

SAFEMed Technical Brief

JUNE 2024



MEDICINES REIMBURSEMENT PROGRAM: BRINGING CARE CLOSER TO THE PATIENT

About SAFEMed

Improving access to safe and affordable medicines for the Ukrainian population is one of the Government of Ukraine's top priorities, with ambitious health reforms underway to ensure that access. The United States Agency for International Development (USAID) Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed)

project (2017-2025) is supporting this effort by applying health system strengthening best practices and evidence-based interventions — working to institutionalize rational medicine selection; systematize public procurement of pharmaceuticals and commodities; support sustainable public-sector pharmaceutical financing; and strengthen the pharmaceutical supply chain in collaboration with the government, civil society, and the private sector.

ABOUT THE AFFORDABLE MEDICINES PROGRAM

The Affordable Medicines Program (AMP) began in 2017 to provide the people of Ukraine with access to affordable medications for chronic diseases. Building on market dynamics, digital solutions, and legislative reforms, the AMP offers patients and providers a simple way to find quality medicines at the right price. The Government of Ukraine (GOU) has institutionalized the program, making the AMP part of the program of medical guarantees for the population. The program has expanded to include more medications, medical devices, and participating pharmacies. Patients, physicians, and pharmacists report satisfaction with the program and support its further expansion. The AMP has been essential for the GOU to uphold its vision of universal access to health care for its people. SAFEMed has been a reliable partner of the GOU in deploying the AMP since its launch. SAFEMed has provided technical assistance in pricing essential medicines, launching the ePrescription platform, providing data system support, and installing feedback loops.

BACKGROUND

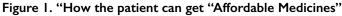
In 2014, Ukraine began a set of ambitious health sector reforms to expand access to quality health care for its population. Reforms sought to address concerns about quality and affordability of medicines in addition to graft and corruption in the sector. In 2015, 90% of all healthcare spending was out of pocket (OOP), with outpatient medicines accounting for 60% of OOP payments. A key reform aimed to establish new financial mechanisms, which were codified through the Law on State Financial Guarantees of Health Care Services to the Population and approved by the Parliament in 2017. In the same year, the Ministry of Health (MOH), in partnership with SAFEMed, introduced the medicines state reimbursement program for outpatient prescription medicines, known as the "Affordable Medicines Program", focusing on providing access to medicines for non-communicable diseases (NCDs). The GOU established the National Health Service of Ukraine (NHSU) in 2018 as the 'national payer' for health care. The NHSU became responsible for contracting and payment for health care as well as coordinating pooling and purchasing policies. NHSU undertook the management of the Affordable medicines program in 2019.

PROGRAM DESIGN

The AMP simplifies access to medicines for patients who require prescriptions as part of their ongoing care for chronic diseases. After a patient receives a diagnosis and a prescription, the physician enters the prescription in the electronic health system. The patient then receives a code on their phone for the prescription and can also request written materials with instructions for medication use. At a pharmacy enrolled in the program, the patient gives the code to the pharmacist who fills the prescription and dispenses the medication. Then, the NHSU directly reimburses pharmacies for the cost of prescription medicines dispensed to patients.

As a rule, medicine is prescribed as an INN (International Nonproprietary Name), except for insulin where brand adherence may be crucial. In the pharmacy, the patient can select the precise medicine they would like to receive among those medicines included within the program. Depending on the contracted price of the manufacturer, the selected medication may be free or come with a small surcharge. The patient can use these benefits at any AMP enrolled pharmacy, regardless of his or her place of residence in Ukraine.





Pharmacies with a participation agreement with the NHSU have a sticker at the entrance to help patients identify participating pharmacies. Since the beginning of the program, pharmacy participation has increased significantly. By the end of 2017 there were around 8,000 contracted pharmacies and, as of end of May 2024, there are 14,000 pharmacies.

PROGRAM IMPLEMENTATION

While the AMP is simple for providers and patients to use, proper implementation of the program relies on key structural components and market dynamics. Communication and monitoring have been critical for keeping users informed and ensuring the program continues to meet evolving needs of the population, particularly during the ongoing war.



