

EVALUATION OF THE AFFORDABLE MEDICINES PROGRAMME IN UKRAINE



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Abstract

This report reviews and analyses the Affordable Medicines Programme, which was introduced in Ukraine in April 2017 to provide patients with improved access to 23 outpatient medicines for the treatment of chronic noncommunicable diseases. The evaluation combines both quantitative and qualitative analysis. The findings confirm that the Programme has contributed to a significant increase in access to needed outpatient medicines in Ukraine. Further, while implementation was successful overall, uptake across regions was uneven. The report concludes by listing a number of policy options to support the sustainability and expansion of the Affordable Medicines Programme.

Keywords

UNIVERSAL HEALTH COVERAGE
AFFORDABLE MEDICINES
UKRAINE
ACCESS TO OUTPATIENT MEDICINES
FINANCIAL PROTECTION

ISBN 978 92 890 5400 3

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Abbreviations

AMP	Affordable Medicines Programme
ATC	Anatomical Therapeutic Chemical [classification]
EML	essential medicines list
INN	international nonproprietary name
NHSU	National Health Service of Ukraine
SAFEMed	Safe, Affordable, and Effective Medicines for Ukrainians
USAID	United States Agency for International Development

Acknowledgments

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The authors are also very grateful to the Ministry of Health of Ukraine (including Deputy Minister of Health Roman Illyk and Mariana Hladkevych, Head of the Policy Coordination Expert Group for Strategic Planning and European Integration) and to the United States Agency for International Development project Safe, Affordable, and Effective Medicines for Ukrainians (Ivan Loboda, Senior Technical Advisor on Pharmaceutical Finance) for their significant support and contribution to this work.

Warm thanks are also extended to Ihor Perehinets, WHO Regional Office for Europe Division of Health Systems and Public Health, and Sarah Thomson, WHO Barcelona Office for Health Systems Strengthening, for reviewing the report and providing valuable comments; Proxima Research for the fruitful collaboration on data analysis; and Marthe Everard, Oleksandr Martynenko and Svitlana Pakhnutova of the WHO Country Office in Ukraine for their continued assistance and support throughout the project.

The development, editing and printing of this report was done in the context of the Biennial Collaborative Agreement 2018–2019 between the Ministry of Health of Ukraine and the WHO Regional Office for Europe and was funded through a grant of the Government of Japan to support progress towards universal health coverage.



1 Introduction

1.1 The health care sector in Ukraine

A 2018 WHO publication (Goroshko, Shapoval & Lai, 2018) showed that public spending on health as a share of gross domestic product has been consistently low in Ukraine in recent years (at 2.9% in 2015), well below the average for countries in the WHO European Region (5%) and the European Union (6%). As a consequence, out-of-pocket payments have grown as a share of total spending on health, reaching 48% in 2015, which is among the highest in the European Region. This means that Ukrainian citizens currently pay twice for their health care: via their taxes and when accessing services.

To address this issue, the country is implementing profound reforms to the health system, as set out in the Law on State Financial Guarantees of Health Care Services to the Population, approved by the Parliament in 2017. The reforms aim to move Ukraine towards universal health coverage. More specifically, the following measures are being developed and enforced.

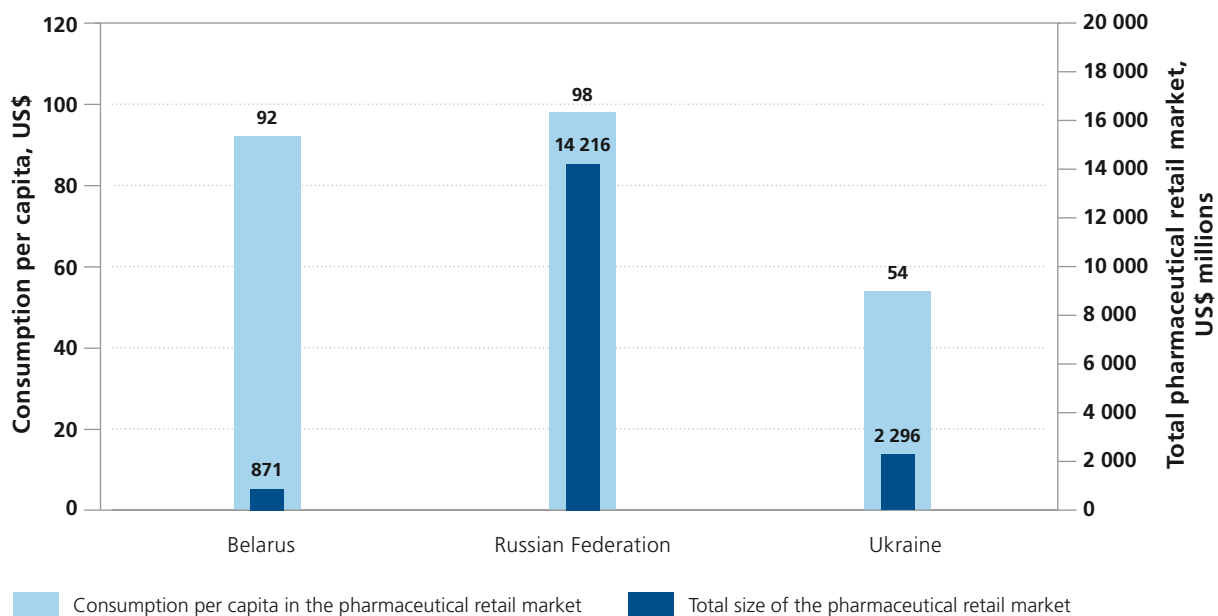
- A government-guaranteed health care benefits package is being introduced. This will cover all Ukrainian citizens and will include primary care, emergency care, key types of outpatient services, inpatient care and outpatient medicines.
- A single national health care purchaser is being established. This institution, the National Health Service of Ukraine (NHSU), will be a central executive body acting on behalf of patients, purchasing medical services within the government-guaranteed health care benefits package via funds accumulated into a single national pool, based on defined tariffs and quality requirements.
- Opportunities for local authorities to design and deliver health care initiatives are being developed. For instance, they will be able to use local budgets to cover additional health care services for communities that may not be included in the central government-guaranteed health care package.
- The autonomy of and payment methods for health care providers are being reformed. A shift towards the principle that “the money follows the patient” will lead to a transition to payments being made to health care providers based on services provided.
- Finally, a modern system of health information management is in development. Availability and accessibility of data on medical and economic parameters of health service provision at all levels are mandatory for the introduction of a strategic medical services purchasing system. Such data are needed for financial planning, contract development and performance monitoring.

The new model will be established in separate stages, with full implementation expected by 2020. In this context, the Affordable Medicines Programme (AMP) was designed and put into force in April 2017.

1.2 The Ukrainian pharmaceutical sector

Total pharmaceutical expenditure in Ukraine was 70 billion hryvnya (around 2 billion euros) in 2017. The market that year represented 1.2 billion packages (of which 91% were consumed in the outpatient sector). As shown in Fig. 1, consumption of medicines per capita in Ukraine is half that in Belarus and the Russian Federation.

Fig. 1 | Consumption per capita in the retail market and size of the retail market in Belarus, the Russian Federation and Ukraine, 2017



Source: data provided by Proxima Research.

One noticeable feature of the Ukrainian pharmaceutical sector is the significance of domestic production. National manufacturers represent around 70% of the market in volume and almost 40% in value. The market is also dominated (in both volume and value) by generic medicines, with traditional medicines making up a significant proportion.¹

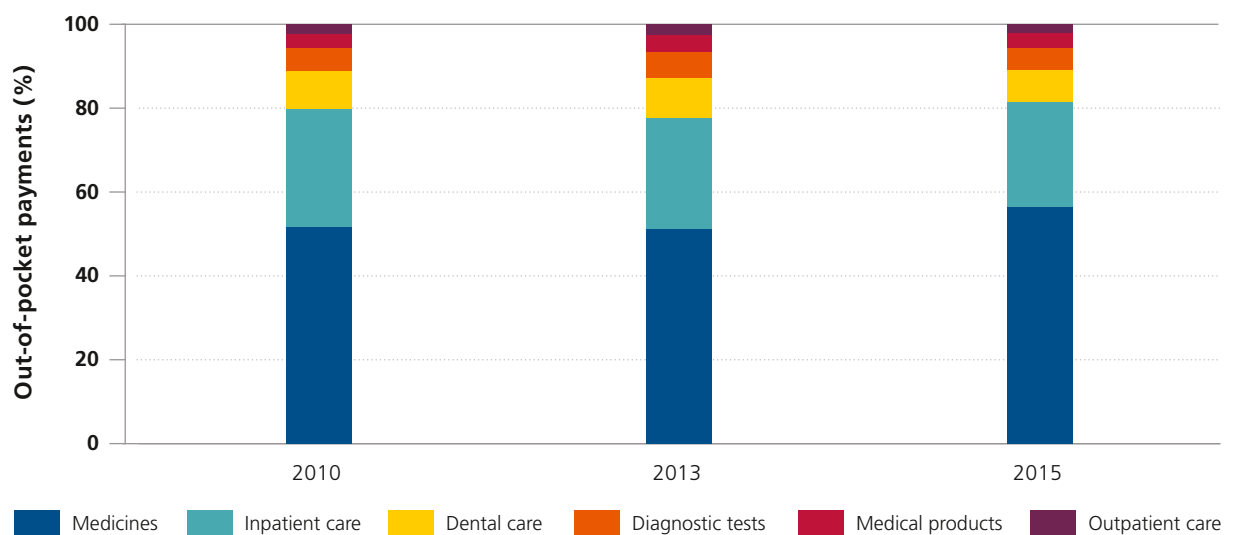
1.3 Access to outpatient medicines in Ukraine

Until the implementation of the AMP no system was in place for public reimbursement of prescription medicines in the outpatient sector in Ukraine. In 2012/2013 the Ministry of Health introduced a pilot scheme to reimburse antihypertensive medicines, but this pilot was not continued once its funds were exhausted. As a consequence, most outpatient medicines have not been publicly subsidized, and the

¹ Conventional nonbiological medicinal products; information provided by Proxima Research.

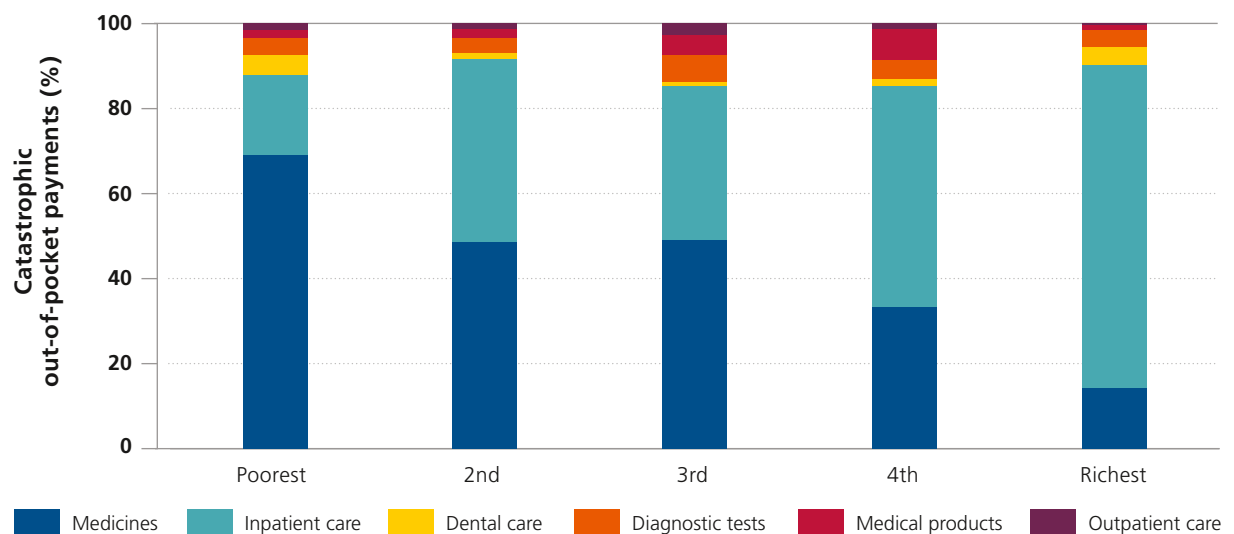
proportion of households reporting unmet need for medicines is very high. It has more than doubled over time, rising from 11.4% in 2010 to 25.4% in 2015, and is much higher among the poorest quintiles (around 30%) than among the richest quintile (around 17%) (Goroshko, Shapoval & Lai, 2018). Outpatient medicines are the largest cause of out-of-pocket payments in health care. Survey data show that spending on medicines accounts for over half of total household spending on health, rising from 51.7% in 2010 to 56.5% in 2015 (Fig. 2). Among the poorest quintile, it accounts for over 70% of household spending on health. Spending on medicines is also the main driver of financial hardship for Ukrainian citizens, representing 46% of out-of-pocket payments among all households with catastrophic health spending in 2010 and 2015, and 69% among households in the poorest quintile (Fig. 3). In 2015, 14.5% of households in Ukraine experienced catastrophic spending on health (Goroshko, Shapoval & Lai, 2018).

Fig. 2 | Breakdown of total out-of-pocket spending by type of health care in Ukraine



Source: Goroshko, Shapoval & Lai, 2018.

Fig. 3 | Breakdown of out-of-pocket payments among households with catastrophic health spending in Ukraine, by consumption quintile, 2015



Source: Goroshko, Shapoval & Lai, 2018.

1.4 The AMP

One key component of the reform of the health care system is the design and implementation (since April 2017) of the AMP. This introduced public coverage for some outpatient medicines for patients diagnosed with cardiovascular diseases, type 2 diabetes or bronchial asthma. As of September 2018, a total of 23 international nonproprietary names (INNs) are part of the scheme (see Annex 1 for a detailed list).

The current system is organized as follows: the patient receives a prescription for a medicine included in the reimbursement scheme in which the INN (active substance) is indicated, visits a pharmacy participating in the AMP (i.e. contracted to the local health authorities) and receives the prescribed medicine either free of charge or with a co-payment (if the medicine's price is above the defined reimbursement tariff – see below). The pharmacy submits the receipt to the health authorities for reimbursement.

Calculation of the reimbursement reference tariff and inclusion in the scheme follows a defined procedure.

- For the 23 INNS included in the AMP, median of the registered prices (per defined daily dose) are collected in five reference countries (Czechia, Hungary, Latvia, Poland and Slovakia) and used to define a median reference price for each INN. Brand-name generics² priced at the reference price or lower are included in the reimbursement programme; this means that all brand-name generics priced above the reference price will not be reimbursed.
- For each reimbursed INN, the cheapest brand-name generic price identified becomes the reimbursement reference tariff (once regulated retail margins and value added tax are added³).
- When the reimbursement reference tariff is defined, companies included in the reimbursement scheme are given a five-day window to perform a “reverse auction” in order to have their brand-name generic fully reimbursed as well.
- All brand-name generics priced below the reimbursement price – but above the reimbursement reference tariff – are reimbursed, but the patient has to co-pay the difference with the reimbursement reference tariff.

According to the Ministry of Health, five cornerstones shaped the design of the AMP:

- voluntary participation by pharmacies and manufacturers;
- high quality and efficiency of all medicines included;
- prescriptions fulfilled on the basis of the INN;
- 100% reimbursement granted for the cheapest products (manufacturers of which have reduced the prices for such medicines to participate in the AMP);
- inclusion of medicines at the primary care level.

² In this report a “brand-name generic” is one version of an off-patent molecule marketed in Ukraine; each manufacturer produces one different brand-name generic with its own packaging, commercial name and so on.

³ In Ukraine the margins of the distribution chain are also regulated:

- for medicines on the national essential medicines list a 10% wholesale mark-up and 25% retail mark-up apply;
- for medicines included in the AMP a 10% wholesale mark-up and 15% retail mark-up apply;
- for all other medicines which are procured from the budget funds, a 10% wholesale mark-up and 10% retail mark-up apply.

1.5 Evaluation of the AMP

In a letter of 3 April 2018, the Ukrainian authorities requested WHO's support in analysis and evaluation of the AMP. They identified three main challenges. First, uneven uptake of the scheme was reported across regions (oblasts) of the country. In some oblasts the programme seemed to not be fully operative, impairing access and undermining equity. Second, political will to upscale the AMP to include more medicines, covering other therapeutic areas than the initial three identified, was strong. Finally, questions were raised about how to ensure that the current programme will transition smoothly from a standalone project to become a pillar of the new government-guaranteed health care benefits package under the NHSU (see section 1.1).

For all these elements, the authorities wanted to benefit from an independent external evaluation of the AMP to support and enlighten their decisions. The objectives of the evaluation defined by WHO in consultation with the authorities were therefore:

- to assess whether the AMP had succeeded in fulfilling its objective to provide more patients with affordable medicines for selected chronic diseases (cardiovascular diseases, type 2 diabetes and bronchial asthma), irrespective of their place of residence, age or previous reimbursement eligibility (for example, as a war veteran);
- to confirm or deny possible uneven uptake of the programme across oblasts and – depending on the findings and data gathered – discuss possible explanatory factors;
- to provide advice to national authorities on how to develop the AMP further and ensure its sustainability and smooth transfer under the NHSU.

The AMP was evaluated based on a factual analysis of its functioning since its creation in April 2017 (from both quantitative and qualitative standpoints). This evaluation report is structured as follows:

- section 2 details the materials and methods used to conduct the quantitative and qualitative analysis;
- section 3 describes and analyses the main features of the AMP;
- section 4 presents the result of the analysis across oblasts and the variations that were unveiled;
- section 5 illustrates the impact of the AMP on the structure of the pharmaceutical market, for both medicines included in the programme and beyond;
- section 6 analyses the impact of the AMP on patient co-payments;
- section 7 is a synthesis of the main findings of the appraisal;
- section 8 presents the suggested policy options identified to address the challenges discovered through the appraisal.



