in a bag, 1 bag together with a measuring cup in a container	1 g of granules contains 0.8 g of sodium aminosalicylate dihydrate and 0.0233 g of isoniazid	PrAT "Technologist"	Ukraine
16	Rifampicin, ethamputhol, isoniacittu**	J04AM	RIFAMPICIN + ISONIAZID + ETHAMBUTOL HYDROCHLORIDE	film-coated tablets, 28 tablets in a blister; 24 blisters in a cardboard box	1 tablet contains rifampin 150 mg, isoniazid 75 mg, ethambutol hydrochloride 275 mg	Lupin Limited	India
			AKURIT-3	film-coated tablets, 28 tablets in a blister, 24 blisters in a cardboard box	1 tablet contains rifampin 150 mg, isoniazid 75 mg, ethambutol hydrochloride 275 mg	Lupin Limited	India
17	Rifampicin and isoniazid	J04AM02	RIFAMPIN AND ISONIAZID	dispersible tablets, 75 mg/50 mg, 6 tablets per strip, 14 strips per carton	1 tablet contains: rifampin 75 mg; isoniazid 50 mg	Lupin Limited	India
			RIFAMPICIN 150 MG - ISONIAZID 75 MG TABLETS	film-coated tablets, 28 tablets in a blister, 24 blisters in a cardboard package	1 film-coated tablet contains: rifampicin 150 mg, isoniazid 75 mg	Lupin Limited	India
			RIFAMPICIN 150 MG/ ISONIAZID 75 MG	150 mg/75 mg tablets, 28 tablets in a blister, 24 blisters in a cardboard box	1 film-coated tablet contains: rifampicin – 150 mg, isoniazid – 75 mg	Svisera Europe B.V.	Netherlands
			RIFAMPICIN 75 MG AND ISONIAZID 50 MG	dispersible tablets 75 mg/50 mg, 28 tablets in a strip; 3 strips in a cardboard box	1 dispersible tablet contains rifampicin 75 mg, isoniazid 50 mg	McLeods Pharmaceutic als Limited	India
			RIFAMPICIN AND ISONIAZID TABLETS	film-coated tablets, 150 mg/75 mg, 28 tablets in a blister, 24 blisters in a carton	1 film-coated tablet contains rifampicin 150 mg, isoniazid 75 mg	Lupin Limited	India
			RIFAMPICIN/ISON IAZID	film-coated tablets 150 mg/75 mg; 28 tablets in a blister, 3 or 24 blisters in a cardboard package	1 film-coated tablet contains rifampicin 150 mg, isoniazid 75 mg	McLeods Pharmaceutic als Limited	India

18	Rifampicin, pyrazinami de and isoniazid	J04AM05	RIFAMPICIN 75 MG/ISONIAZID 50 MG/PYRAZINAMI DE 150 MG	dispersible tablets, 75 mg/50 mg/150 mg No. 84 (28x3): 28 tablets per strip; 3 strips in a cardboard box	1 dispersible tablet contains rifampicin 75 mg, isoniazid 50 mg, pyrazinamide 150 mg	McLeods Pharmaceutic als Limited	India
19	Rifampicin, pyrazinami de, ethambutol and isoniazid	J04AM06	RIFAMPICIN 150 MG- 1SONIAZID 75 MG - PYRAZINAMID 400 MG- ETHAMBUTOL E 275 MG TABLETS F.USA (RIFAMPICIN 150 MG- ISONIAZID 75 MG - PYRAZINAMID E 400 MG - ETHAMBUTOL ETHAMBUTOL ETHAMBUTOL E 275 MG TABLETS USP)	film-coated tablets, 28 tablets in a blister; 24 blisters in a cardboard box	I film-coated tablet contains: rifampicin 150 mg, isoniazid 75 mg, pyarazinamide 400 mg, ethambutol hydrochloride 275 mg	Lupin Limited	India
			RIFAMPICIN 150 MG / ISONIAZID 75 MG / PYRAZINAMIDE 400 MG / ETHAMBUTOL HYDROCHLORID E 275 MG	film-coated tablets, 150 mg/75 mg/400 mg/ 275 mg, 28 tablets in a blister, 24 blisters in a cardboard box	1 film-coated tablet contains: rifampicin – 150 mg, isoniazid – 75 mg, pyrazinamide - 400 mg, ethambutol hydrochloride - 275 mg	Svisera Europe B.V.	Netherlands
			RIFAMPICIN, ISONIAZID, PYRAZINAMIDE AND ETHAMBUTOL HYDROCHLORID E TABLETS	film-coated tablets 150 mg/75 mg/400 mg/275 mg; 28 tablets in a blister, 24 blisters in a cardboard box	1 film-coated tablet contains rifampicin 150 mg, isoniazid 75 mg, pyrazinamide 400 mg, ethambutol hydrochloride 275 mg;	Lupin Limited	India
			FORECOX TRACK	film-coated tablets, 6 tablets in a strip, 10 strips in a cardboard box; 28 tablets in a blister, 24 blisters in a cardboard box	1 tablet contains rifampicin 150 mg, pyrazinamide 400 mg, ethambutol hydrochloride 275 mg, isoniazid 75 mg	McLeods Pharmaceutic als Limited	India