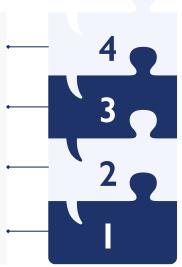
Figure 2. Sticker indicating availability of Affordable Medicines Determining competitive pricing models to set fair but reduced prices and mature the market

Digitalization played a crucial part in facilitating the program's transparency, reporting agility, and adaptability

Building a strong private-public partnership among the central government, health facilities, and private pharmacies

Updating and restructuring an outdated and fragmented legal framework for the program to fit into

Figure 3 . AMP structural elements



LEGALIZATION AND INSTITUTIONALIZATION

Multiple legal reforms paved the way for program implementation and continue to do so as the program evolves and adapts, even in the context of the full-scale invasion. Core legal documents include:

- Law of Ukraine "State Financial Guarantees of Medical Service to the population" (Oct 10, 2017, No. 2168-VIII)
- Cabinet of Ministers Decree "Certain Issues of Reimbursement Contracts" (Feb 27, 2019, No. 136)
- Cabinet of Ministers Decree "Certain Issues of Implementation of the Program for State Guarantees of Medical Service to the Population in 2022" (Dec 29, 2021, No.1440)

In 2019, decrees of the Cabinet of Ministers (CMU) shifted the administration of the AMP to the newly created NSHU. Resolutions of the CMU regulate the interaction between the NHSU and participating pharmacies.

Together with the MOH, SAFEMed established a team of experts to administer the AMP and strengthen the capacity of the NHSU to execute the program. Through a competitive and transparent recruitment process, SAFEMed hired a highly qualified team responsible for the AMP's administration and who were eventually recruited by the NHSU. SAFEMed supported the establishment of business processes for the NHSU such as ePrescription business logic; stakeholder function requirements for ePrescription and eDispense; pharmacy contracting; and reimbursement policy. SAFEMed continues to support capacity strengthening and team building efforts via embedded consultants – experts in the field necessary for the implementation of specific IT, business, or program functions.

Since 2018, SAFEMed has held trainings for the MOH, eHealth technical team, Ukraine medical system vendors (private sector), and NHSU staff. Several educational events for key government counterparts were organized to build better understanding of the current trends in the pharmaceutical market.

PUBLIC-PRIVATE PARTNERSHIPS

The AMP provides an opportunity for private businesses to offer solutions for medication access while building business partnerships guaranteed by the state. As of May 2024, 73% of all pharmacies in the country are part of the AMP, up from just 30% at program launch in 2017. Private pharmacies make up the majority of all those in the program, making them critical for the provision of medicines to the public. The number of medicine manufacturers participating in the program increased from 47 in 2019 to 85 manufacturers in 2024. This public-private partnership harnesses private sector agility to ensure availability of affordable medicines for the public while also supporting positive economic growth for involved businesses.

SAFEMed and the NHSU host a bi-annual reimbursement forum to elicit feedback from and steward relationships between government, public, and private sector stakeholders. This forum creates a platform to discuss the results of the AMP, program performance, challenges, and barriers; share development plans; and gather feedback. Commitment to hosting these discussions continued during the COVID-19 pandemic and through the first year of the invasion virtually and have moved to a hybrid model.

DIGITALIZATION AND E-PRESCRIPTION

In 2019, the GOU launched ePrescriptions within the AMP, allowing for more accurate, timely, and complete program reporting while reducing corruption risks associated with prescribing practices. Use of ePrescriptions improved utilization of the AMP by monitoring scale and impact, avoiding prescribing errors, and reducing inconvenience of lost prescriptions. Digitalization also made refills simpler with remote options.

Further, ePrescriptions also improved the overall quality of health care through prevention of patient self-prescribing, irresponsible use of prescription drugs, and increased transparency and control of prescription-only medicines. It also laid the groundwork for the construction of a clinical monitoring system for medication efficacy in Ukraine linked to the

eHealth system. SAFEMed supported the GOU, MOH, and NHSU to introduce ePrescription at all stages of implementation and assisted with legislation drafting, information systems expertise, and private sector engagement.