2 Methods

WHO engaged a team of international and national experts to undertake the evaluation. The United States Agency for International Development (USAID) project Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) and the Ministry of Health of Ukraine provided significant technical support and shared an important proportion of the quantitative and qualitative information necessary for preparation of the evaluation.

Since no adequate formal procedure for evaluation of such a public policy intervention was found,⁴ the team developed a context-relevant analytical framework that relied on a combination of quantitative and qualitative analysis. Four specific components were appraised: efficiency of the AMP (organizational aspects), access to medicines (availability and affordability), acceptance of the system and perceived quality and outcomes (see Annex 2).

Data collection took place between April and September 2018; analysis and reporting in September and October 2018. The data collection included the following activities:

- collection (including translation) of material (literature and legal documents) addressing the AMP and the national pharmaceutical market;
- a preliminary fact-finding field visit by WHO experts in June 2018 to initiate data collection and hold preliminary discussions with central authorities, decision-makers and other relevant stakeholders;
- collection and analysis of quantitative data on the pharmaceutical sector in Ukraine and on the medicines covered by the AMP from data provided by the Ministry of Health and a private company specializing in intelligence collection on the national pharmaceutical sector (Proxima Research⁵);
- structured interviews, conducted between July and September 2018, using an interview guide (see Annex 3) developed by the team of experts, of local and national stakeholders involved in the

⁴ A query sent to competent authorities of pricing and reimbursement policies in 46 countries (members of the Pharmaceutical Pricing and Reimbursement Information Network) in May 2018 did not yield suitable evaluation frameworks for reimbursement policies; nor did a review of the scientific literature.

⁵ The company was selected because of its longstanding collaboration with the national authorities.

AMP, representing all perspectives of the policy framework – policy-makers, prescribers, patients and pharmacists – and covering the following cities and oblasts:

- Kharkiv city and oblast;
- Lviv city and oblast;
- Odesa city and oblast;
- Ivano-Frankivsk city and oblast;
- Vinnytsia city and oblast;
- Kherson city and oblast;
- Dnipro city and oblast.

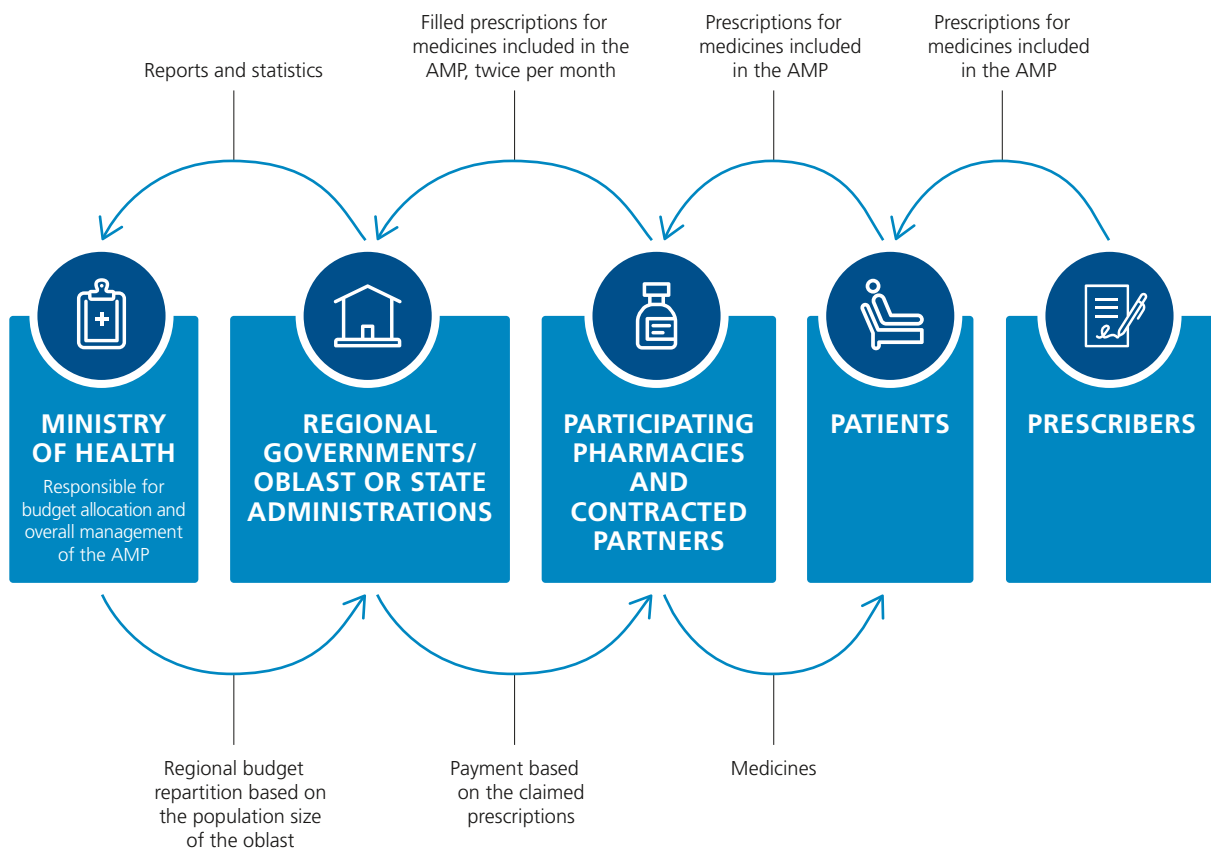
The choice of oblasts for interview settings was made in consultation with national authorities to ensure a balanced representation of rural and urban areas, as well as different levels of economic development. Another important element was to include oblasts adjacent to European Union countries, where it is reported that patients regularly cross the border to buy medicines because they are said to be cheaper than in Ukraine. Finally, mountainous oblasts where access to health care is reported generally to be more difficult were also included. Participation in the interviews was voluntary and all necessary precautions for protection of sources and anonymization of data were taken.

3

Results of the evaluation of the AMP

This section describes and analyses all the different features of the AMP, based on the four components of the evaluation framework. The current organization is described in section 1.4 above and summarized in Fig. 4.

Fig. 4 | Flowchart of the organization of the AMP



3.1 Budget allocation and organization at the oblast level

The state budget allocated to the AMP in 2017 was 700 million hryvnya (21.8 million euros); this was increased to 1 billion hryvnya (31 million euros) in 2018. The total budget was set by a political decision.

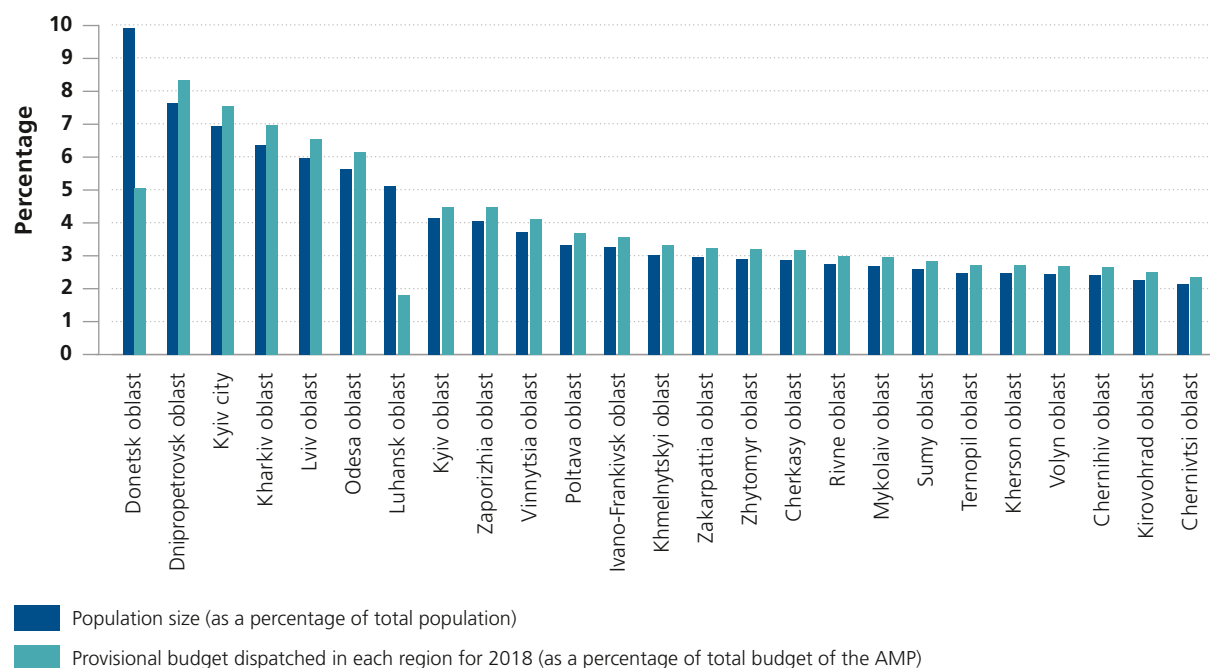
The State Treasury divides the fund into regional budgets based on population size and distributes one twelfth of the budget each month to the oblast health authorities. Within oblasts, health authorities dispatch funds to contracted pharmacies based on the prescriptions claimed. Pharmacists send bills twice a month to the responsible regional health authorities (depending on local agreements). Fig. 5 compares the regional repartition of the AMP budget to the population size of the oblast in 2018 (provisional).

Regional health authorities then further divide the budget by district. The flow of money into the AMP seems to work well, compared to previous pilots. In interviews it was stated that, from the experience of the participating pharmacies, reimbursement from local health authorities to pharmacies is executed on time, with no major complaints reported.

Nevertheless, some issues exist. Due to budget processing issues from one fiscal year to the next, breaks in reimbursement were reported in December 2017 and January 2018. This was confirmed in the interviews – notably in Lviv oblast and Dnipro city. Some problems were also reported in summer 2018, probably related to the changing of the legislation transforming the status and autonomy of public noncommercial medical institutions. Such elements are not surprising, considering that the AMP was introduced very recently on a large scale and needs some fine tuning.

In addition, due to the rapid development of the AMP, a few areas (including Lviv oblast and Odesa city) expressed their concern that funds might not be enough to cover the needs for the entire year

Fig. 5 | Budget repartition across oblasts



Note: The discrepancies between the population size and the budget allocated for Donetsk and Luhansk oblasts relate to the fact that the central government provided a budget to these only for the proportion of the population under its direct authority.

Source: data provided by the Ministry of Health; analysis undertaken by the authors.

2018. For instance, in Odesa city debts to pharmacies totalled 3 176 400 hryvnya (98 000 euros) on 13 July 2018, of which 1 437 000 hryvnya (44 900 euros) was redeemed from the budget of November–December 2018.

Further, a few stakeholders reported difficulties in 2017 in the initial phase of the AMP: for example, some of the rules were not very clear for the parties involved and shortages of the medicines selected for reimbursement occurred. According to the Ministry of Health, such hurdles were expected at the beginning of a project of such large dimensions.

Regarding management of the AMP at the regional level, data on dedicated resources (such as human resources responsible for its functioning) were not available. It was reported that the local authorities in each oblast use different approaches to steer the AMP. For instance, Skype conferences with all administrative units involved are organized in Lviv oblast every month to discuss topics such as uptake of the scheme or availability of financial resources and medicines in regional wholesalers and pharmacies. In Chernomorsk (Odesa oblast) every prescription redeemed in pharmacies is checked by the regional health authority. Such control can be provided because of the small number of pharmacies that participate in the programme. In Odesa city the number of patients complying with treatment under the AMP is constantly monitored, and prescribers have a well established communication channel with the regional administration and pharmacies regarding availability of funds and medicines (via a group on a mobile message platform). Communication between participants is also effectively organized in Kharkiv oblast, since they provide daily statistical reports about fulfilment of the AMP. Finally, in Lviv oblast average regional performance indicators of the programme and rankings of districts are used to monitor progresses. It was mentioned that in Kharkiv oblast local television and media were used to inform the public about the AMP, which seems to have had a positive effect and helped with initiation.

Regional authorities have set up many local initiatives to ensure good steering and monitoring of the AMP; however, systematic controls in all oblasts are lacking, which may make miscarriage of the funds possible. Switching from paper-based to electronic prescriptions (currently being piloted) will help to improve the situation, according to the Ministry of Health. This will help to optimize the programme's costs, but it should not be forgotten that the limited Internet coverage in mountainous areas (such as Lviv oblast) may be a limiting factor for both local family doctors and patients. Representatives of pharmacies and national pharmaceutical manufacturers also described the introduction of the electronic prescription system as a necessary step to ensure long-term sustainability.

It appears that providing opportunities for exchange of experience and practices across different oblasts would be a promising approach. Furthermore, regional authorities mentioned that it would be beneficial to organize conferences with the participation not only of representatives from health care departments but also of mayors of cities and governors of oblasts to discuss and develop common approaches for improvement of the AMP.

All representatives of authorities (regional administrations, the Ministry of Health and so on) interviewed pointed out that the AMP is extremely necessary and useful for the population. Termination of the programme would cause social disturbances and would harm the positive indicators and treatment compliance obtained so far. In Odesa city the mayor personally patronizes the AMP; in Kherson oblast it was mentioned that, thanks to the AMP, treatment can be provided for the poorest parts of society. According to the Ministry of Health, the AMP has already achieved very positive results, since it represents a first attempt at price regulation in the country; this has had an influence on the market. It also shows the strong commitment of the authorities to reforming the health care sector and their ability to handle pressure.

3.2 Selection of medicines included in the AMP

A new national essential medicines list (EML) was adopted by the Government of Ukraine in March 2017. Its objective is to list a limited number of selected medicines eligible for public procurement and reimbursement. The national EML is therefore the basis of all other medicines lists used in the country, including the AMP reimbursement list.

To develop the national EML, a committee was established in July 2016, composed of 17 members (with reported management of conflict of interests). The secretariat of the EML committee consists of three staff based at the State Expert Centre, and members are appointed by ministerial order for a period of four years. The committee acts as an advisory body to the Ministry of Health and meets at least once a month, publishing outcomes of decisions on the Internet. Its main role is to advise the Ministry on listing or delisting medicines from the national EML, which has been developed based on the WHO EML (WHO, 2018a) and adapted to local needs (427 INNs are currently on the list). The committee is currently assessing additional dossiers submitted by industrials (50 dossiers under evaluation).

The State Expert Centre proposed the three therapeutic areas (cardiovascular diseases, type 2 diabetes and bronchial asthma) and respective INNs to be included when the AMP was launched; this decision was endorsed by the Ministry of Health. The three groups of pathologies were prioritized because of their burden of disease, their prevalence and the availability of effective and cost-effective treatments.

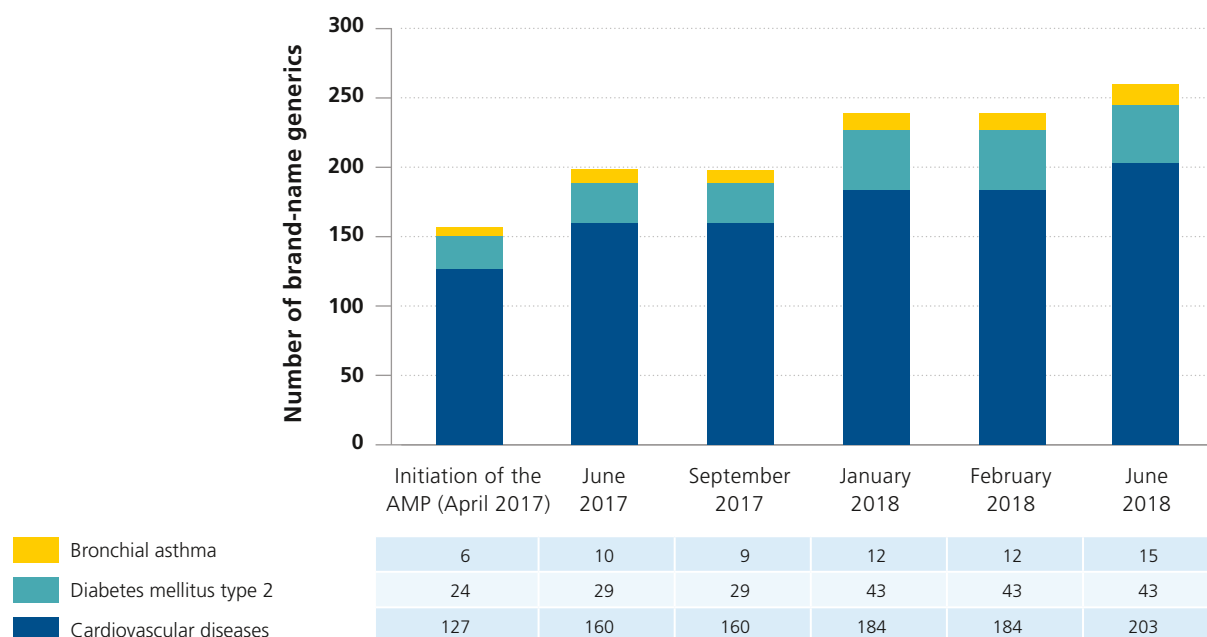
Some stakeholders, however, were critical that the decision-making process was not performed in a transparent way and was not communicated to them (prescribers and regional health authorities, for instance). This fostered some resentment towards the AMP and the directions taken. During the evaluation, the link between the AMP and the newly established EML committee could not be clearly stated; nor was any formalized process to decide whether and how to enlarge the therapeutic areas covered by the programme reported. Prescribers expressed their wish to be involved, informed and trained.

As noted above, to be included in the reimbursement programme, molecules need to be listed on the EML. At the inception of the AMP in April 2017, 21 molecules were selected to provide treatment to patients suffering from cardiovascular diseases, type 2 diabetes and bronchial asthma. Insulins, though, are not part of the AMP (they are dispensed through a separate programme). The number of INNs included in the AMP rose to 23 at the end of 2017.