Table 1 presents medications by their International Nonproprietary Name (INN) — a total of 19 entries, ATC classification codes, trade names — 78 entries, and their corresponding dosage forms, compositions of medications by active substance doses, as well as the applicant and the applicant's country for each drug.

The analysis conducted revealed that the leaders among the applicant countries for positions of medicinal products represented in the Ukrainian market are as follows: India - 44 positions, Ukraine - 24 positions. Other countries have lower indicators: the Netherlands - 3 positions, the United Kingdom - 2 positions, and Latvia, Greece, Germany - 1 position each.

Analysis of the List of Essential Medicines in Ukraine regarding anti-tuberculosis drugs and development of the fundamental scheme of the IT import substitution program

We processed the List of Essential Medicines in Ukraine (Table 2) to establish a list of all anti-tuberculosis drugs available on the country's pharmaceutical market as of 2023.

Table 2 presents medications by their International Nonproprietary Name (INN) – a total of 16 entries, ATC classification codes, trade names – 69 entries, and their corresponding dosage forms, compositions of medications by active substance doses, as well as the applicant and the applicant's country for each drug.

The analysis conducted allowed to establish that the leaders among the applicant countries are India with 39 positions and Ukraine with 22 positions. Other countries are ranked as follows: the Netherlands - 3 positions, the United Kingdom - 2 positions, Latvia, Greece, and Germany - 1 position each for pharmaceuticals.

The comparative analysis of the data presented in the two tables allowed us to establish a list of pharmaceuticals that should be included in the Program for Import Substitution of Tuberculosis Drugs in Ukraine⁹⁵. It also allowed us to identify domestic pharmaceutical manufacturers as potential candidates for the production of these drugs within their own facilities. To create the IT program, Scheme 1 was developed, outlining the steps for searching and selecting pharmaceuticals for import substitution concerning specific pharmacological groups of medicinal products.

 $^{^9}$ Венгрин Н. М., Кричковська А. М., Заярнюк Н. Л. Модель пошуку переліку ліків для імпортозаміни на прикладі протитуберкульозних препаратів // Chemical and biopharmaceutical technologies: collection of scientific papers. -2023.-2023.-P.230-231.

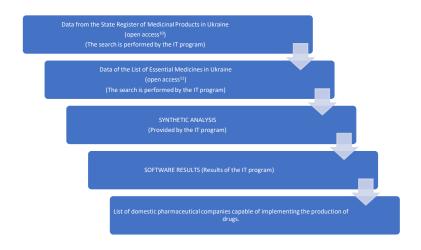
Table 2
Anti-tuberculosis drugs included in the List of Essential Medicines in Ukraine (As of October 20, 2023)