In 2020, pleased by the early success and likely expansion of ePrescriptions, the NHSU requested support from SAFEMed to review global experience in ePrescription fraud detection and prevention practices and provide recommendations for application in Ukraine. Based on these recommendations, SAFEMed secured technical experts to automate data capture, develop a contract validation algorithm, improve data storage, and identify most-likely fraud scenarios. The improved health information system allows for more efficient financial planning, contract development, and performance management. SAFEMed provides ongoing analysis of import, production, and retail data to the NHSU for program improvements through its contracted private medicine data firm, Support to Market Development (SMD).

PRICING MODELS

A key feature of the AMP is the negotiation of set reimbursement prices for eligible medicines using external reference pricing. This approach allows for more competitive pricing. The GOU further incentivizes participation in the AMP with a reduced VAT rate for medicines (7%) and further price modification by limiting wholesale and retail profit margins (10% and 15%, respectively, except for insulin, which has a retail profit margin cap of 10%).

To establish the compensation price of a given INN, the NHSU externally references the price for the recommended daily dose of the drug in five countries (Poland, Slovakia, the Czech Republic, Latvia, and Hungary). The median of these prices determines the upper price limit for a specific name product to the AMP. For insulins, a separate model of external reference pricing is used that includes additional reference countries such as Bulgaria, Greece, and Romania.

After the compensation value is set, the NHSU determines the minimum value of the recommended daily dose of the drug which sets the fully reimbursed value. If the patient wants a specific brand that is not fully covered, there is a surcharge. The patient would then cover the difference between the specific brand and the fully covered medication. To reduce prices, companies are invited to take part in a "reverse auction" where the fully reimbursed price is posted and companies have the chance reduce the price of their medicine to match. This process increases the chances of patients buying a particular retailer's medication. Marginal wholesale and retail prices for medicines and medical products under the AMP are updated twice a year and posted publicly.

The ability to use reference prices and offer reverse auctions has lowered prices overall, matured the market by reducing the number of market players, and engaged the private sector to expand their market by offering more affordable medicine.

COMMUNICATIONS

Patients cannot use the AMP if they do not know about it. SAFEMed supports the NHSU's ongoing communication activities to inform Ukrainian citizens of the government's health care services, including the AMP, which was particularly important after the full-scale invasion. At the start of the program, SAFEMed supported the development of infographics, booklets, and branded products to raise the visibility of the AMP. SAFEMed has also created four short, animated videos that informed patients of ways to receive their medications and insulin for free or with a small copayment via the AMP. A video was also developed to shared the story of how the NHSU reimbursement program and health care system functioned during the first critical months of the war when large territories were occupied to highlight the resilience and heroism of the people involved in maintaining access to treatment.



MONITORING

To understand the AMP's impact, SAFEMed supported the GOU and NHSU to select indicators surrounding accessibility, availability/utilization, affordability, patient satisfaction, health outcomes, and management. Key performance indicators (KPIs) are collected through ePrescription data to monitor corruption risks and provide accurate and reliable data, such as the ratio of prescriptions written to prescriptions filled and proportion of medication consumed under the AMP. SAFEMed also provided the GOU and NHSU with access to the SMD market trends and behavior database.

PROGRAM EXPANSION AND WARTIME OPERATIONS

At its start, the AMP included only medications used for commonly treated cardiovascular diseases, type II diabetes, and bronchial asthma. Over time, the AMP expanded to include medications for more diseases, now including medicines and devices for nine different disease categories, including insulin preparations and blood glucose test strips (see figure below). The number of INNs included in the program has increased from 21 to 107. Currently, the AMP includes 412 individual drugs, 68 insulin medicines, 9 combination drugs, and 43 blood glucose test strips. Glucose test strips, included in the program in 2023, were the first medical device included in the program, undertaken after a detailed analytical review of best practices by SAFEMed on test strip reimbursement.