Market forces certainly contributed to the initial uptake of the AMP, but it was reported that programme managers at the regional level also played an important role in motivating local and foreign pharmaceutical companies to take part. At its inception, the number of different brand names included in the scheme was 157; this rose by 66% in August 2018 to 261 (Fig. 6). The important number of suppliers helped to ensure an effective supply of the selected molecules, despite some shortages reported by local stakeholders (in Lviv and Kharkiv oblasts, among others). As a result, in most cases the brand-name generics included account for a significant proportion of medicine consumption in the corresponding therapeutic classes, especially by volume (as shown in Table 1).

3.3 Pricing mechanisms for the medicines included in the AMP

Affordability of the products included in the AMP is essential for its success. The tariff calculation is described in section 1.4. Data analysis suggests that the prices of the products reimbursed have decreased since the introduction of the programme (see section 5.2 for more detailed analysis).

Fig. 6 | Total number of brand-name generics included in the AMP

Note: data provided by Proxima Research; analysis undertaken by the authors.

Table 1 | Brand names included in the AMP as a proportion of total sales (June 2018)

Anatomical Therapeutic Chemical (ATC) group (level 2) ⁶	Volume (%)	Value (%)
C08 – Calcium channel blockers	64	27
C03 – Diuretic drugs	55	22
C07 – Beta-blocking agents	52	29
A10 – Drugs used in diabetes	48	19
C10 – Lipid-modifying agents	32	19
C09 – Agents acting on the renin-angiotensin system	29	7
R03 – Drugs for obstructive airway diseases	29	24
B01 – Antithrombotic agents	22	16
C01 – Cardiac therapy	5	3
Antihypertensive drugs (C03 + C07 + C08 + C09)	41	15
Cardiovascular drugs (C01 + C03 + C07 + C08 + C09 + C10)	26	12

Note: The analysis excludes the ATC code R01, for which the drug included in the AMP (budesonide, a corticosteroid used in asthma) accounts for a very small percentage of the entire class, encompassing frequent other indications.

Source: data provided by Proxima Research; analysis undertaken by the authors.

The pricing mechanism was criticized by pharmaceutical manufacturers, however, who expressed concern that the system relies on the calculation of a price per defined daily dose (which in most cases

⁶ The analysis used ATC classifications – an internationally accepted system for medicines maintained by WHO. WHO assigns ATC codes to all active substances contained in medicines, based on the therapeutic indication for the medicine (WHO, 2018b).

excludes combination drugs from eligibility for inclusion in the reimbursement list). They suggested that an approach that would open the door for the inclusion of combination therapies as part of the AMP would be preferable.

Manufacturers also felt that the biannual price revision should also be handled in a way that allows them to manage their stocks better (in other words, there should be a washout period, allowing stocks to be finished before prices are changed and products are taken out of the reimbursement scheme).

Representatives of the pharmaceutical industry also spoke of their frustration with some recent practices from competitor companies that proposed the lowest price (and were therefore granted full reimbursement status) but were not able to supply sufficient quantities to the market, leading to potential shortages. The manufacturers called for enforcement of sanctions in such cases, and suggested amendments to the national antitrust legislation to prevent such practices. A possible explanation of the reported shortages could be that volume estimations by companies were too low at the beginning and that the actual uptake of the AMP was quicker than expected, however.

Finally, it was mentioned that inclusion in the AMP did not necessarily always push manufacturers to reduce the prices of their products. Some were already at the level defined after tariff calculation by the authorities.

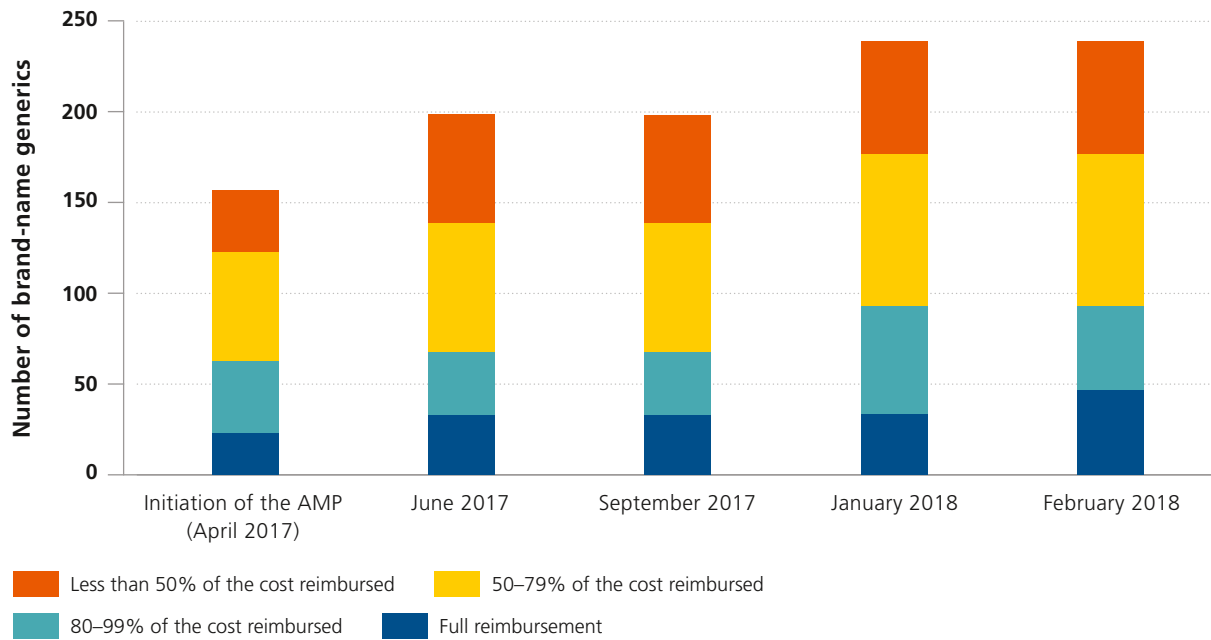
3.4 Level of coverage provided by the AMP

As noted above, brand-name generics priced up to the reference price are fully reimbursed, while for higher-priced products patients need to co-pay the difference between the reference price and the actual price of the brand-name generic. The proportion of fully reimbursed brand-name generics in the AMP has slightly increased since implementation. Around 20% of the total number of brand-name generics included is currently dispensed without any patient co-payments. For another 20% of the medicines dispensed, co-payments are less than 20% of the price of the medicine (Figs. 7 and 8). Such findings suggest that the pricing mechanism in place is functioning and that manufacturers have agreed to participate in the AMP, thereby making medicines more affordable for patients.

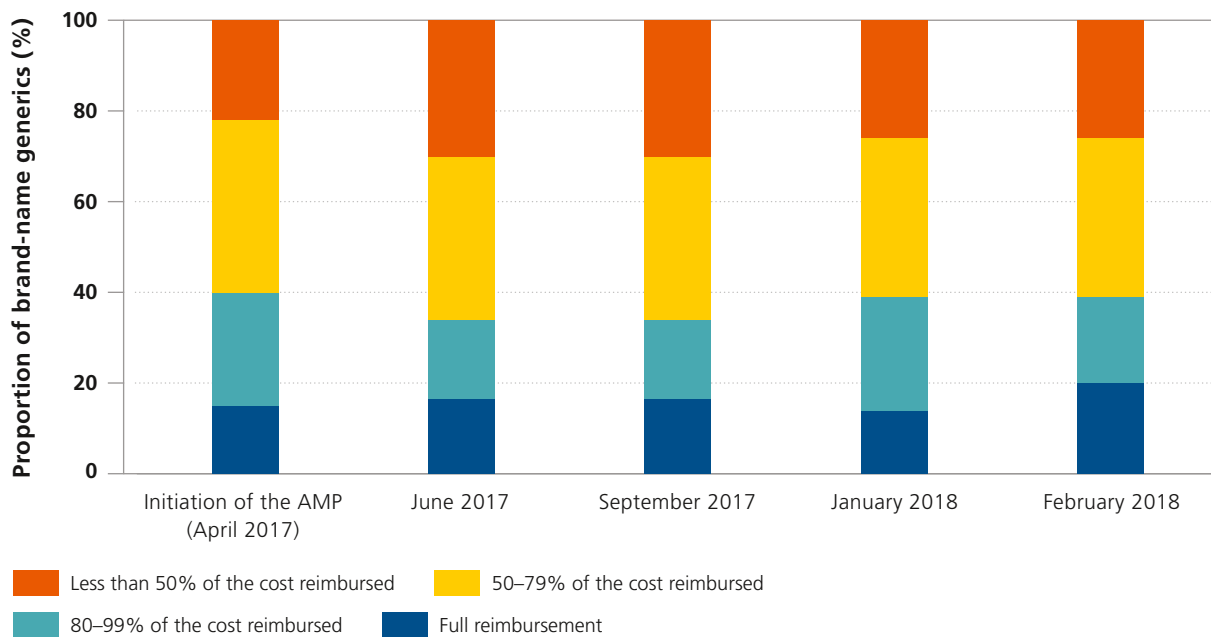
Coverage of the programme is also noticeable when looking at its weight in the national pharmaceutical market. Although the share of the AMP is modest as a percentage of the total national market (1 billion hryvnya of a total market of 70 billion: 1.3%), a different picture emerges when examining the specific therapeutic areas that have been prioritized. In most cases, the brand-name generics included account for a significant proportion of drug consumption in the corresponding therapeutic classes, more particularly in volume (see Table 1 in section 3.2). For instance, the brand names included in the AMP represent 41% of the total antihypertensive drugs consumed in Ukraine, 29% of drugs for obstructive airway diseases and 48% of the drugs used in diabetes.

3.5 Prescribers and patients

To obtain medicines through the AMP patients need to receive a prescription form from their doctor. The system is currently paper-based.

Fig. 7 | Breakdown of reimbursement rates for brand-name generics included in the AMP (absolute numbers)

Source: data provided by Proxima Research; analysis undertaken by the authors.

Fig. 8 | Breakdown of reimbursement rates for brand-name generics included in the AMP (proportions)

Source: data provided by Proxima Research; analysis undertaken by the authors.

In general, prescribers reported being satisfied with the AMP as it provides increased access to medicines. They stated that for many patients the programme was their only chance to receive treatment; is therefore particularly needed for vulnerable groups. They observed an increasing number of patients being treated, as well as increased loyalty and adherence to treatment. Overall, from the perspective of the prescribers the system works and has already achieved tangible impacts.

One important feature of the AMP they highlighted was that it is universal by nature. Before, only specific categories of the population could receive treatment at a discounted price (war veterans, for instance). Now, the entire population is covered; this is seen as a positive step. The system also changed their prescribing patterns for reimbursed products (see section 5.3). Finally, some prescribers reported that a significant number of patients new to treatment had come to their practices since the initiation of the AMP; this may imply that the patients were previously foregoing treatment for financial reasons.

The situation concerning the profiles of prescribers across oblasts seems to vary. In some areas only family doctors (no specialists) prescribe medicines included in the AMP (including Lviv oblast), whereas in some oblasts specialists can also prescribe these (such as Odesa oblast). In Kharkiv oblast, since January 2018 feldschers⁷ can also prescribe medicines included in the AMP. Feldschers of health care establishments, irrespective of their forms of ownership and subordination, have the right to prescribe medicines for patients with lingering and chronic illnesses in case of the attending physician continues the treatment.

Some issues and suggestions for improvement of the current prescription arrangements were mentioned during the interviews.

- In Lviv and Odesa oblasts representatives of the prescribers highlighted the necessity of extending the list of medicines covered.
- In Kherson oblast it was stressed that prescriptions should only be issued by family doctors and not specialists, since only the former have full information about the patient; further, the AMP is meant to be oriented to the primary care level.

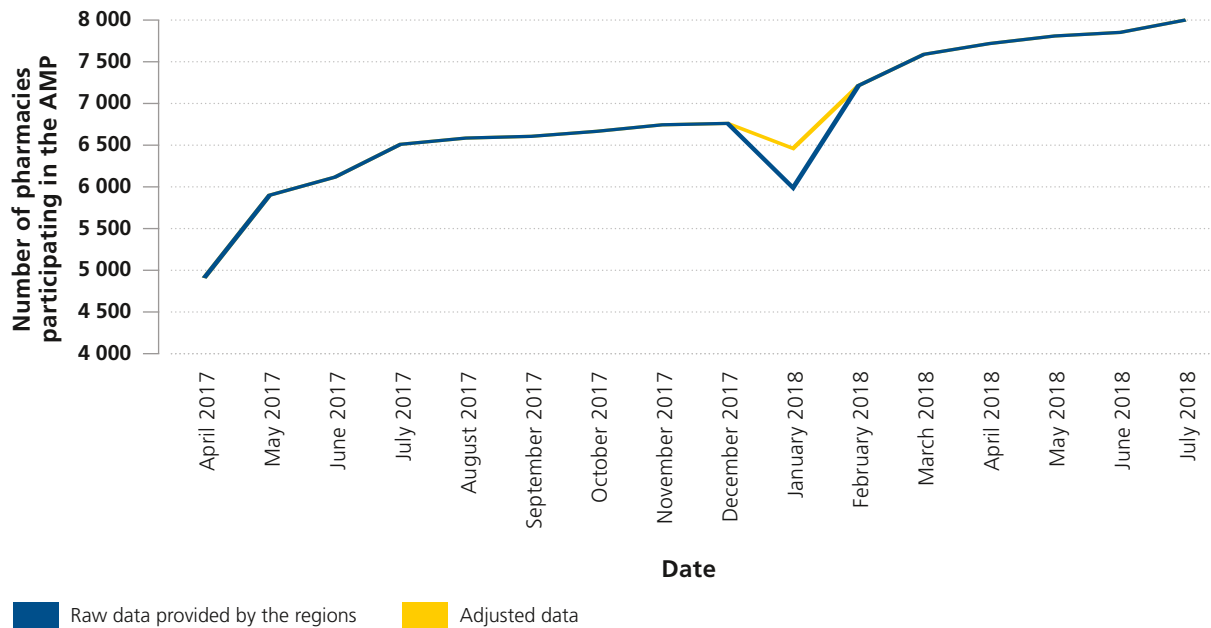
In Ukraine it is mandatory to prescribe by INN, but a lack of trust in generics among prescribers and patients and a lack of information about the efficacy of national generic products were reported in interviews. Representatives of international pharmaceutical manufacturers also expressed their concern about the appraisal of bioequivalence of generics by the health authorities. In their opinion, too many poor-quality generics are available on the Ukrainian market. This question is critical for the success of the AMP and the authorities reported that an analysis of the situation and legal acts is under way (with the technical support of USAID project SAFEMed), to improve the requirements for products placed on the market.

Patients reported that the AMP is particularly important for vulnerable groups and that many of them had never received treatment before. According to their perception, many people in their circle of acquaintance are involved in the programme. In some regions (including Odesa and Kharkiv oblasts) patients are afraid that the AMP could be stopped because of lack of funds, while in Kherson oblast patients mentioned that it helps them to receive treatment: prior to the programme they did not apply for treatment because they did not want to take the money away from the family budget. Finally, patients did not express any specific complaints regarding the availability of medicines included in the AMP (except that it sometimes seems necessary to wait one day).

3.6 Dispensing at the pharmacy level

As of July 2018, 8000 pharmacies participated in the AMP: 40% of the pharmacies operating in Ukraine. The number of pharmacies enrolled has steadily increased since April 2017 (from 4900 to 8000, an increase of 63%) (Fig. 9).

⁷ A health professional with a secondary special medical education who has the right to diagnose, conduct self-treatment or refer the patient to a specialist doctor.

Fig. 9 | Total number of pharmacies participating in the AMP

Note: For two regions the figure was 0 in January 2018. In the adjusted data this figure has been replaced by the average number of pharmacies in December 2017 and February 2018.

Source: data provided by the Ministry of Health; analysis undertaken by the authors.

Pharmacies participate on a voluntary basis, forming agreements with the regional state administrations. Each participating pharmacy uses the sign below (Fig. 10) to notify consumers of their involvement in the scheme.

Fig. 10 | Sign displayed in participating pharmacies

Source: Ministry of Health.

As shown in Fig. 9 the total number of participating pharmacies increased almost continuously between 2017 and 2018, but with important interregional variations. Some districts faced high dropout rates (of 10% in Pustomyty district in Lviv oblast, for instance), but others saw high increases in enrolment (a rise of 180% in Zhovkva district in Lviv oblast). Also, in some districts (including Verkniorogachyn, Velykolepetyvsk and Ivankiv in Kherson oblast), only one pharmacy participates in the AMP. Reasons for these developments are diverse. The voluntary nature of participation is perceived as a risk in the programme's organization and a possible explanatory factor of the uneven uptake between oblasts (see section 3.7). Given the difficulty at initiation of the AMP (which was due to be launched in January 2017 but postponed to April 2017 to ensure all necessary systems were in place) and negative experiences of pharmacies with previous pilots, however, the voluntary nature of enrolment was a prerequisite in order to re-establish trust with authorities and state programmes. Indeed, participation requires additional manpower to dispense the medicines and process the paperwork after selling the products; no compensation for this extra work is currently provided. Some pharmacies (in Lviv oblast, for example) have allocated a separate pharmacist and a separate "window" for prescription services under the AMP to avoid it interfering with other sales.

Overall, pharmacists reported being satisfied with the AMP regarding the timely transfer of reimbursements. Some alternative dispensing channels were also described in certain oblasts. In Kharkiv oblast, for instance, agreements were set up with pharmacy corners (small pharmacy boutiques based within health centres) and primary health care centres. In Kherson oblast it was reported that 180 primary health care ambulances have agreements with paramedics from small villages for distribution of the medicines under the AMP, although it was also reported that some administrative requirements such as drawing up of labour contracts between the staff of the paramedic stations and the pharmacies may complicate the supply of medicines (particularly in mountainous areas).

Finally, representatives of pharmacies also stated that the current distribution margin for medicines included in the AMP was not high enough to compensate for the extra costs related to management of these medicines. Nevertheless, it was acknowledged that the programme creates patient loyalty and increases client traffic in participating pharmacies.