Ni	INN	ATX code	Trade Name	Release form	Composition (active ingredients)	Applicant: name in Ukrainian	Applicant: Country
1	Sodium aminosalicyl ate	J04AA02	SODIUM AMINOSALICYLATE	enteric granules 0.8 g/1 g, 100 g in a bag; 1 packet together with the dosing device in the container	1.0 g of granules contains 0.8 g of sodium aminosalicylate dihydrate	PrAT "Technologist"	Ukraine
			ПАС	enteric granules, 80 g/100 g, 100 g in an aluminum foil pouch enclosed in a plastic bag, complete with a measuring spoon and a silica gel sachet in a plastic container	100 g of granules contain 80 g of sodium aminosali cylate	SCAN BIOTECH LTD	India
			PASK SODIUM SALT	powder for oral solution, 5.52 g; 12.5 g of the drug in a laminate bag; 25 or 300 sachets in a cardboard box	1 sachet contains 5.52 g of para- aminosalicylic acid of the sodium dihydrate salt, which corresponds to 4.00 g of para- aminosalicylic acid	JSC "Olainfarm"	Latvia
2	Cycloserine	J04AB01	COXERINE	250 mg capsules No. 100 (10x10): 10 capsules in a strip; 10 strips in a cardboard package; No 90 (10x9): 10 capsules in a blister; 9 blisters in a cardboard box; No. 100 (10x10): 10 capsules in a blister; 10 blisters in a cardboard box	1 capsule contains cycloserine 250 mg	McLeods Pharmaceuticals Limited	India
			HELPOSERIN	250 mg capsules; 10 capsules in a blister; 5 blisters in a pack; 50 capsules in a plastic or glass bottle; 1 bottle in a carton	1 capsule contains 250 mg of cycloserine	Help S.A.	Greece
			CYCLOSERINE	hard capsules 125 mg, 10 capsules in a blister, 3 blisters in a cardboard pack	1 capsule contains cycloserine 125 mg	PrAT "Technologist"	Ukraine
			CYCLOSERINE	hard capsules 125 mg, 10 capsules in a blister, 3 blisters in a cardboard pack	1 capsule contains cycloserine 125 mg	PrAT "Technologist"	Ukraine
			CYCLOSERINE	hard capsules 250 mg, 10 capsules in a blister, 3 blisters in a cardboard pack, 60 capsules in a container, 1 container in a cardboard pack	1 capsule contains cycloserine 250 mg	PrAT "Technologist"	Ukraine
			CYCLOSERINE	hard capsules 250 mg, 10 capsules in a blister, 3 blisters in a cardboard pack, 60 capsules in a container, 1 container in a cardboard pack	1 capsule contains cycloserine 250 mg	PrAT "Technologist"	Ukraine
			Cycloserine capsules Ph. Int. 250 mg	250 mg capsules, 10 capsules in a blister, 10 blisters in a cardboard pack	1 capsule contains: cycloserine 250 mg	M.BIOTECH LIMITED	United Kingdom