Since the February 2022 invasion, the NHSU has continued managing the AMP. To maintain patient access to treatment, several changes were introduced. For example, the CMU passed a decree allowing paper-based prescriptions for the first several months after the invasion, given the mass exodus of Ukrainian citizens away from regions with active fighting. In addition, as part of martial law, all 47 registered insulin medicines became free of charge for all patients and internally displaced patients could receive their medication at primary health care centers without needing a new prescription. The NHSU has continued to pay AMP registered pharmacies throughout the war with no interruptions.

To specifically support the AMP during the war, SAFEMed embedded consultants to bolster the NHSU IT department operations and expanded support through SMD to track the impact of the war on the program and identify ways to adapt to challenges. SAFEMed also provided immediate legal support through a legal partner to draft necessary regulations to ensure patient access.

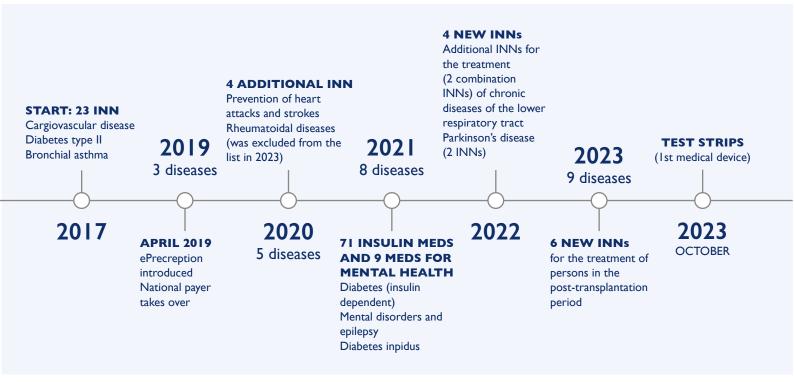


Figure 4. The AMP has steadily included more INNs each year based on MOH priorities

SAFEMED SUPPORT

RESULTS AND IMPACT

The AMP has seen a steady increase in the number of prescriptions filled under the program, barring a significant drop in February 2022 due to Russia's invasion (Fig 5). Overall, the baseline of **1**,897 prescriptions has increased about **800%** over the lifetime of the AMP, reflecting the expansion of the number and type of medicines reimbursed and illustrating the program's significant impact on providing access to medications. As of May 2024, more than 4.6 million unique patients received medications under the AMP, with around \$248 million USD reimbursed.

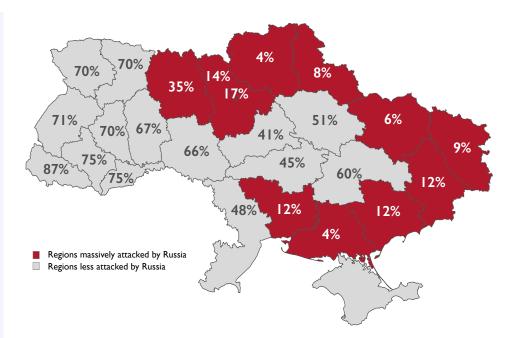


Figure 5. Full-scale invasion impact: Percentage of patients that were able to receive their medication from 24 February 2022 to 15 March 2022, compared to the pre-war period 01-23 February 2022.

PATIENT ACCESS TO MEDICATIONS

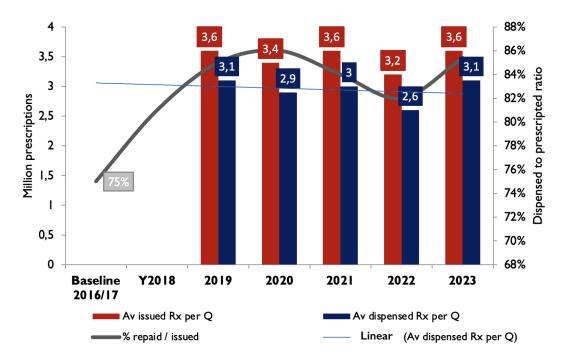


Figure 6. Number of prescriptions filled out of total number of medicines prescribed under the AMP (eHealth official data available at the NHSU website)

The ratio of medication prescribed to filled under the program has also shown a positive trend over the years, surpassing 85% in 2023 from the baseline of 75% in 2016/17, reflecting the program's increasing popularity in patients, providers, and pharmacists.