Some factors supporting the participation of pharmacies were mentioned during the interviews – such as, for instance, the strong commitment of local politicians/administrations and leading physicians or the establishment of financial incentives for pharmacies to participate in the AMP.

3.7 Impact of the AMP on population health outcomes

Considering that the AMP was initiated only 18 months ago, it is not yet possible to measure any tangible impacts on the health status of the Ukrainian population (especially considering that cardiovascular diseases and diabetes are chronic diseases that evolve over several years). It is therefore recommended that general health status data continue to be collected and that regular analysis is performed over the ensuing years to build evidence on possible impacts of the AMP on population health outcomes. The authorities reported some preliminary findings (for example, that the number of emergency calls had decreased since initiation), but it was not possible to confirm these.



4

Uptake of the AMP across oblasts

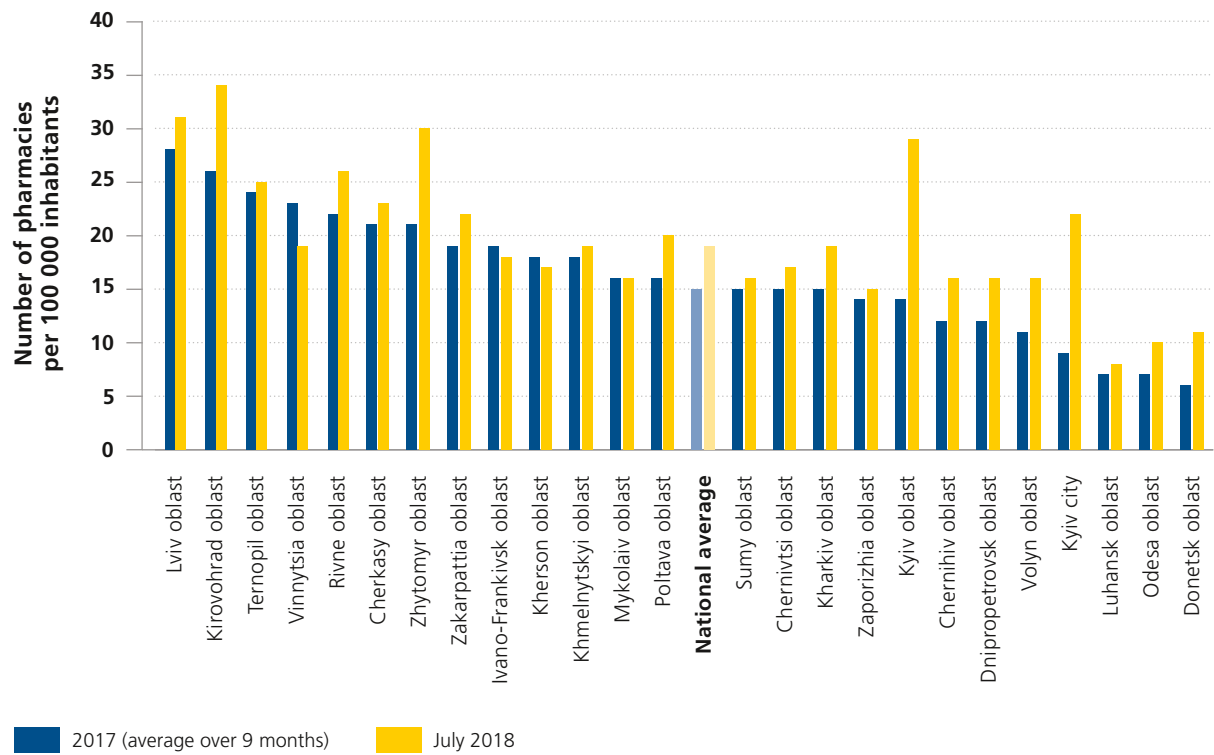
Despite some initial problems in the first week of implementation, access to the medicines covered became operational soon after the launch of the AMP in April 2017. Since then, on average, 2 million prescriptions have been dispensed each month within the programme's framework. Due to budget processing issues from one fiscal year to the next, however, a break in reimbursement was reported in December 2017 and January 2018, and during the summer 2018 period.

Reimbursement was provided for 80% of the prescriptions dispensed. According to the Ministry of Health, different factors may explain this gap, including possible shortages of some medicines at the beginning of the AMP or patients asking for a medicine that is not reimbursed, despite being prescribed a reimbursed alternative.

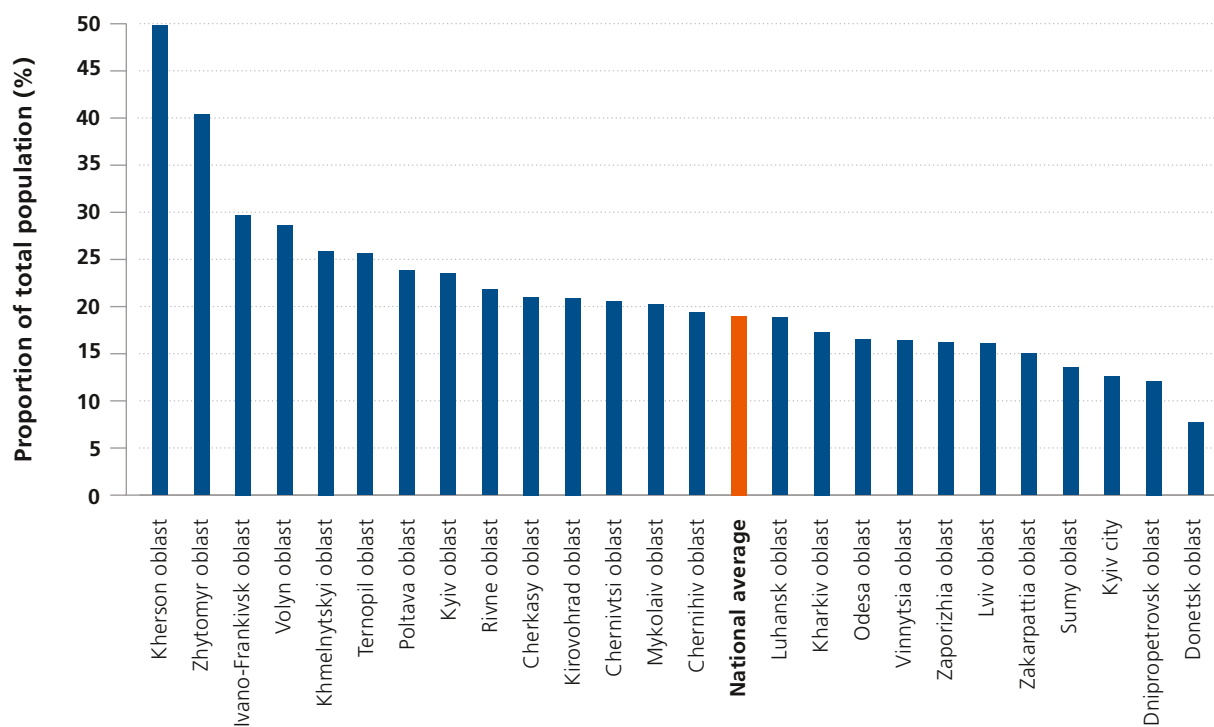
Looking beyond the country averages, and as suspected by the national authorities, an initial observation is that the uptake of the AMP is uneven among oblasts. In 2017 (averaged over nine months) the number of pharmacies involved varied between oblasts by a factor of four (from 6 to 28 per 100 000 inhabitants). In 2018 the upward trend has been general, with a few exceptions (Vinnysia oblast, and to a lesser extent Ivano-Frankivsk and Kherson oblasts). The number of participating pharmacies has more than doubled in Kyiv city and Kyiv oblast, and has increased by more than 50% in the oblasts of Donetsk, Odesa and Volyn (Fig. 11), but disparities between oblasts remain high.

Wide variations are also present between oblasts in the proportions of population benefiting from the AMP during the first nine months of implementation (April to December 2017), ranging from 8% in Donetsk oblast to 50% in Kherson oblast (Fig. 12).

Variation in the prevalence of patients registered as suffering from the three diseases concerned could be an explanation of these differences, and a correlation between the two factors was identified. With the same proportion of patients registered with bronchial asthma, type 2 diabetes and cardiovascular diseases, however, some oblasts seem to achieve better results in terms of coverage of these populations by the AMP (Fig. 13).

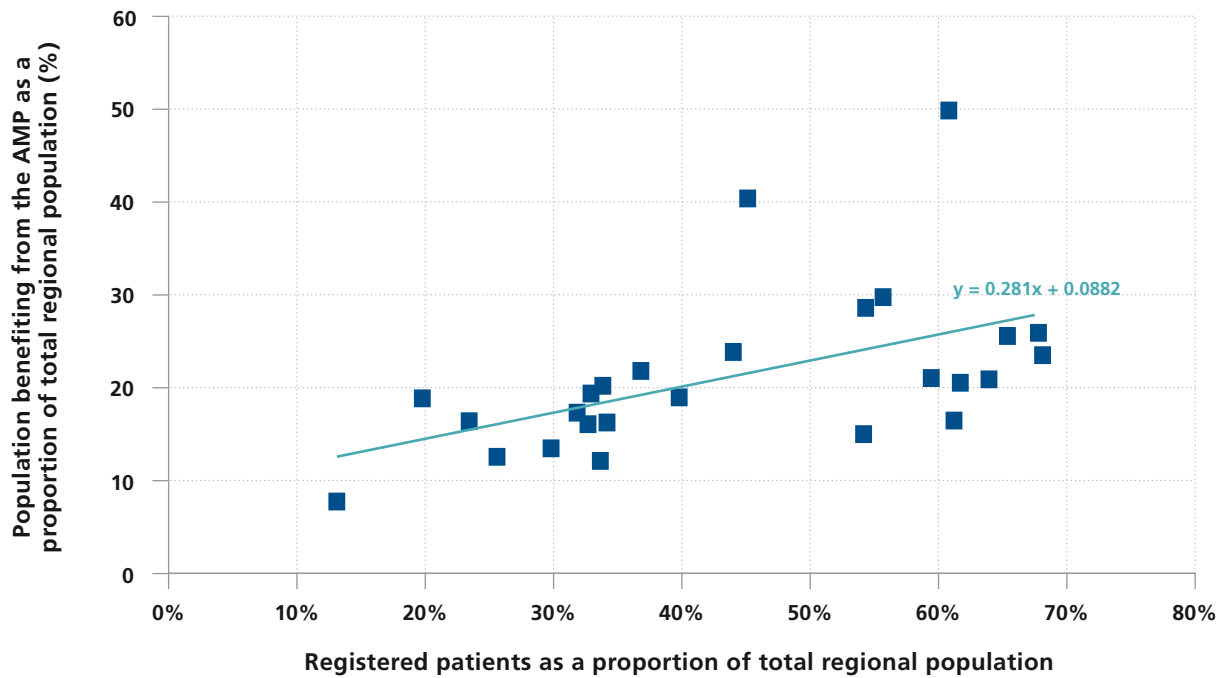
Fig. 11 | Number of pharmacies enrolled in the AMP per oblast (per 100 000 inhabitants)

Source: data provided by the Ministry of Health; analysis undertaken by the authors.

Fig. 12 | Patients benefiting from the AMP as a proportion of total population

Source: data provided by the Ministry of Health; analysis undertaken by the authors.

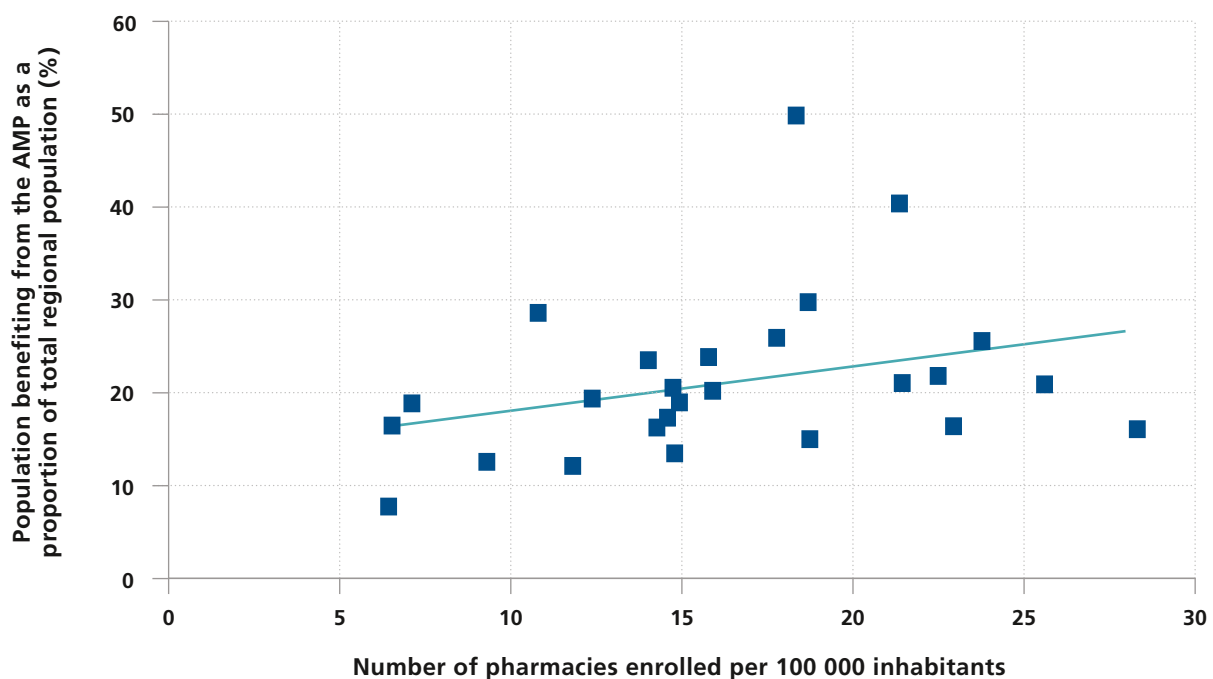
Fig. 13 | Proportion of the regional population registered for the three diseases versus proportion of the population benefiting from the AMP, 2017



Source: data provided by Proxima Research and the Ministry of Health; analysis undertaken by the authors.

Another explanatory factor may be the level of participation of pharmacies and the territorial network accessible to the population. Again, a positive link can be seen with the proportion of the population covered by the AMP (Fig. 14), but this alone cannot explain the discrepancies between oblasts.

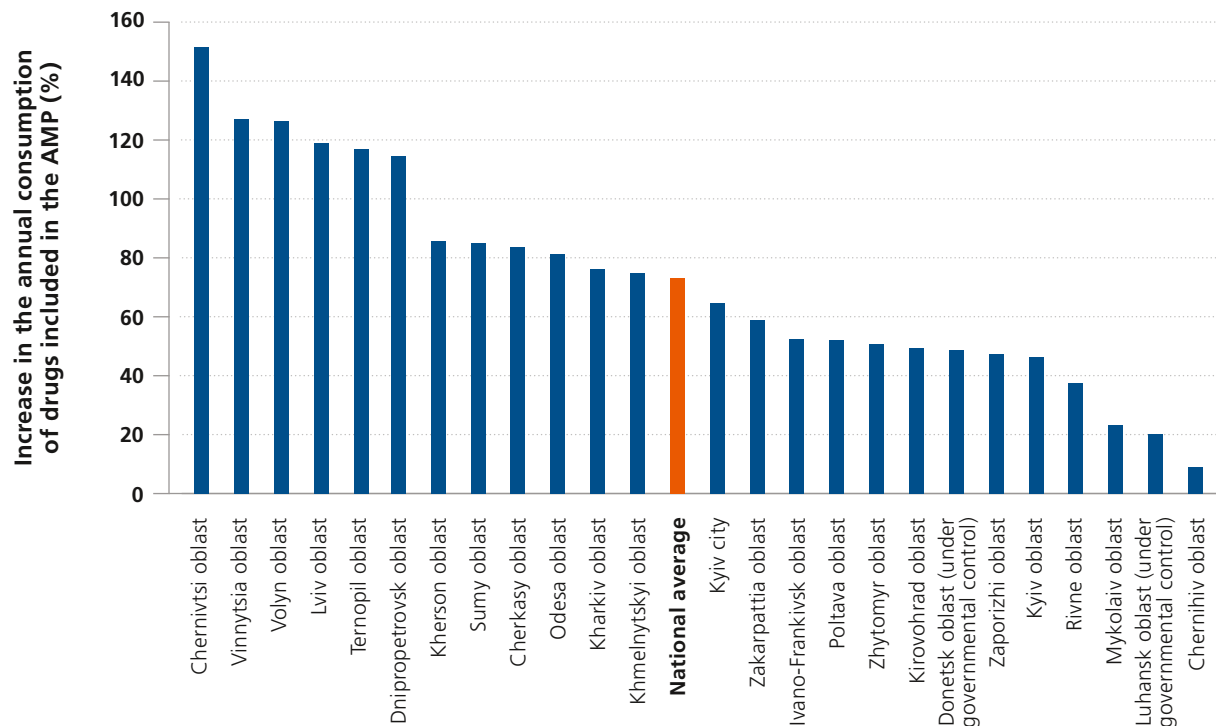
Fig. 14 | Proportion of patients benefiting from the AMP versus number of pharmacies enrolled, 2017



Source: data provided by Proxima Research and the Ministry of Health; analysis undertaken by the authors.

Also, as illustrated in Fig. 15, the AMP led to an increase in consumption of reimbursed medicines in all oblasts (80% at the national level, comparing consumption data one year before implementation and one year after). The level of this uptake was not identical across oblasts, however.

Fig. 15 | Evolution of annual consumption of medicines included in the AMP in each region before and after implementation (April 2017 to March 2018 versus April 2016 to March 2017)



Source: data provided by Proxima Research; analysis undertaken by the authors.