			CYCLOSERINE CAPSULES USP 125 MG	125 mg capsules, 10 capsules in a blister; 10 blisters in a cardboard box	1 capsule contains: cycloserine 125.00 mg	McLeods Pharmaceuticals Limited	India
3	Rifampicin	J04AB02	MAKOX 150	150 mg capsules, 10 capsules in a blister; 10 blisters in a cardboard box; 10 capsules in a strip; 10 strips in a cardboard box	1 capsule contains rifampicin 150 mg	McLeods Pharmaceuticals Limited	India
			MAKOX 300	300 mg capsules, 10 capsules in a blister; 10 blisters in a cardboard box; 10 capsules in a strip; 10 strips in a cardboard box	1 capsule contains rifampicin 300 mg	McLeods Pharmaceuticals Limited	India
			R-CIN	150 mg capsules, 100 or 1000 capsules in jars	1 capsule contains rifampicin 150 mg	Lupin Limited	India
			R-CIN	capsules of 300 mg, 100 or 1000 capsules in jars	1 capsule contains rifampicin 300 mg	Lupin Limited	India
			RIFAMPIN	powder for solution for injection 600 mg, 600 mg powder in a 20 ml vial; 1 bottle in a cardboard box	1 vial contains: rifampicin 600 mg	Mylan Laboratories Limited	India
			RIFAMPIN	Lyophilized powder for the preparation of solution for infusion 600 mg, 1 vial of powder in a cardboard box	1 vial contains rifampicin 600 mg	M.BIOTECH LIMITED	United Kingdom
			RIFAMPICIN	150 mg capsules, 10 capsules in a blister, 2 blisters in a pack, 1000 capsules in a container, 90 capsules in a plastic container with a lid with first closure control, 1 container in a pack	1 capsule contains 150 mg of rifampicin (on a 100% dry matter basis)	Public Joint Stock Company "Research and Production Center "Borshchahivsk iy Chemical and Pharmaceutical Plant"	Ukraine
4	Rifabutin	J04AB04	RIFABOUTIN	150 mg capsules, 10 capsules in a blister, 3 blisters in a cardboard package	1 capsule contains rifabutin 150 mg	Lupin Limited	India
			RIFABOUTIN 150	150 mg capsules No. 100 in a plastic jar	1 capsule contains rifabutin 150 mg	Lupin Limited	India
5	Capreomycin	J04AB30	CAPREOMYCIN	powder for solution for injection, 1.0 g in vials	1 vial contains sterile capreomy cin sulfate equivalent to 1 g of capreomy cin.	Pat "Kisovmedprep aration"	Ukraine
6	Isoniazid	J04AC01	БПУБФ	solution for injection, 100 mg/ml, 5 ml in a vial; 10 or 30 bottles in a pack; 5 ml in an ampoule; 5	1 ml of solution contains 100 mg of isoniazid	LLC "Yuria- Pharm"	Ukraine