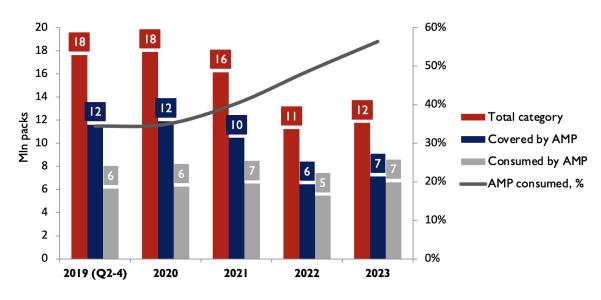


Figure 7. Percentage of prescriptions covered and consumed under the AMP in total medicines in the therapeutic direction

The amount of medicines in the Anatomical Therapeutic Chemical (ATC) Classification covered by the AMP and consumed by patients has been increasing steadily as the program has included more INNs and become more popular. As of 2023, an average of 57% of medicines consumed were covered and bought under the AMP, up from 35% in 2019.

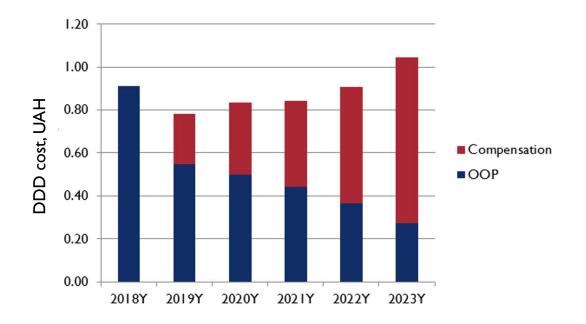


Figure 8. Average DDD cost for the part of C09 class (Agents acting on the renin-angiotensin system) included into the AMP: split by OOP and amounts compensated by AMP

The average OOP cost for a DDD decreased for medicines included in the AMP, despite an overall increase in the market price. The specific example of decreasing OOP costs of the C09 class (agents acting on the renin-angiotensin system, typically used in hypertension) is shown in Figure 8. It is likely that the AMP along with other pharmaceutical reforms contributed to this reduction.

PATIENT SATISFACTION

A SAFEMed-led AMP user satisfaction survey in 2023 assessed the flagship reimbursement program's overall effectiveness. The assessment gathered quantitative and qualitative data on patient, doctor, and pharmacist experiences, opinions, and challenges regarding their engagement with the program. The assessment revealed high satisfaction among patients, doctors, and pharmacists. Patients viewed the program as a significant source of assistance and a demonstration of the state's care during challenging times. Specific findings included:

Patients, doctors, and pharmacists are satisfied with the AMP. All patients positively assess the AMP, seeing it as a real help and care of the state for people in difficult times. Patient satisfaction is also due to the high level of trust in the AMP: about 70% of respondents said that they trusted the AMP more or completely. Likewise, more than 70% of doctors surveyed consider the AMP successful, and almost 90% express their trust in the AMP and are ready to recommend it to their colleagues. Almost 90% of pharmacists expressed confidence in the AMP, 80% considered it successful, and more than 70% considered their experience using the AMP positive.

	■ Definitely do not trust		Rather do not trust	Sometimes do not trust, some	times trust
	■ Rather trust		Definitely trust	■ Difficult to answer	
60+	4 6	16	32	34	8
50-59	3 7	13	42	33	3
40-49	<mark>2</mark> 5	18	42	31	3
30-39	5	14	53	27	
Women	<mark>з</mark> 6	16	38	33	5
Men	3 6	14	39	31	6
Total	3 6	15	38	33	5

Figure 9. Distribution of patients response: How much do you trust the "Affordable medicines" program?(%)

The AMP increases access to medicines and reduces costs. About two-thirds of patients and 80% of doctors and pharmacists say the AMP improves access to medicines. Patients find the AMP clear, easy to use, efficient, and effective. More than 80% of patients appreciated the convenience of receiving a prescription from a doctor through the program. Further, almost 80% of the AMP users reported that pharmacies have the required medicines available almost always or most of the time. In terms of personal experience, overall, almost 80% of program users said that they had experienced a reduction in treatment costs when using the AMP.