No correlation was found between uptake of the AMP and the number of patients benefiting (see Fig. A1 in Annex 4), but the evidence shows that the programme probably contributed to reducing inequalities across oblasts. Indeed, two further important correlations were identified during the analysis. First, the AMP contributed to a “catching-up effect” for some oblasts. A negative correlation was found (Fig. A2 in Annex 4) between growth in consumption of the medicines covered and the level of consumption before implementation. This means that the lower the level of consumption of medicines covered in an oblast before implementation, the higher the growth in consumption afterwards. This seems likely to reflect the fact that the AMP provided a needed opportunity to access medicines in less-well-off areas. This element is further confirmed by another finding (Fig. A3 in Annex 4): a negative correlation was found between growth in consumption of the medicines covered by the AMP and the level of economic development in each oblast. This means that the poorest oblasts also saw the highest increases in consumption after implementation.



5 Market evolutions in the therapeutic areas covered by the AMP

Patient access to medicines became operational quickly after the launch of the AMP in April 2017. Since then, on average, 2 million prescriptions have been dispensed each month in the framework of the programme. Altogether, up to September 2018 more than 28 million prescriptions have been reimbursed through the AMP; in 2017 more than 8 million Ukrainians benefited, of whom 7.2 million suffered from cardiovascular diseases, 700 000 from type 2 diabetes and about 160 000 from bronchial asthma. They account for half of the patients registered for these diseases (46%, 65% and 85% respectively).

As stated in section 3.2 (Table 1), the most recent data show that the drugs included in the AMP make up a significant proportion of the volume of drug consumption in the corresponding ATC group.⁸ Further detailed analysis of the consumption information reveals important findings.

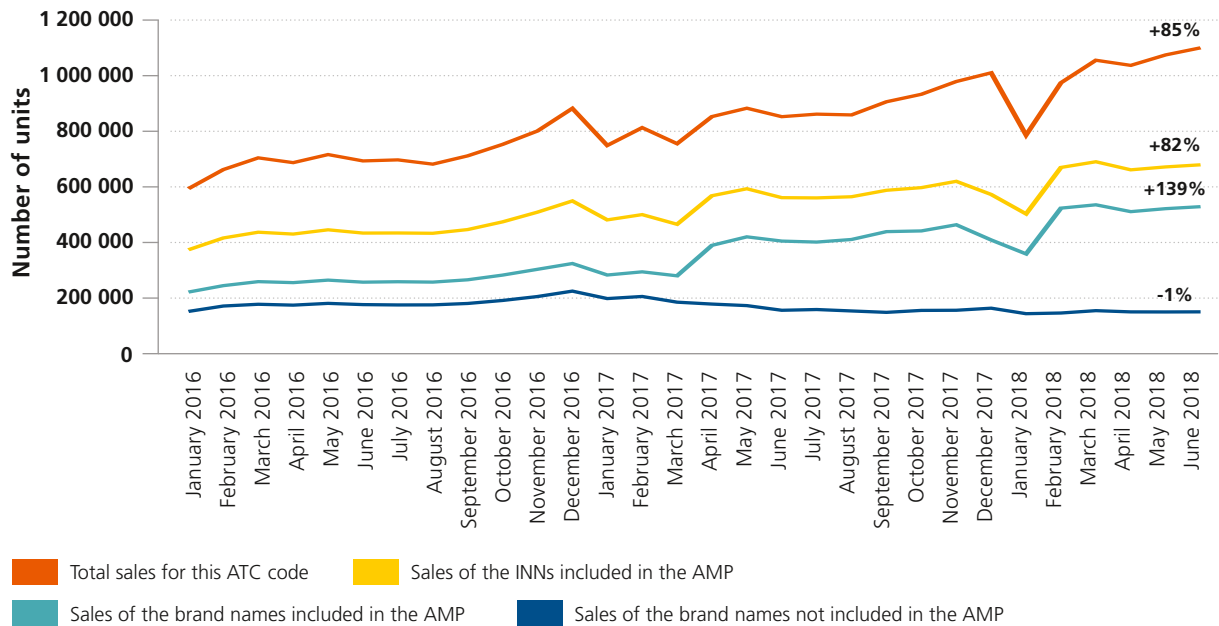
5.1 Sales of the drugs included in the AMP

For all ATC groups, sales of the drugs admitted for reimbursement increased sharply with implementation of the AMP: between January 2016 and June 2018 they rose 139% for diabetes drugs, 441% for antithrombotic agents, 117% for all cardiovascular drugs and 50% for drugs for obstructive airway diseases. These growth rates exceed by far the dynamic of the rest of the market in the corresponding groups, which enables this increase in consumption to be linked directly to implementation of the programme (see Fig. 16 for ATC group A10; graphs for the other groups are showed in Annex 4: Figs. A4 to A10). Overall, the AMP has led to an increase in consumption in each ATC group targeted, even if the magnitude of the effect varies between the therapeutic groups considered.

These findings are confirmed by manufacturers, which reported that implementation of the AMP changed the pattern of consumption in their medicine portfolios.

⁸ Excluding ATC code R01, as noted above.

Fig. 16 | Evolution of sales of ATC group A10 (diabetes medicines)

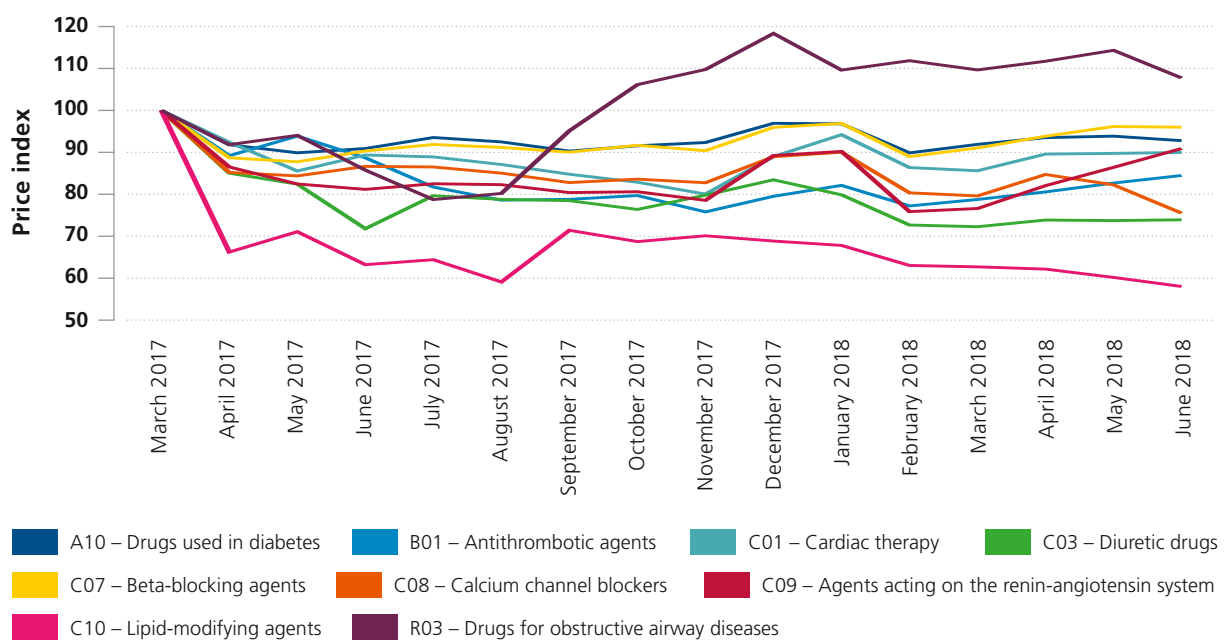


Source: data provided by Proxima Research; analysis undertaken by the authors.

5.2 Prices of the drugs included in the AMP

The impact of the AMP on prices was confirmed by the data analysis for most therapeutic areas. As shown in Fig. 17, price decreases are very significant for drugs to treat cardiovascular diseases, notably for lipid-modifying agents, diuretics and calcium channel blockers.

Fig. 17 | Evolution of unit prices of drugs included in the AMP for each ATC group (price per pack) since its inception (index 100 in March 2017)

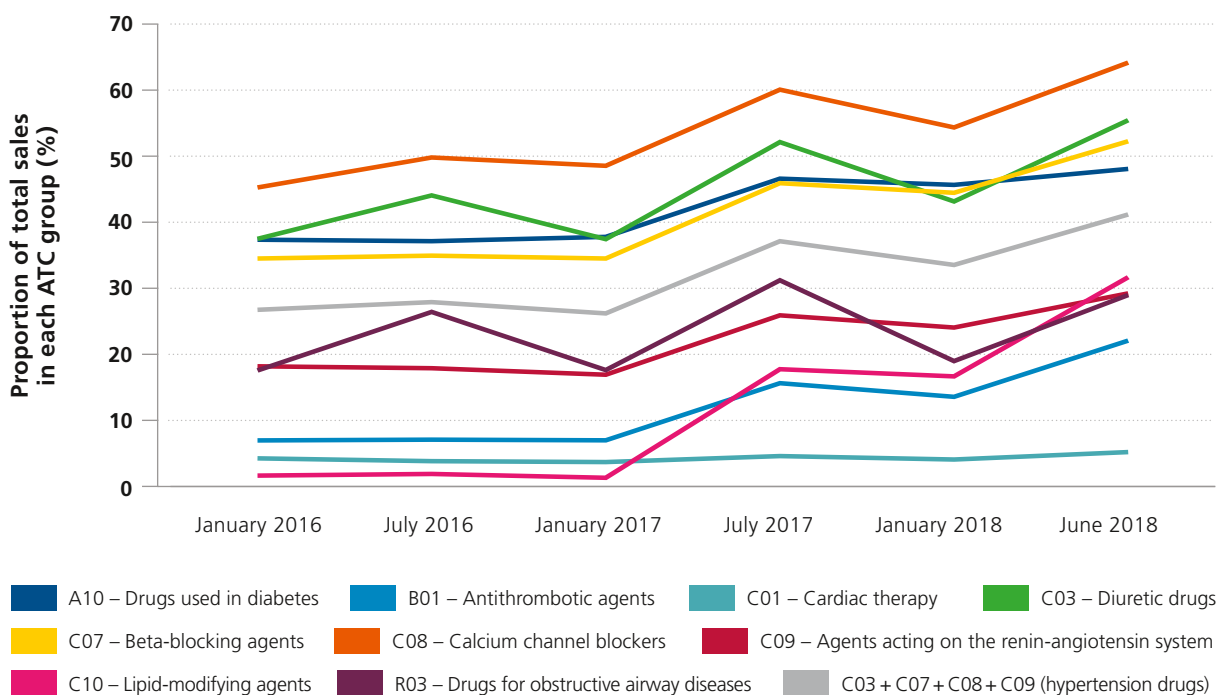


Source: data provided by Proxima Research; analysis undertaken by the authors.

5.3 Prescribing behaviour of physicians

As a result of this dynamic growth, the market share of the drugs included in the AMP has increased sharply since April 2017 (Fig. 18). For instance, the molecules included accounted for about 10% of the total volume of antithrombotic agents up to March 2017, but this proportion more than doubled after implementation of the AMP. A notable increase can also be seen for diuretics (proportion rising from 40% to 57%), calcium channel blockers (66% to 74%) and all hypertension drugs (42% to 51%). The therapeutic area showing the most significant increase is lipid-modifying agents, with simvastatin gaining around 30 points (4% to 32%). Such findings suggest that prescribing patterns have tended to change to favour molecules included in the reimbursement scheme.

Fig. 18 | Volumes of sales of the brand names included in the AMP as a proportion of total sales in each corresponding ATC group

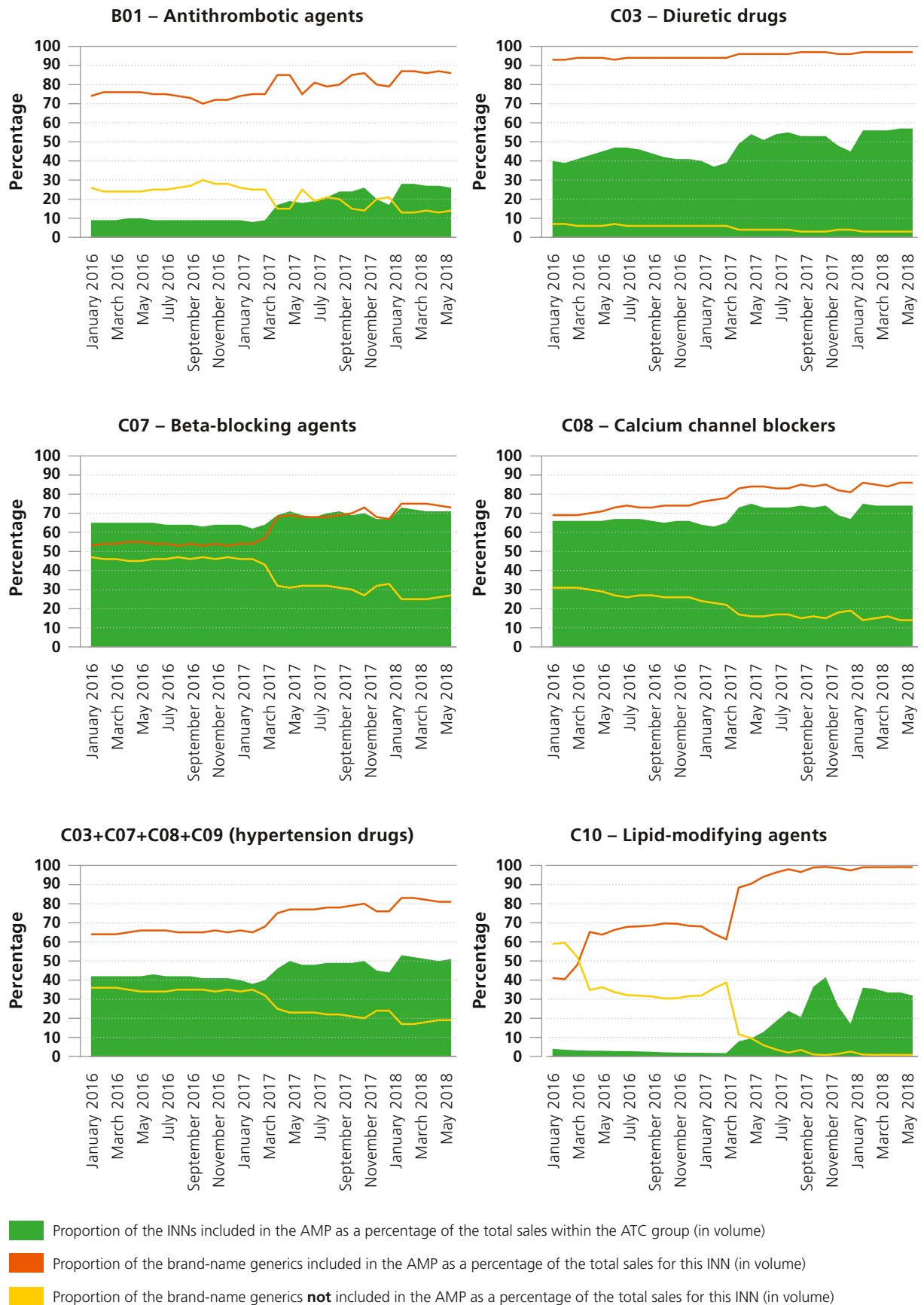


Source: data provided by Proxima Research; analysis undertaken by the authors.

More precisely, and as illustrated for cardiovascular medicines in Fig. 19, the AMP has had two main consequences. First has been a switch – within the INNs included in the programme – between the brand names reimbursed and those not reimbursed; second has been an increase in market share of the INNs included within each therapeutic group (ATC level 2). This means that medicines that are reimbursed are more frequently dispensed (which was anticipated) but also that prescribers are actively choosing to prescribe molecules that are reimbursed compared to those not included in the scheme.

For diabetes (A10) and obstructive airway diseases (R03) the market share of the INNs included in the AMP (metformin, gliclazide and later glibenclamide, beclametasone, budesomide and salbutamol) has been stable since the beginning of 2016. This means that prescribing patterns may have been less affected. However, it is still noticed a switch, within the INNs included, between brand names included and not included (see Fig. A11 and A12 in Annex 4).

Fig. 19 | Evolution of the structure of consumption for each cardiovascular disease-related ATC group

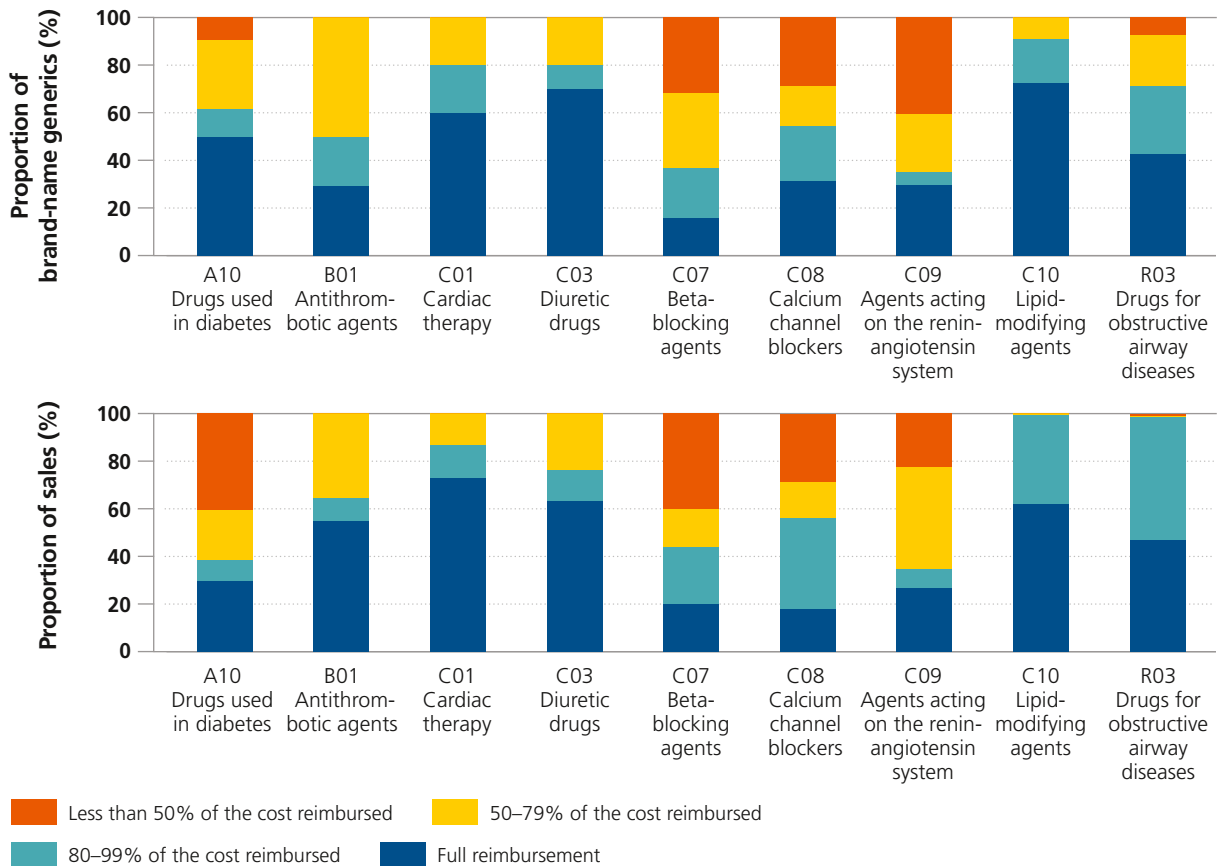


Source: data provided by Proxima Research; analysis undertaken by the authors.