			ampoules in a blister pack; 2			
		ISONIAZID	syrup, 100 mg/5 ml; 200 ml in	5 ml of syrup	LLC "Yuria-	Ukraine
			bottles; 200 ml in a bottle; 1 bottle in a cardboard pack	contains 100 mg of isoniazid	Pharm"	MADAVOM SEC.
		ISONIAZID	100 mg tablets, 10 tablets in a blister, 10 blisters in a cardboard box	1 tablet contains: isoniazid 100 mg	Micro Labs Limited	India
		ISONIAZID	100 mg tablets, 10 tablets in a blister, 3, 9 or 10 blisters in a cardboard package; 28 tablets in a blister, 3 or 24 blisters in a cardboard package; 1000 tablets in a plastic bag, 1 package in a plastic container	1 tablet contains isoniazid 100 mg	McLeods Pharmaceuticals Limited	India
		ISONIAZID	100 mg tablets, 10 tablets in a blister; 5 blisters per pack	1 tablet contains 100 mg of isoniazid (on a dry matter basis)	Public Joint Stock Company "Research and Production Center "Borshchahivsk iy Chemical and Pharmaceutical Plant"	Ukraine
		ISONIAZID	200 mg tablets, 10 tablets in a blister; 5 blisters per pack	1 tablet contains isoniazid (in terms of dry matter) 200 mg	Public Joint Stock Company "Research and Production Center "Borshchahivsk iy Chemical and Pharmaceutical Plant"	Ukraine
		ISONIAZID	300 mg tablets, 28 tablets in a blister; 24 blisters in a cardboard box	1 tablet contains: isoniazid 300 mg	Micro Labs Limited	India
		ISONIAZID	300 mg tablets, 10 tablets in a blister, 3, 9 or 10 blisters in a cardboard package; 28 tablets in a blister, 3 or 24 blisters in a cardboard package; 1000 tablets in a plastic bag, 1 package in a plastic container	1 tablet contains isoniazid 300 mg	McLeods Pharmaceuticals Limited	India
		ISONIAZID- DARNITSA	solution for injection, 100 mg/ml; 5 ml in an ampoule; 5 ampoules in a blister pack; 2 blister packs per pack	1 ml of solution contains isoniazid 100 mg	PrJSC "Pharmaceutica I Firm "Damitsa"	Ukraine
		ISONIAZID- DARNITSA	300 mg tablets, 10 tablets in a blister pack; 5 blister packs per pack; 1000 or 1500 or 2500 tablets in containers	1 tablet contains isoniazid 300 mg	PrJSC "Pharmaceutica I Firm "Damitsa"	Ukraine
Protionamide	J04AD01	PROTEKH	film-coated tablets 250 mg; 10 tablets in a blister, 5 or 10 blisters in a cardboard pack; 10 tablets in a blister, 50 or 100 blisters in a cardboard box	1 tablet contains 250 mg of prothionamide	PrAT "Technologist"	Ukraine
		PROTHIONAMIDE	film-coated tablets, 250 mg, 10 tablets in a blister; 10 blisters in a cardboard box	1 tablet contains: prothionamide 250 mg	Micro Labs Limited	India
		PROTHIONAMIDE	film-coared tablets, 250 mg; 10 tablets in an ALPVC/PVDF UD tablets in an ALPVC/PVDF UD tablets in an ALPVC/PPPP/DF UD tablets in an ALPVC/PPP/DF UD tablets; 10 blisters in a cardboard box; 28 tablets in an ALPVC/Alear blister; 10 blisters in a cardboard box; 26 tablets in a Cardboard box; 50 tablets in a Cardboard box; 50 tablets in a Cardboard box; 50 tablets in a Participant Cardboard box; 50 tablets in a	1 film-coated tablet contains 250 mg of prothionamide	Lupin Limited	India
		PROTHIONAMIDE TABLETS 250 MG PROTOMIDE	film-coated tablets, 250 mg; 10 tablets in a blister, 10 blisters in a cardboard package 250 mg film-coated tablets, 10	1 tablet contains: prothionamide 250 mg 1 tablet contains	Lupin Limited McLeods	India India
		578-500 A78-500 W 125-6	tablets per strip, 5 strips per carton	prothionamide 250 mg	Pharmaceuticals Limited	
Ethionamide	J04AD03	ETHIONAMIDE	dispersible tablets, 125 mg, 10 tablets in a blister; 10 blisters in a cardboard box	1 tablet contains: ethionamide 125 mg	Micro Labs Limited	India
		ETHIONAMIDE DISPERSIBLE TABLETS 125 MG	dispersible tablets of 125 mg; 10 tablets in a strip; 10 strips in a cardboard box	1 tablet contains: ethionamide 125 mg	McLeods Pharmaceuticals Limited	India
		ETHOMIDE	film-coated tablets 250 mg; 10 tablets in a strip; 5 or 10 strips in a carton	1 tablet contains ethionamide 250 mg	McLeods Pharmaceuticals Limited	India
Pyrazinamide	J04AK01	MACROSIDE 500	500 mg tablets, 10 tablets in a blister; 10 blisters in a cardboard box	1 tablet contains pyrazinamide 500 mg	McLeods Pharmaceuticals Limited	India
		PAIZINA	500 mg tablets of 100 or 1000 tablets in jars	1 tablet contains pyrazinamide 500 mg	Lupin Limited	India
		PYRAZINAMIDE	500 mg tablets, 10 tablets in a blister; 5 blisters per pack	1 tablet contains pyrazinami de 500 mg equivalent to 100% anhydrous substance	Public Joint Stock Company "Research and Production Center "Borshchahivsk iy Chemical and Pharmaceutical Plant"	Ukraine