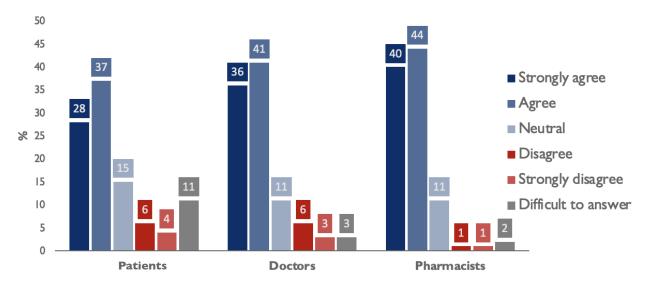


Figure 10. Distribution of responses to the question 'In your opinion, has the AMP generally improved patients' access to medicines?'(%)

Patients are generally satisfied with the medication list, but doctors and pharmacists see opportunities for expansion: Almost 80% of patients are satisfied with the list of medicines available under the AMP. Doctors are less enthusiastic about the list of medicines, with 40% rating it as good and 60% recommending expansion, as compared to pharmacists where 60% rate it as good and 40% recommending expansion.

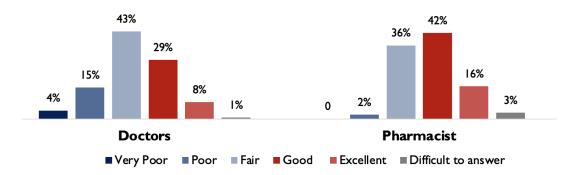


Figure 10. Distribution of responses to the question 'In your opinion, has the AMP generally improved patients' access to medicines?'(%)

Patients consider cost and quality when choosing medicines. In general, the determining factor in choosing medicines for patients is perceived quality, and somewhat less so is the possibility of getting them free of charge. In general, only 20% of respondents receive medicines entirely free of charge. Most patients know that prescribed medicines have free alternatives but try to choose a more expensive and perceived better-quality medicine.



Doctors and physicians support patients, yet some patients still do not fill their prescriptions: A quarter of patients said that they had situations when they did not use the AMP to fill a prescription, despite medication eligibility. The most common reasons are that the patient forgets to use the prescription within the specified period, cannot do so for personal reasons, or cannot buy the full course of the drug.



The AMP helps doctors provide targeted care. Doctors state that the health of patients using the Program has improved and that the systematic prescription of medicines allows them to monitor the patient's medication intake, to see unfulfilled prescriptions, to communicate with the patient, and to select the right medication for the patient.

CONCLUSION AND WAY FORWARD

SAFEMed provided strong technical assistance to the GOU throughout the reform process, in particular improving patient access to safe and effective medicines and supporting the reform of primary care financing, public health, and integration of components of the electronic health care system.

Moving forward, SAFEMed will continue to support the NHSU in the following ways:

- Monitoring program performance via internal KPIs;
- Supporting the NHSU in the expansion of the AMP with inclusion of new products and expanding geographical access via mobile pharmacies;
- Strengthening the quality of services by training doctors who are prescribing through the program via online modules;
- Targeted training for users and NHSU specialists to increase utilization of the AMP modules;
- Strengthening electronic services through automation of NHSU business procedures, including contract management with health facilities, budget and document management, and other processes.

¹https://iris.who.int/bitstream/handle/10665/311654/9789289054058-eng.pdf

"(https://edata.e-health.gov.ua/e-data/dashboard/pharmacy-pay).

"As the ePrescription was launched in 2019, the statistics here depict eHealth official data from 2019. Baseline data here is according to the MOH data, based on the paper-based prescription reports.

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