6 Evolution of patient co-payments

As described in section 3, the AMP managed to include a significant number of manufacturers and, as of September 2018, the majority of products dispensed through the scheme were either fully reimbursed or covered with a co-payment of less than 20% (Fig. 20).

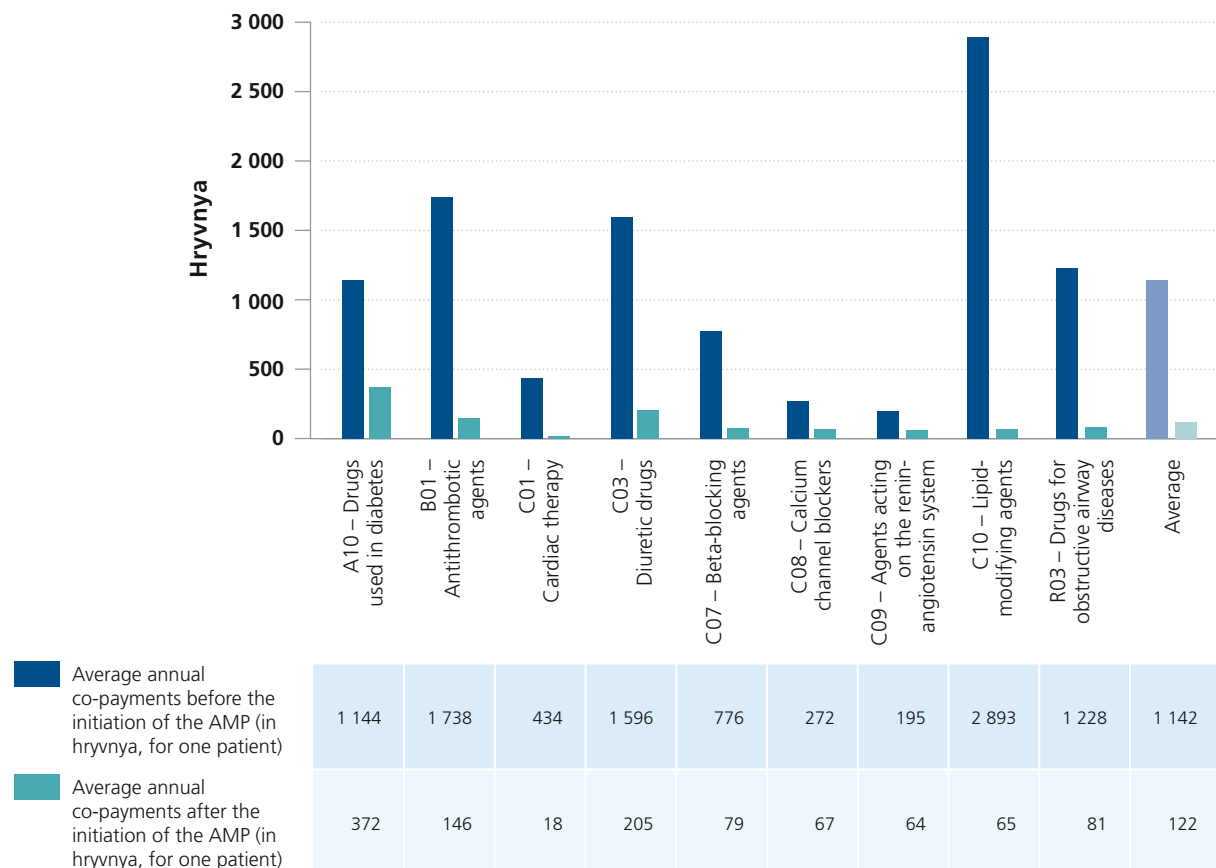
Fig. 20 | Breakdown of medicines included in the AMP by reimbursement level (September 2018)



Source: data provided by Proxima Research; analysis undertaken by the authors.

This had direct impacts on the co-payments made by patients. As shown in Fig. 21, a patient treated with a medicine included in the AMP saw annual co-payments become 1020 hryvnya (32 euros) lower than before the programme existed. Some therapeutic areas such as antithrombotic agents (B01) and statins (C10) saw very important reductions in the level of patient co-payments; on average, the AMP led to a reduction of 85% on previous co-payments required to access these medicines.

Fig. 21 | Annual co-payments before and after implementation of the AMP (absolute values)



Source: data provided by Proxima Research; analysis undertaken by the authors.



7 Summary of the findings

Based on the analysis presented above, the following conclusions can be drawn about the AMP.

The programme's uptake was quick. The AMP seems to have been functional from the first day, giving patients immediate access to the medicines covered. A few stakeholders reported difficulties due to unclear processes in the starting phase of the programme in 2017, but such issues may be inevitable when an important public policy reform is implemented.

Since April 2017, on average, 2 million prescriptions have been dispensed each month within the AMP framework (of which 80% have been reimbursed). Due to budget processing issues from one fiscal year to the next, however, a break in reimbursement was reported in December 2017 and January 2018, and during the summer 2018 period in some oblasts.

The AMP increased affordability of the medicines covered. The proportion of fully reimbursed medicines has slightly increased since implementation. Around 20% of the total number of brand-name generics included are currently dispensed without any co-payments by patients. For another 20% of the medicines dispensed, co-payments are less than 20% of the price of the medicine. Such findings suggest that the pricing mechanism in place is functioning and that manufacturers have agreed to participate, thereby making medicines more affordable for patients.

The AMP also had a significant impact on the prices of the medicines included. In all but one of the therapeutic areas covered (bronchial asthma) prices decreased after initiation, and this remained consistent over time. Such reductions were particularly significant for cardiovascular diseases – notably for lipid-modifying agents, diuretics and calcium channel blockers (with reductions ranging from 30% to 40%). The programme led to an 85% average reduction in patient co-payments, which is equivalent to a saving of 1020 hryvnya annually.

The AMP significantly increased access to the medicines covered. More than 8 million Ukrainians benefited; they account for one half of the patients who are registered as suffering from these diseases. Various stakeholders in the oblasts (prescribers and health authorities) reported that for many patients the programme was their only chance to access treatment.

Evidence also shows that the AMP has increased access to the selected medicines for the population. For all ATC groups covered, sales of medicines admitted for reimbursement increased sharply with implementation: between January 2016 and June 2018 consumption growth rates were 139% for diabetes medicines, 441% for antithrombotic agents, 117% for all cardiovascular medicines and 50% for medicines for obstructive airway diseases. These far exceed the dynamic of the rest of the market in the corresponding groups, allowing a direct link to be made to implementation of the programme. Overall, the AMP has led to an increase in consumption of medicinal products included in the WHO EML (WHO, 2018a).

The programme changed prescribing patterns. As a result of this dynamic growth, the market share of the medicines included in the AMP increased sharply from April 2017. For instance, the INNs included in the programme accounted for about 10% of the total volume of antithrombotic agents until March 2017; this proportion more than doubled after implementation. A similar evolution can be seen for diuretics (proportion rising from 40% to 57%), calcium channel blockers (66% to 74%) and all hypertension medicines (42% to 51%). The therapeutic area showing the most significant increase is lipid-modifying agents, with simvastatin rising by around 28 percentage points (4% to 32%).

These findings suggest that prescribing preferences have moved towards molecules included in the reimbursement scheme. In general, prescribers reported being very satisfied with the AMP, as they noticed an increase in access to medicines for their patients. They confirmed that for many patients the programme was their only chance to access treatment. As an unintended consequence, some patients with chronic bronchitis sought a change in their diagnosis in order to be registered as suffering from asthma and thereby gain eligibility for free-of-charge (or reduced-cost) treatment under the programme. This demonstrates that the AMP is seen as a means for the population to access needed medicines and legitimates the idea of a revision or expansion of the list of medicines covered.

The programme managed actively to engage the pharmaceutical industry. Market forces certainly contributed to the initial uptake of the AMP, but it was reported that programme managers also played an important role in motivating local and foreign pharmaceutical companies to take part. At its inception, the number of different brand names included in the scheme was 157; this rose by 66% in August 2018 (to 261). This important number of suppliers helped to ensure an effective supply of the selected molecules, despite some shortages reported by local-level stakeholders (in Lviv and Kharkiv oblasts, among others). As a result, in most cases the brand-name generics included account for a significant proportion of medicine consumption in the corresponding therapeutic classes, especially by volume.

On the question of shortages, pharmaceutical manufacturers reported their concerns with some practices from competitor companies that proposed a low price (and were therefore granted full reimbursement status) but were not able to provide sufficient quantities to cover the needs of the market, leading to potential shortages.

The AMP seems to have had an impact on the Ukrainian health care sector already. It is not yet possible to draw any formal conclusions about the effects on the health of the population: the time since initiation is too short in view of the natural evolution of the diseases considered. It is therefore important to collect current health outcome indicators to define the baseline for future analysis and monitoring of the effects of the programme. This specific point was mentioned as one of the critical shortcomings of previous attempts to initiate outpatient medicine reimbursement programmes. The future development and stabilization of the AMP will require evidence of its impact on the health of Ukrainian citizens. Despite this, all stakeholders interviewed stressed the substantial influence of the AMP on the Ukrainian health system and recommended that the programme should be further maintained, expanded and integrated into the general health care reforms in the country.

General enforcement of the programme is uneven across oblasts. As noted above, the AMP has led to an increase in consumption of the medicines reimbursed in all oblasts (a 73% rise nationally in consumption data one year before and one year after implementation). Nevertheless, the level of uptake is not identical across oblasts. Important variations were also identified in the proportion of the population benefiting from the programme during the first nine months of implementation (April to December 2017). This ranges from 8% in Donetsk oblast to 50% in Kherson oblast.

The difference across oblasts is also reflected in the number of pharmacies involved in the AMP. In 2017 (average over nine months), the number of participating pharmacies per 100 000 inhabitants in each oblast was in the range 6–28. In 2018 the trend was generally upward, with a few exceptions (Vinnytsia oblast, and to a lesser extent Ivano-Frankivsk and Kherson oblasts). The number of participating pharmacies more than doubled in Kyiv city and Kyiv oblast, and increased by more than 50% in the oblasts of Donetsk, Odesa and Volyn. Disparities among oblasts remain high in 2018, however. It was reported that the local situation and arrangements (such as public support of the AMP by local political leaders) were the main factors behind these regional differences.

Further, social media analysis suggests that availability of medicines in the AMP is uneven across pharmacies (the lowest priced and thus fully reimbursed product is claimed to be less frequently available than other products). Such inequalities need to be tackled because the density of participating pharmacies seems to be a factor in the differences in programme uptake across oblasts. Indeed, a positive correlation was identified between the proportion of the population benefiting from the AMP in each oblast and the density of participating pharmacies. Another positive correlation was found between the prevalence of registered patients with any of the three diseases covered and the proportion of the population benefiting from the AMP. This supports the idea that local organizational arrangements contributed positively to enforcement of the programme.

Nevertheless, the evidence also shows that the AMP probably contributed to reducing inequalities across oblasts. Indeed, two further important correlations were identified during the analysis. First, the programme contributed to a “catching-up effect” for some oblasts. A negative correlation was found between growth in consumption of the medicines covered by the programme and the level of consumption before implementation. This means that the lower the level of consumption of medicines covered by the programme in an oblast before implementation, the higher the growth in consumption afterwards. This seems likely to reflect the fact that the AMP provided a needed opportunity for access to medicines in less-well-off areas. This element is further confirmed by another finding: a negative correlation was also found between growth in consumption of the medicines covered by the programme and the level of economic development in each oblast. This means that the poorest oblasts also saw the highest increases in consumption after implementation.

Finally, the transparency of the management of the list of reimbursed medicines needs to be strengthened. The establishment of the EML committee is a good signal given by the authorities to illustrate that transparency of the pharmaceutical sector is a priority. Yet even though the decision was made to reimburse only INNs listed in the WHO EML as part of the AMP, most stakeholders reported difficulties in understanding some decisions made by the authorities. The initial choice of therapeutic areas and INNs covered by the AMP was not made in consultation with representatives of the stakeholders (prescribers and regional health authorities, for instance). This fostered some resentment towards the programme and the decisions made. During the evaluation, the link between the AMP and the newly established EML committee, which had prepared a recommended version of the national EML, could not be clearly stated; nor was any formalized process to decide whether and how to enlarge the therapeutic areas covered by the programme reported.

8

Potential policy options for further implementation of the AMP

Based on the findings of the evaluation, the following policy options are proposed for consideration by authorities to ensure further access to treatment. Some should be considered for introduction in the short term (within the next two years); others could be discussed at a later stage.

8.1 Short-term actions

The government's communication strategy should be developed. The government needs to communicate its views and objectives with all the stakeholders involved (giving particular attention to local authorities, physicians, patients' groups and industry representatives). The following questions could constitute a starting-point for discussions.

- What is the overall vision pursued?
- What will the reimbursement system look like in three years?
- How can collegiate governance of the programme be ensured, whereby all stakeholders have the opportunity to have their say in the choices and directions taken?

The budget allocated to the AMP should be secured and increased. It was reported that the current budget (1 billion hryvnya/31 million euros) will be maintained for 2019. This is a good sign, but since the programme is functioning and needs are far from being met, the authorities need to consider an increase in the allocated budget both to treat more patients and to extend the number of INNs covered. Further, the budget calculation needs to be changed from a political decision to a technical one. It is important to develop technical capacity in health budget costing and forecasting. This activity could be taken forward in the context of establishment of the NHSU and creation of the single-purchaser function. Oblasts may have a role in providing input on the needs to be covered, but it is recommended that responsibility for this remains at the central level. Finally, relevant amendments to Ukraine's budget code should be made to avoid issues of programme disruption from one fiscal year to the next.

Uneven uptake of the AMP across oblasts should be addressed. The voluntary nature of pharmacies' involvement in the programme was mentioned by participants as a risk to its sustainability. Since the number of participating pharmacies was identified as a driver for access, it is important to

encourage their involvement. One important action could be to introduce a stronger financial incentive to dispense medicines included in the AMP, to compensate for the administrative burden related to its management (for instance, the dispensation mark-up for essential medicines outside the AMP is currently higher than for products in it: 25% versus 15%). Such an incentive could be either a higher level of dispensation margin for pharmacists or a prescription fee. A specific estimate of pharmacies' costs related to their involvement should be a prerequisite, however. Considering options for alternative distribution channels to reach isolated oblasts (such as mobiles pharmacies like the "Pharmacies on Wheels" used in Baltic countries) could also be part of the solution.

As noted, it remains difficult to isolate factors explaining all the differences observed across the oblasts. Further investigations are required, and a solid monitoring and evaluation system needs to be developed to document and create evidence for policy action. On this basis, collaborations between oblasts could be initiated to share promising practices. One option could be, for instance, to organize a biannual national conference gathering representatives of central authorities and regional stakeholders to discuss implementation of the AMP and the difficulties faced at the local level. This would also be an opportunity to disseminate initiatives developed at the local level, such as:

- communication via local media – in Kharkiv oblast local media were used to inform the population about the programme, which seems to have had a positive effect and helped with initiation;
- direct training of prescribers – in Vinnytsia oblast courses for prescribing doctors were organized in collaboration with the medical university and prescription guidelines for medicines included in the AMP were developed, which could be shared with other oblasts;
- accurate tools for management and monitoring of implementation of the programme within oblasts, such as regular teleconferences or performance indicators for districts.

Mechanisms should be put in place to prevent shortages, especially of medicines dispensed at no cost. The most important element is to ensure that reports of shortages are based on facts rather than perceptions. Establishment of a central telephone number or email address where patients, pharmacists and wholesalers could notify the authorities of non-availability of reimbursed medicines is suggested, with contact details obligatorily displayed in participating pharmacies. It also appears desirable to define a system to penalize companies that do not provide medicines in adequate quantities when selected as the cost-free dispensing choice. Pharmacists should also be obliged to suggest the next cheapest alternative to patients if the option dispensed free of charge is not available.

The list of INNs covered by the AMP should be increased. The current medicines list constitutes a solid starting-point, but the number of INNs covered needs to be increased significantly but progressively in the coming years, based on public health priorities and ability to ensure quality of diagnosis and service delivery. The case of patients asking to be re-diagnosed to receive reimbursed medicines highlights the need to expand the benefit package.