			PYRAZINAMIDE	500 mg tablets, 28 tablets in a blister, 24 blisters in a cardboard box	1 tablet contains: pyrazinamide 500 mg	Micro Labs Limited	India
			PYRAZINAMIDE	dispersible tablets of 1.50 mg, 10 tablets in an aluminum strip; 10 strips in a cardboard box	1 tablet contains: pyrazinamide 150 mg	Micro Labs Limited	India
			PYRAZINAMIDE- DARNITSA	500 mg tablets, 10 tablets in a blister pack, 5 blister packs in a pack; 1000 tablets in containers	1 tablet contains pyrazinami de 500 mg	PrJSC "Pharmaceutica I Firm "Damitsa"	Ukraine
10	Ethambutol	J04AK02	ECOKS 400	film-coated tablets, 400 mg, 10 tablets in a blister, 10 blisters in a carton	1 tablet contains ethambutol hydrochloride 400 mg	McLeods Pharmaceuticals Limited	India
			ETAMBUTOL	400 mg tablets, 10 tablets in a blister; 5 blisters in a pack; 120 tablets in a plastic container; 1 container in a pack; 1000 tablets in a plastic container	1 tablet contains ethambutol hydrochloride (in terms of 100% dry substance) – 400 mg	Public Joint Stock Company "Research and Production Center "Borshchahivsk iy Chemical and Pharmaceutical Plant"	Ukraine
			ETAMBUTOL	400 mg tablets, 10 tablets in a blister pack; 5 blister packs per pack; 1000 tablets in containers	1 tablet contains ethambutol hydrochloride 400 mg	PrJSC "Pharmaceutica 1 Firm "Darnitsa"	Ukraine
			ETAMBUTOL	film-coated tablets, 400 mg, 1000 tablets in a plastic jar	1 film-coated tablet contains: 400 mg ethambutol hydrochloride compliant with the requirements of the British Pharmacopoeia	Svisera Europe B.V.	Netherlands
			ETHAMBUTOL DISPERSIBLE TABLETS 100 MG	dispersible tablets of 100 mg, 10 tablets in a blister; 10 blisters in a cardboard box; 6 tablets in a strip; 10 strips in a cardboard package; 10 tablets in a strip; 8 strips in a cardboard box	1 tablet contains ethambutol hydrochloride 100.00 mg	McLeods Pharmaceuticals Limited	India
			ETHAMBUTOL DISPERSIBLE TABLETS 100 MG	100 mg dispersible tablets, 10 tablets in a blister, 10 blisters in a cardboard package	1 tablet contains ethambutol hydrochloride - 100.00 mg	McLeods Pharmaceuticals Limited	India
			Ethambutol Hydrochloride 400 mg tablets	400 mg film-coated tablets, 10 tablets in a blister; 10 blisters in a cardboard box; 28 tablets in a blister; 24 blisters in a cardboard box	1 tablet contains: ethambutol hydrochloride - 400 mg	Cadilla Pharmaceuticals Limited	India
			INBUTOL®	concentrate for solution for infusion, 100 mg/ml, 10 ml in glass vials; 20 ml in glass bottles	1 ml of solution contains 100 mg of ethambutol hydrochloride	LLC "Yuria- Pharm"	Ukraine
			INBUTOL®	solution for injection, 100 mg/ml in 10 ml or 20 ml vials	1 ml of solution contains 100 mg of ethambutol hydrochloride	LLC "Yuria- Pharm"	Ukraine
1	Terizidon	J04AK03	TERISIDON	hard capsules 250 mg, 10 capsules in a blister; 1 blister in a cardboard pack	1 capsule contains terizidone 250 mg	PrAT "Technologist"	Ukraine
			TERIZ	250 mg capsules, 10 capsules in a strip, 10 strips in a carton	1 capsule contains terizidone 250 mg	McLeods Pharmaceuticals Limited	India
12	Bedaquiline	J04AK05	SIRTURO	100 mg tablets; 188 tablets in a bottle, 1 bottle in a cardboard box; 6 tablets in a blister, 4 blisters in a cardboard package	1 tablet contains 120.89 mg of bedaquiline fumarate (corresponds to 100 mg of bedaquiline)	Johnson & Johnson Ukraine LLC	Ukraine
			SIRTURO	20 mg tablets; 60 tablets in a white opaque high-density polyethylene bottle with a polypropylene cap with an aluminum crimp to protect against opening by children; 1 vial together with silica gel desiccant in a cardboard box	1 tablet contains 24.18 mg of bedaquiline fumarate, which corresponds to 20 mg of bedaquiline	Johnson & Johnson Ukraine LLC	Ukraine
13	Delamanid	J04AK06	DELTABA®	50 mg film-coated tablets; 48 tablets per pack: 8 tablets in a blister; 6 blisters in a cardboard box	1 film-coated tablet contains 50 mg of delamanid	R-Pharm Germani GmbH	Germany
4	Blackmanid	J04AK08	DOVPRELA	200 mg tablets, 14 tablets in a blister; 1 or 13 blisters in a cardboard box, 26 or 182 tablets in a bottle; 1 bottle in a cardboard box	1 tablet contains pretomanida 200 mg	Mylan Laboratories Limited	India
			PRETOMANID TABLETS	200 mg tablets, 26 tablets in a bottle in a cardboard box	1 tablet contains: pretomanida - 200.0 mg	Mylan Laboratories Limited	India
1.5	Comb drug	J04AM	COMBITUB-NEO	film-coated tablets, 10 tablets in a strip, 4, 6 or 10 strips in a carton	1 tablet contains lomefloxacin (as lomefloxacin (as lomefloxacin) hydrochloride) 200 mg, prothionamide 188 mg, pyrazinamide 400 mg, ethambutol hydrochloride 360 mg/	Simex Pharma Pvt. LTD.	India