The process for listing/delisting decisions should be set out in a transparent and accountable way, under the responsibility of the EML committee, and follow an accepted protocol (which needs to be defined). It is strongly advised that the initial focus for expansion of the list is on outpatient primary care medicines. Based on WHO's previous experience and the information collected during the evaluation, the following therapeutic areas could be considered priorities for upscaling the programme:

- chronic obstructive pulmonary disease
- primary care gastrointestinal medicines (proton-pump inhibitor and similar)
- broad-spectrum antibiotics
- analgesics, including controlled medicines for palliative care

- steroidal and non-steroidal anti-inflammatory molecules
- neuro-psychiatric molecules (antidepressants, antiepileptics, neuroleptics and anxiolytics).

The role of prescribers should be strengthened. Prescribers have a critical role to play to ensure the success and sustainability of the AMP, but some misconceptions exist about the programme, its objectives and the medicines covered. National clinical guidelines should be developed for all the diseases covered by the reimbursement scheme. Further, continuous professional education of prescribers should be enforced, with an initial focus on responsible use of medicines and the role of generics.

8.2 Medium-term actions

Careful integration of the programme into other reforms of the health care sector should be ensured. Work on development and training of the EML committee should be an opportunity to ensure that a transparent and accountable system is implemented for reimbursement listing and delisting decisions. The committee needs to define its protocols and explain how decisions to add or remove a molecule are made. Integration of the AMP and the NHSU (as well as future interrelations between the two) needs to be prepared carefully. Budget allocation to the programme needs to be done in a timely fashion to avoid any risk of disruption of service. Dedicated meetings around this issue are required between the NHSU, the Ministry of Health and the State Expert Centre as early as possible.

Digitalization of the prescription system should be considered. The Ministry of Health is piloting an electronic prescription system that, if successful, would eliminate paper prescriptions and produce reports to provide the Ministry of Health and/or NHSU with accurate statistics and information about which diseases are dominant in which oblasts; these could be used to improve budget spending. This reform might help to optimize the reimbursement scheme, but it should not be forgotten that the complexity of Internet coverage in remote areas (such as Lviv oblast) would be an impairing factor and a complication for both local family doctors and patients.

Specific adaptations of the AMP for vulnerable populations should be considered. It is currently universal by nature, and even people on low incomes may have to co-pay for medicines if the fully reimbursed alternative is not available. This situation is highly regressive in the light of the fact that outpatient medicines are the main driver of catastrophic health spending and that almost 80% of households with catastrophic health spending are in the poorest quintile. Discussion of possible co-payment exemption mechanisms for vulnerable populations – such as people on low incomes or pensioners – needs to be initiated.

8.3 Other actions

Health status indicators should be collected and monitored. As noted above, the short time between initiation of the AMP and the evaluation makes it impossible to draw any firm conclusions on the potential effects of the programme on the population's health. Health data need to be collected and monitored closely to allow an evaluation of the effects of the programme in ensuing years. The following indicators are mentioned as suggestions by USAID project SAFEMed to the authorities for further consideration and discussion:

- process indicators:
 - percentage of registered diabetic patients receiving adequate treatment;
 - percentage of registered asthmatic patients receiving adequate treatment;

- percentage of registered patients suffering from hypertension receiving adequate treatment;
- proportion of prescriptions actually delivered to patients;
- indicators of access and financial protection:
 - analysis of regular household surveys to monitor unmet need for health care and medicines to see whether the AMP has a positive impact on access;
 - analysis of household budget survey data to assess changes in the incidence, distribution and drivers of catastrophic health spending to see how the AMP affects financial protection;
- health outcome indicators:
 - number of patients hospitalized with a diagnosis of acute myocardial infarction;
 - number of patients hospitalized with a diagnosis of stroke;
 - number of ambulance calls (or visits to emergency rooms) for suspected myocardial infarction/stroke;
 - number of patients hospitalized (or ambulance calls or visits to emergency rooms) with a diagnosis of bronchial asthma crisis;
 - number of patients with controlled HbA1c (glycated haemoglobin) level per 100 patients with a diagnosis of type 2 diabetes mellitus;
 - number of patients hospitalized (or ambulance calls or visits to emergency rooms) for a complication from type 2 diabetes.

The current indicators collected are relevant to further monitoring and evaluation of the programme: maintaining their regular collection is recommended.

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Goroshko A, Shapoval N, Lai T (2018). Can people afford to pay for health care? New evidence on financial protection in Ukraine. Copenhagen: WHO Regional Office for Europe (<http://www.euro.who.int/en/countries/ukraine/publications/can-people-afford-to-pay-for-health-care-new-evidence-on-financial-protection-in-ukraine-2018>, accessed 26 November 2018).

WHO (2018a). WHO Model Lists of Essential Medicines. In: World Health Organization [website]. Geneva: World Health Organization (<https://www.who.int/medicines/publications/essentialmedicines/en/>, accessed 26 November 2018).

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Annex 1. INNs included in the AMP

Table A1 lists the INNs included in the AMP as of September 2018 and the dates of their inclusion in the scheme.

Table A1 | INNs included in the AMP as of September 2018

INN	Date of inclusion
Cardiovascular diseases	
Amiodarone	1 April 2017
Amlodipine	1 April 2017
Atenolol	1 April 2017
Bisoprolol	1 April 2017
Verapamil	1 April 2017
Hydrochlorothiazide	1 April 2017
Digoxin	1 April 2017
Isosorbide dinitrate	1 April 2017
Carvedilol	1 April 2017
Clopidogrel	1 April 2017
Losartan	31 December 2017
Metoprolol	1 April 2017
Nitroglycerin	1 April 2017
Simvastatin	1 April 2017
Spironolactone	1 April 2017
Furosemide	1 April 2017
Enalapril	1 April 2017
Type 2 diabetes	
Glibenclamide	31 December 2017
Gliclazide	1 April 2017
Metformin	1 April 2017
Asthma	
Beclometasone	1 April 2017
Budesonide	1 April 2017
Salbutamol	1 April 2017

Annex 2. Evaluation framework

An analytical framework was developed for the evaluation, setting out the key indicators initially considered for collection and analysis.

The objectives of the evaluation were:

- to show whether the AMP had succeeded in fulfilling its objectives to provide more patients with affordable medicines for selected chronic diseases (cardiovascular diseases, type 2 diabetes and bronchial asthma), irrespective of their place of residence, age or previous reimbursement eligibility (for example, as a war veteran) in an efficient manner;
- to develop recommendations for national authorities on how to overcome potential shortcomings identified and ensure the sustainability of the programme as a pillar of general reform of the health care system in Ukraine.

More precisely, the assessment focused on four components (accessibility of medicines, affordability for patients, acceptance by stakeholders and general functioning of the AMP), asking the following questions.

- Is accessibility of medicines evidenced (in all territories and for all groups of population)?
- How has out-of-pocket expenditure for patients (and thus affordability) evolved for the INNs included in the programme?
- What is stakeholders' acceptance and/or satisfaction with the programme, its functioning and the selected INNs – this includes patients, prescribers, pharmacies, payers and manufacturers?
- How is the AMP functioning and is it fulfilling its mission?

Table A2 sets out the key indicators used to analyse the interview responses and quantitative data collected during the evaluation.

Table A2 | Key indicators to be collected for each component of the assessment

Objective	Indicators	Data sources
Accessibility	<ul style="list-style-type: none"> • Number of patients enrolled in/covered by the AMP: <ul style="list-style-type: none"> – absolute figures and per 100 000 inhabitants – by oblast – as a share of total eligible patients – by age • Number of participating (enrolled) pharmacies: <ul style="list-style-type: none"> – absolute figures – as a proportion of all pharmacies – by oblast – changes since the beginning of the AMP 	Data from national and regional authorities and private companies

Table A2 | Contd.

Objective	Indicators	Data sources
Affordability	<ul style="list-style-type: none"> • Reductions in patients' out-of-pocket spending for the INNs reimbursed • Cost evolution: changes in price per pack per INN (time-series analysis) – before and after introduction of the AMP • Funds used by the Ministry of Health for the reimbursed products as a share of the total funds allocated to the programme 	Data from national and regional authorities and private companies
Acceptability	<ul style="list-style-type: none"> • Complaints brought forward by the different market players 	Qualitative interviews
Efficiency	<ul style="list-style-type: none"> • Number of INNs included in the AMP and sales data: <ul style="list-style-type: none"> – reimbursed products as a share of total market for INNs – share of reimbursed INNs in total pharmaceutical market – development of numbers since the beginning of the programme, on a quarterly basis (time-series analysis) – by oblast • Transparent criteria for including products/INNs in the programme • Perception of the quality of medicines in the AMP – before and after the beginning of the programme • Time delay from market launch of an eligible product to decision on reimbursement and access for patients • Success factors and hindering factors for the uptake of the programme: <ul style="list-style-type: none"> – factors that have contributed to the success of the programme – factors that have impeded further uptake of the programme • A system in place to prevent miscarriage or fraud 	Qualitative interviews Data from national and regional authorities and private companies

Annex 3. Interview guide for meetings at the regional level

The following guide was developed for the qualitative assessment of the AMP through stakeholder interviews.

Principles for the interview

- Ask many open questions.
- Quotes of the respondents may be used in the final report and should be therefore carefully documented.
- Transcripts of the interviews should be validated by the interviewees before the information is used in the evaluation report.

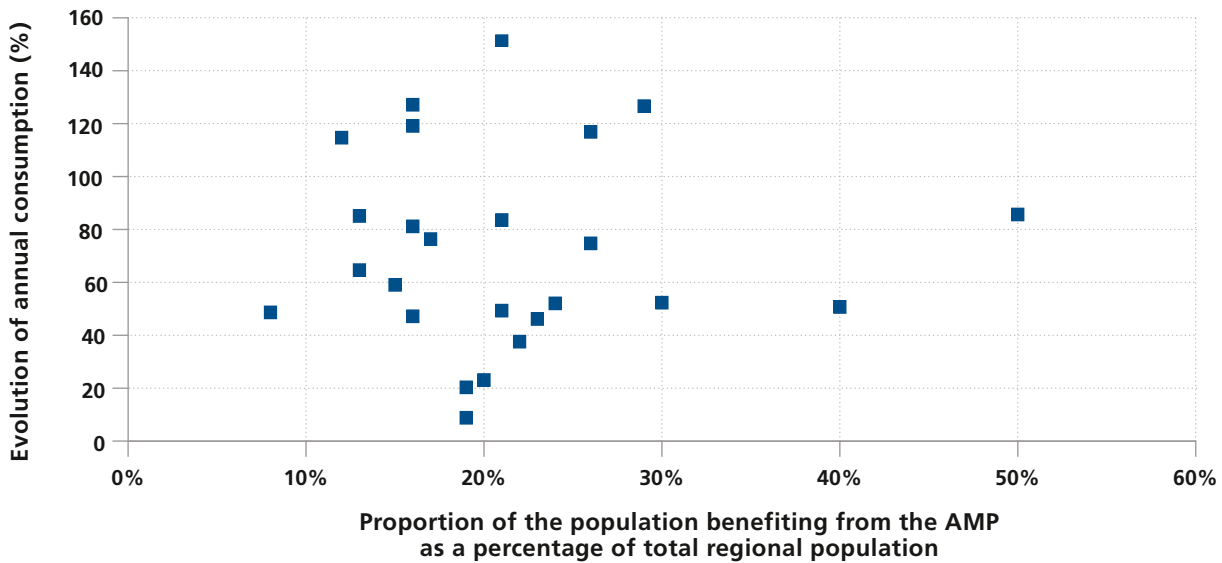
Questions to be asked

- What was the situation before the introduction of the AMP? What changed thereafter?
- Do you think the AMP as it is set up fulfils its intended objectives (increasing access to medicines)?
 - What factors have contributed to its success?
 - Which factors do you think have impeded further uptake?
- What have been the consequences for the stakeholders involved:
 - pharmaceutical companies
 - pharmacies (What are the incentives for pharmacies to participate?)
 - wholesalers
 - prescribers
 - doctors
 - regional health authorities
 - patients (Do patients, who would benefit most from participation, have access to the AMP?).
- What complaints have reached you?
 - Did you experience medicine shortages?
 - If so, how could they be prevented?
- To investigate differences among the oblasts, please consider these factors.
 - Data suggest differences in the uptake between oblasts – what are the reasons for this?
 - Are there differences between rural and urban areas regarding access to the AMP?
- How reliable are the data prepared by the oblasts?
- From your experiences so far, should the AMP be extended?
- If so, to which therapeutic areas?
- What will be the impact of future developments on the AMP?
- How will the introduction of an electronic prescription system change application of the programme?
- What will be the impact of the new health financing law and new agency (NHSU)?
- What would be the result of participation in the AMP being made compulsory – for example, linking licensing of pharmacies to participation?

Annex 4. Additional figures from the analysis

Annex 4 contains the additional detailed figures mentioned throughout the report. Fig. A1 shows the absence of correlation between uptake of the AMP and the number of patients benefiting.

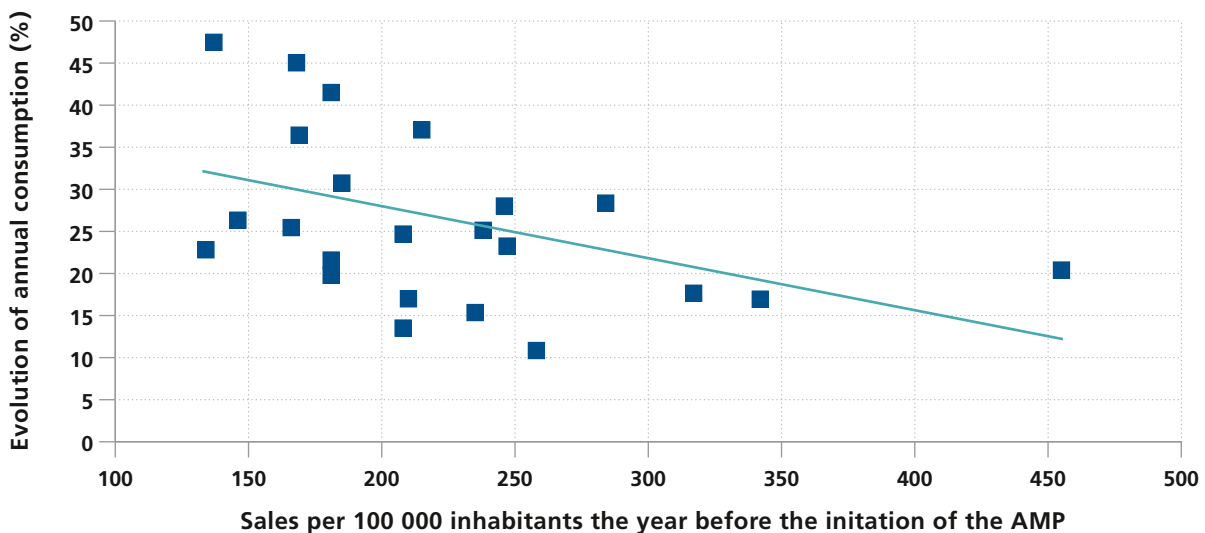
Fig. A1 | Evolution of annual consumption of reimbursed medicines compared to the proportion of the population benefiting from the AMP in each oblast



Source: data provided by the Proxima Research and the Ministry of Health; analysis undertaken by the authors.

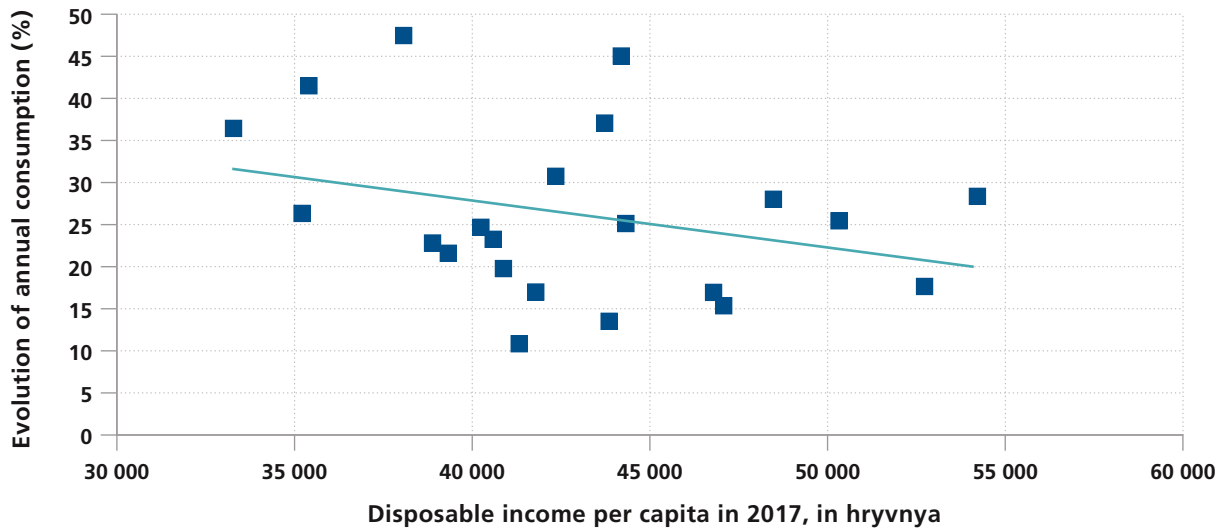
Figs. A2 and A3 show the correlations highlighting the idea that the AMP had a “catching-up” effect for the oblasts (uptake was higher in places where the level of consumption was lower or the level of economic development less advanced).

Fig. A2 | Level of drug consumption per inhabitant before implementation of the AMP (total sales value) compared to the evolution of annual consumption of reimbursed medicines in each oblast



Source: data provided by the Proxima Research and the Ministry of Health; analysis undertaken by the authors.