			PAS ISO	enteric granules, 100 g granules in a bag, 1 bag together with a measuring cup in a container	1 g of granules contains 0.8 g of sodium aminosali cylate dihydrate and 0.0233 g of isoniazid	PrAT "Technologist"	Ukraine
16	Rifampicin, ethamputhol, isoniacittu*	J04AM	RIFAMPICIN + ISONIAZID + ETHAMBUTOL HYDROCHLORIDE	film-coated tablets, 28 tablets in a blister, 24 blisters in a cardboard box	1 tablet contains rifampin 150 mg, isoniazid 75 mg, ethambutol hydrochloride 275 mg	Lupin Limited	India
			AKURIT-3	film-coated tablets, 28 tablets in a blister, 24 blisters in a cardboard box	1 tablet contains rifampin 150 mg, isoniazid 75 mg, ethambutol hydrochloride 275 mg	Lupin Limited	India
.7	Rifampicin and isoniazid	J04AM02	RIFAMPIN AND ISONIAZID	dispersible tablets, 75 mg/50 mg, 6 tablets per strip, 14 strips per carton	1 tablet contains: rifampin 75 mg; isoniazid 50 mg	Lupin Limited	India
			RIFAMPICIN 150 MG - ISONIAZID 75 MG TABLETS	film-coated tablets, 28 tablets in a blister, 24 blisters in a cardboard package	1 film-coated tablet contains: rifampicin 150 mg, isoniazid 75 mg	Lupin Limited	India
			RIFAMPICIN 150 MG/ ISONIAZID 75 MG	150 mg/75 mg tablets, 28 tablets in a blister, 24 blisters in a cardboard box	1 film-coated tablet contains: rifampicin - 150 mg, isoniazid - 75 mg	Svisera Europe B.V.	Netherlands
			RIFAMPICIN 75 MG AND ISONIAZID 50 MG	dispersible tablets 75 mg/50 mg, 28 tablets in a strip; 3 strips in a cardboard box	1 dispersible tablet contains rifampicin 75 mg, i soniazi d 50 mg	McLeods Pharmaceuticals Limited	India
			RIFAMPICIN AND ISONIAZID TABLETS	film-coated tablets, 150 mg/75 mg, 28 tablets in a blister, 24 blisters in a carton	1 film-coated tablet contains rifampicin 150 mg, isoniazid 75 mg	Lupin Limited	India
			RIFAMPICIN/ISONIA ZID	film-coated tablets 150 mg/75 mg; 28 tablets in a blister, 3 or 24 blisters in a cardboard package	1 film-coated tablet contains rifampicin 150 mg, isoniazid 75 mg	McLeods Pharmaceuticals Limited	India
8	Rifampicin, pyrazinamide and isoniazid	J04AM05	RIFAMPICIN 75 MG/ISONIAZID 50 MG/PYRAZINAMIDE 150 MG	dispersible tablets, 75 mg/50 mg/150 mg No. 84 (28x3): 28 tablets per strip; 3 strips in a cardboard box	dispersible tablet contains rifampicin 5 mg, isoniazid 50 mg, pyrazinamide 150 mg	McLeods Pharmaceuticals Limited	India
19 Rifampicin, pyrazinamide , ethambutol and isoniazid	pyrazinamide , ethambutol	J04AM06	RIFAMPICIN 150 MG - ISONIAZID 75 MG - PYRAZINAMIDE 400 MG - ETHAMBUTOL, HYDROCHLORIDE 275 MG TABLETS F.USA (RIFAMPICIN 150 MG - ISONIAZID 75 MG - PYRAZINAMIDE 400 MG - ETHAMBUTOL, HYDROCHLORIDE 275 MG TABLETS USP)	film-coated tablets, 28 tablets in a blister; 24 blisters in a cardboard box	1 film-coated table contains; rifampicin 150 mg, isoniazid 75 mg, pyrazinamide 400 mg, efambutol hydrochloride 275 mg	Lupin Limited	Indi a
			RIFAMPICIN 150 MG / ISONIAZID 75 MG / PYRAZINAMIDE 400 MG / ETHAMBUTOL HYDROCHLORIDE 275 MG	film-coated tablets, 150 mg/75 mg/400 mg/275 mg, 28 tablets in a blister; 24 blisters in a cardboard box	1 film-coated tablet contains: rifampicin - 150 mg, isoniazid - 75 mg, pyrazinamide - 400 mg, ethambutol hydrochloride - 275 mg	Svisera Europe B.V.	Netherlands
			RIFAMPICIN, ISONIAZID, PYRAZINAMIDE AND ETHAMBUTOL HYDROCHLORIDE TABLETS	film-coated tablets 150 mg/75 mg/400 mg/275 mg, 28 tablets in a blister; 24 blisters in a cardboard box	1 film-coated tablet contains rifampicin 150 mg, isoniazid 75 mg, pyrazinamide 400 mg, ethambutol hydrochloride 275 mg;	Lupin Limited	Indi a
			FORECOX TRACK	film-coated tablets, 6 tablets in a strip, 10 strips in a cardboard box; 28 tablets in a blister, 24 blisters in a cardboard box	1 tablet contains rifampicin 150 mg, pyrazinamide 400 mg, ethambutol hydrochloride 275 mg, isoniazid 75 mg	McLeods Pharmaceuticals Limited	India



Scheme 1
The sequence of steps in processing data by the IT program for the list of medications requiring import substitution in Ukraine

⁶ The scheme is based on the analysis of the State Register of Medicinal Products and the List of Essential Medicines, and the IT program identifies potential domestic manufacturers of drugs that require import substitution in Ukraine.

Yes, using the group of anti-tuberculosis drugs as an example, we analyzed the State Register of Medicinal Products and compiled a list of anti-tuberculosis drugs registered in Ukraine. In total, 19 medicinal products with 74 trade names were registered. Among them, 16 are included in the National List of Essential Medicines. Therefore, they are critically important, especially during the state of war in Ukraine. We processed the list of these medicinal products and formed a list of anti-tuberculosis drugs that do not have a Ukrainian analogue. Additionally, it was established that domestic enterprises such as PJSC "Technolog", PJSC "Kyivmedpreparat", and PJSC "Scientific Production Center "Borshchahivsky Chemical and Pharmaceutical Plant", which have extensive experience in the production of anti-tuberculosis drugs, can implement new technological production lines within the Import Substitution Program in Ukraine.

11 Переліку Основних лікарських засобів в Україні. Retrieved from https://www.kmu.gov.ua/npas/32796318

 $^{^{10}}$ Державний реєстр лікарських засобів в Україні. Retrieved from http://www.drlz.com.ua/

CONCLUSIONS

- 1. One of the key factors of a country's defense capability is the physical location of pharmaceutical production lines in Ukraine. To achieve this, it is necessary to implement a Drug Import Substitution Program. For this purpose, we have proposed a scheme for creating an IT program to search for a list of drugs for import substitution and to identify promising pharmaceutical manufacturers capable of producing these drugs on their facilities.
- 2. According to the obtained data, the Drug Import Substitution Program may include 7 anti-tuberculosis drugs: Rifabutin, Ethionamide, Delamanid, combination drug 1 (Rifampicin, Ethambutol, Isoniazid), combination drug 2 (Rifampicin, Isoniazid), combination drug 3 (Rifampicin, Pyrazinamide, Isoniazid), combination drug 4 (Rifampicin, Pyrazinamide, Ethambutol, Isoniazid).
- 3. There is a need to implement new production lines for drugs such as Rifabutin, Ethionamide, and Delamanid, which can be manufactured by PJSC "Technolog", PJSC "Kyivmedpreparat", and PJSC "Scientific and Production Center "Borshchahivsky Chemical and Pharmaceutical Plant", which have extensive experience in producing anti-tuberculosis drugs.
- 4. The development of an IT program as a resource provision for the drug import substitution program, with the elaboration of a model for compiling the list of drugs for a specific pharmacological group, is promising for Ukraine and other countries worldwide.

SUMMARY

The section of the monograph is dedicated to analyzing the market of antituberculosis drugs in Ukraine and developing informational support for the IT import substitution program.

The pharmacological group of anti-tuberculosis drugs was chosen by the authors as a model series for establishing the list of drugs for import substitution due to Ukraine's ranking fourth in the rate of tuberculosis spread in the European region.

To create the IT program as a resource provision for the import substitution program, the authors analyzed legislative acts regulating the circulation of medicinal products in Ukraine. The State Register of Medicinal Products of Ukraine and the National List of Essential Medicines of Ukraine served as the basic legislative acts for studying and modeling the step-by-step scheme of the IT program.

Analysis and processing of existing legislative acts were conducted regarding the group of anti-tuberculosis drugs. However, extrapolating the

proposed step-by-step scheme, which involves separate stages for searching and selecting drugs for import substitution, is possible for specific pharmacological groups of medicinal products and serves as the basis for describing tasks for IT technology professionals and creating the IT program.

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