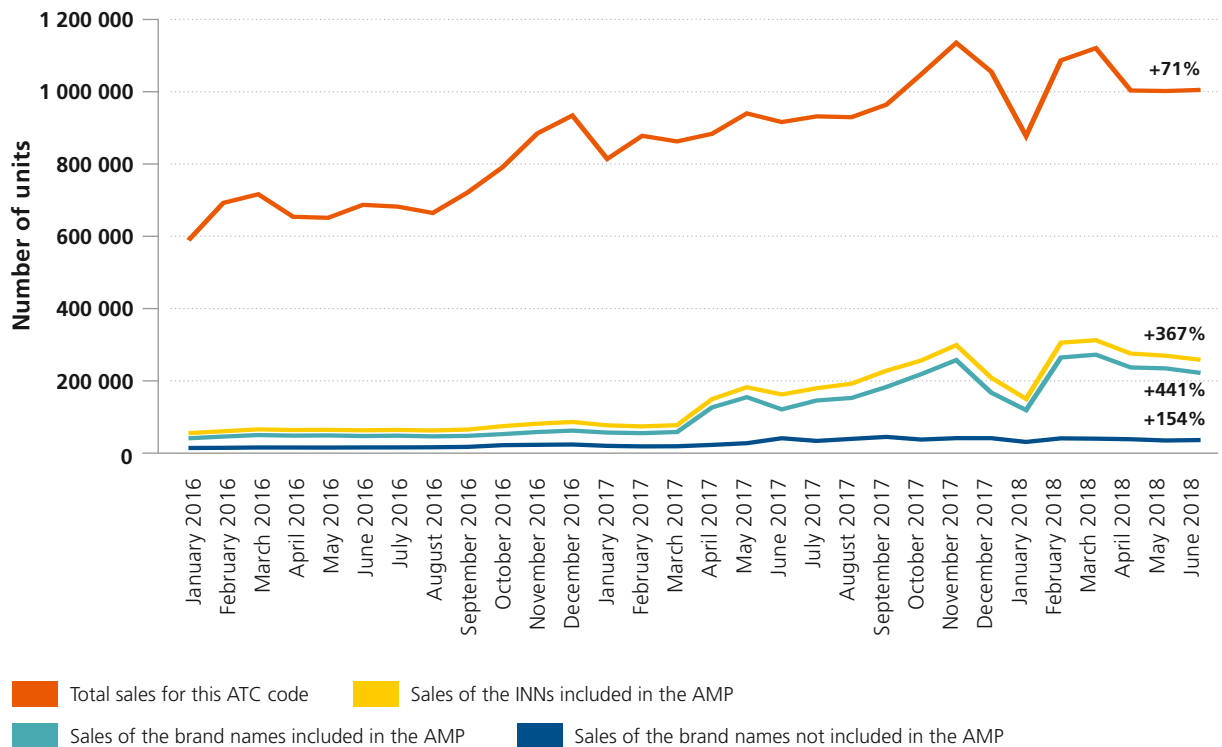
Fig. A3 | Per capita disposable income compared to the evolution of consumption of reimbursed medicines in each oblast



Source: data provided by Proxima Research and the Ministry of Health; analysis undertaken by the authors.

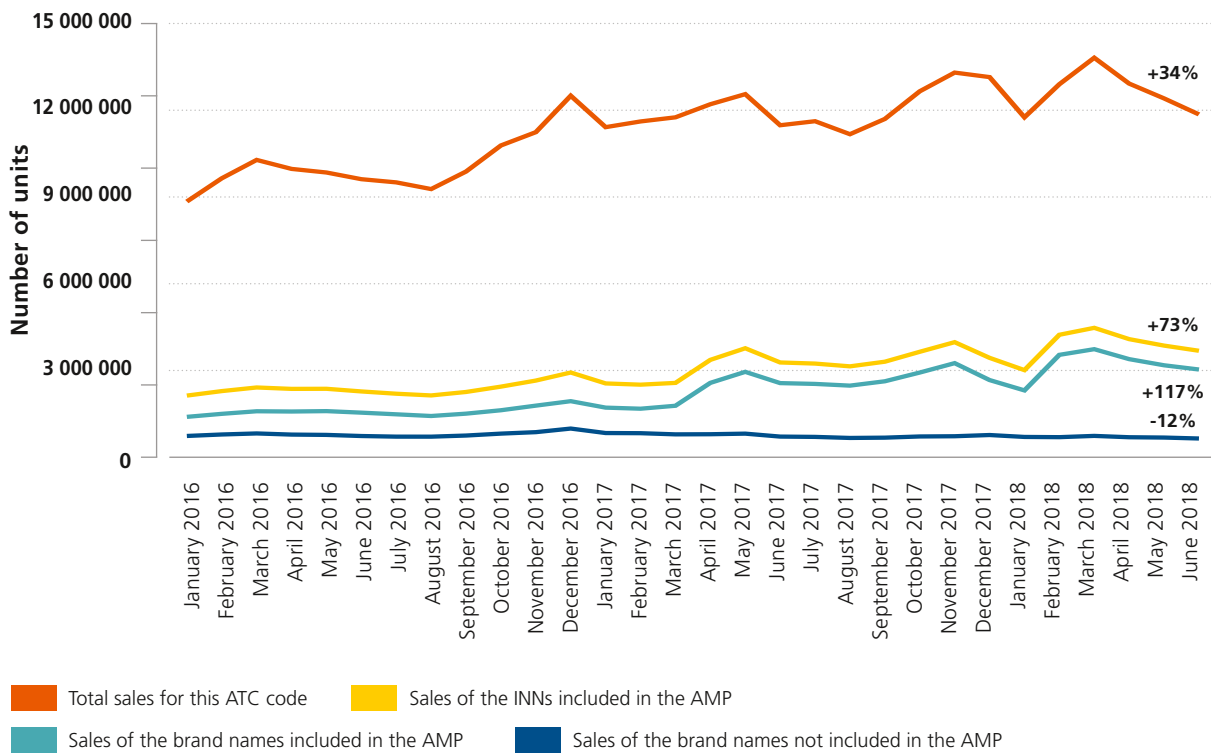
Figs. A4 to A10 illustrate the evolution of sales in each of the ATC groups included in the AMP.

Fig. A4 | Evolution of sales of ATC group B01 (antithrombotic agents)



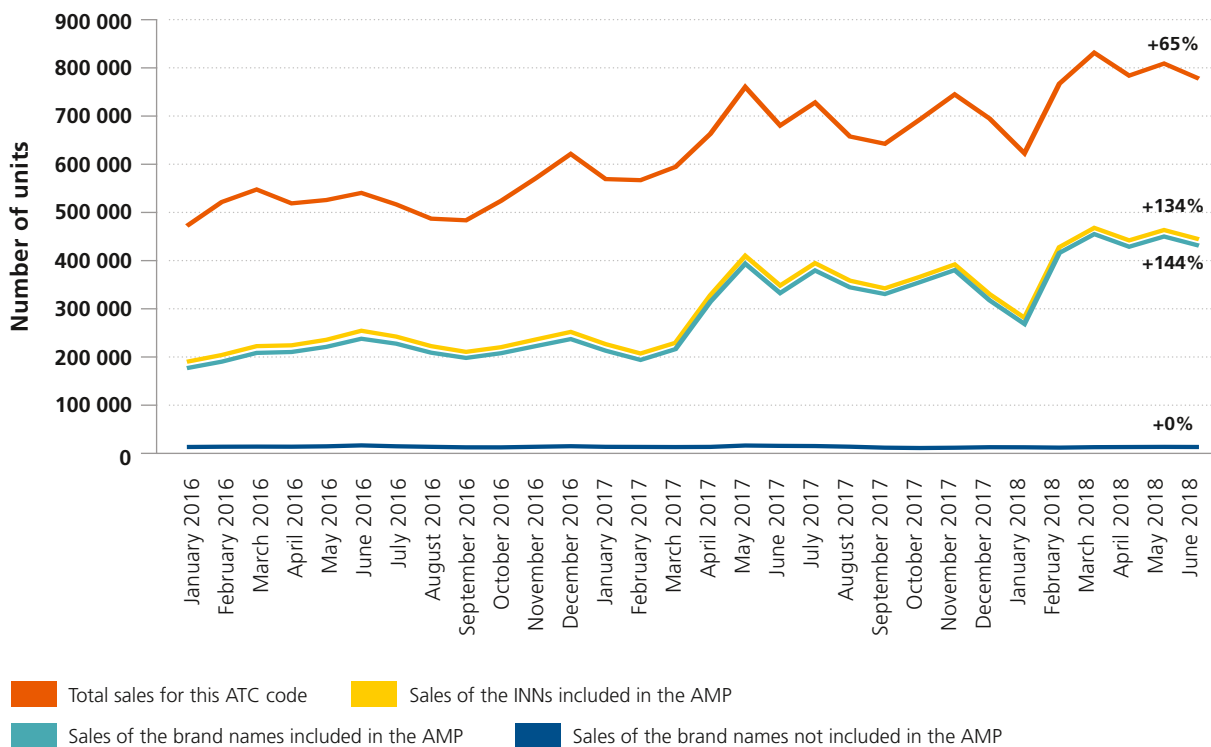
Source: data provided by Proxima Research; analysis undertaken by the authors.

Fig. A5 | Evolution of sales of all cardiovascular drugs (ATC groups C01, C03, C07, C08, C09, C10)



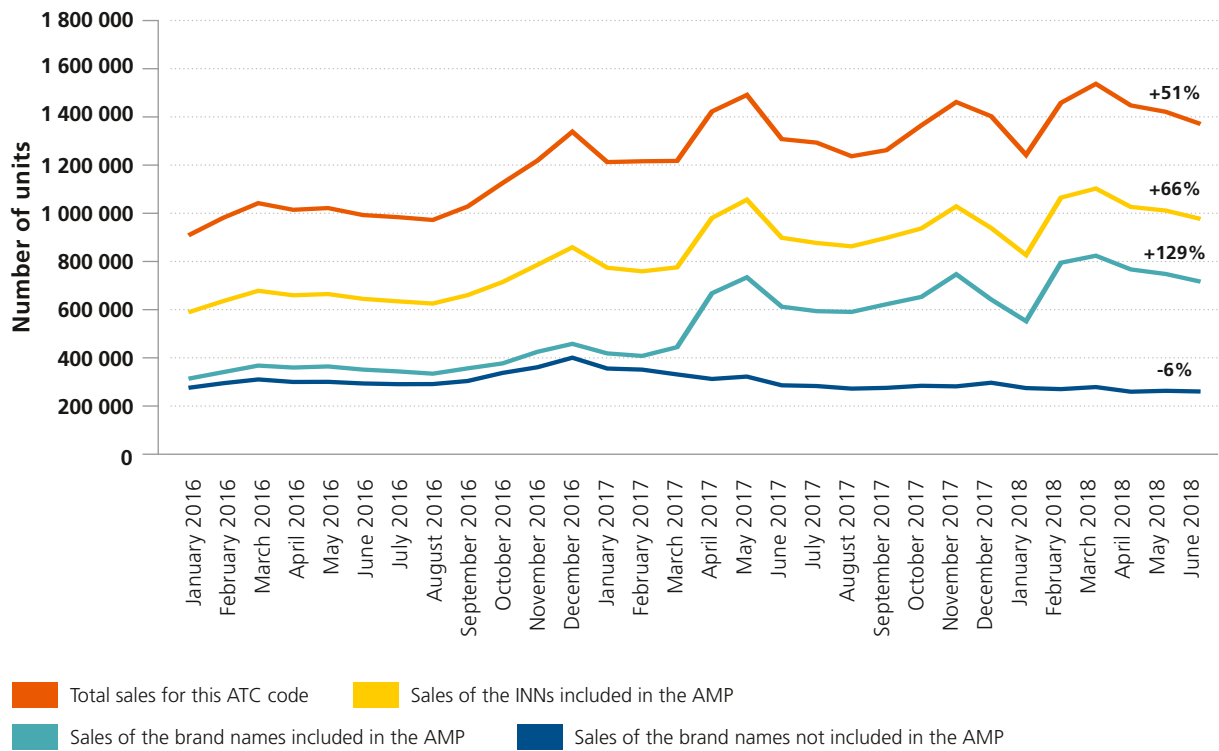
Source: data provided by Proxima Research; analysis undertaken by the authors.

Fig. A6 | Evolution of sales of ATC group C03 (diuretic drugs)



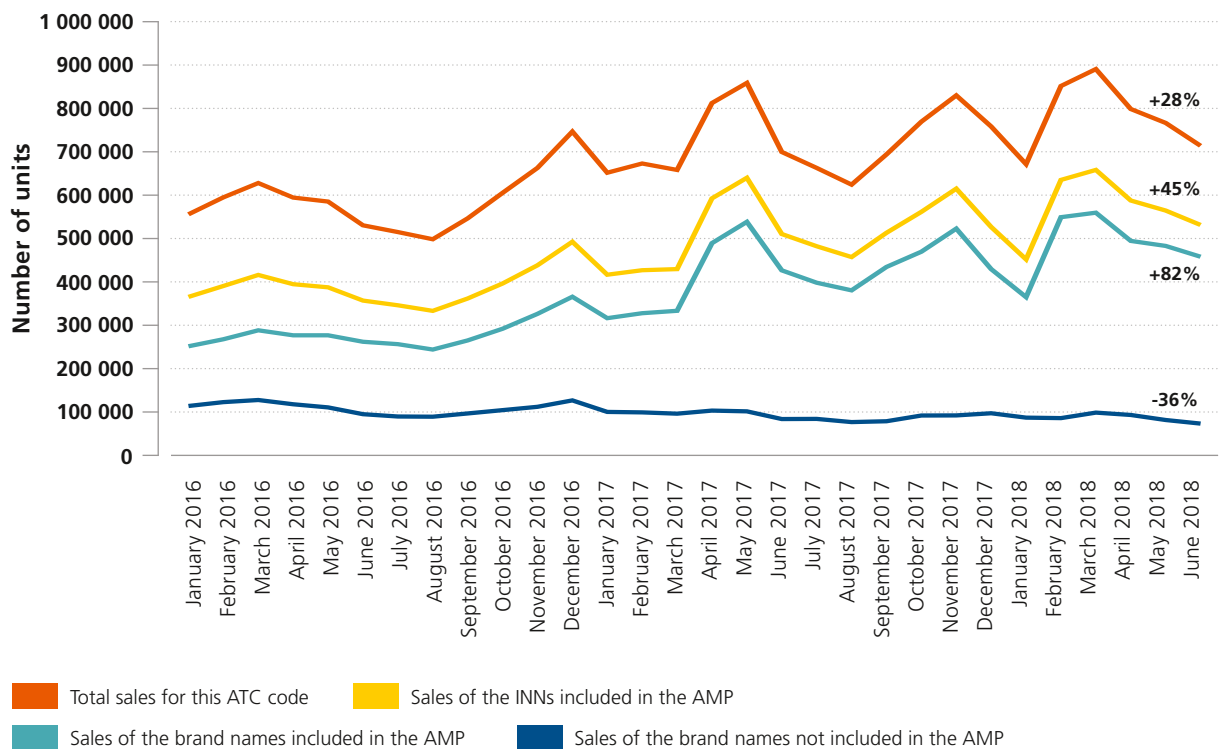
Source: data provided by Proxima Research; analysis undertaken by the authors.

Fig. A7 | Evolution of sales of ATC group C07 (beta-blocking agents)



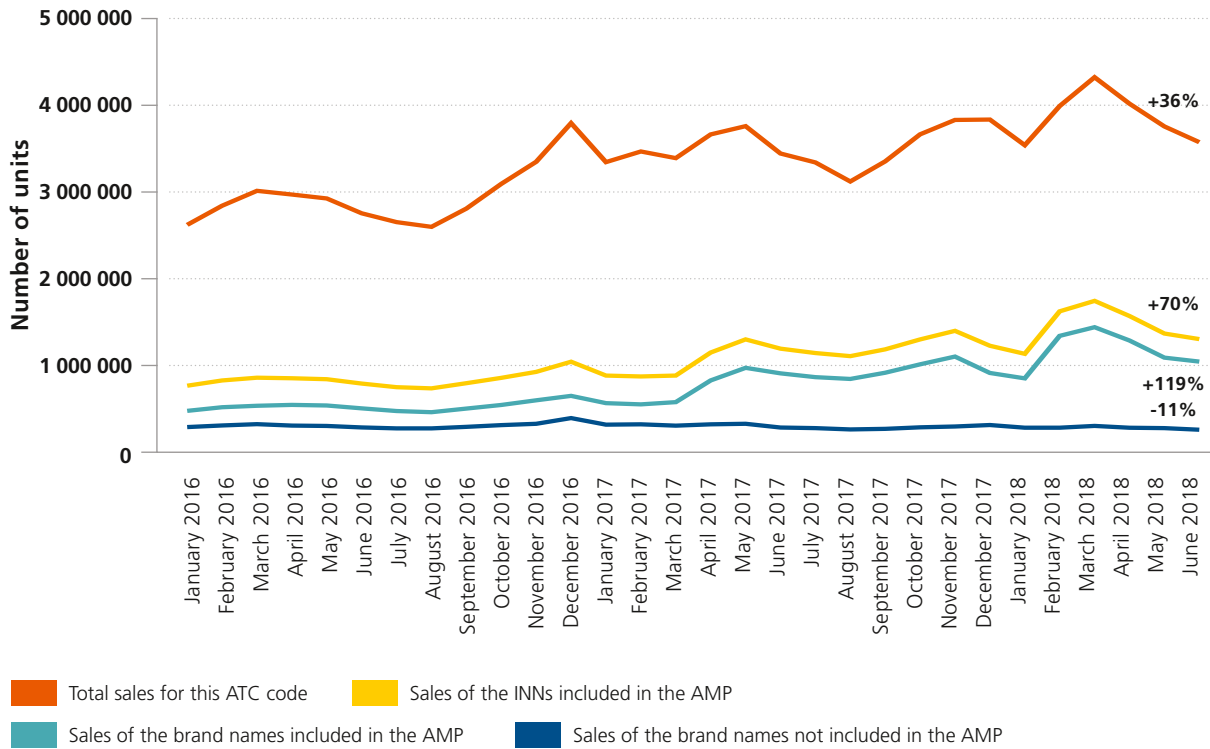
Source: data provided by Proxima Research; analysis undertaken by the authors.

Fig. A8 | Evolution of sales of ATC group C08 (calcium channel blockers)



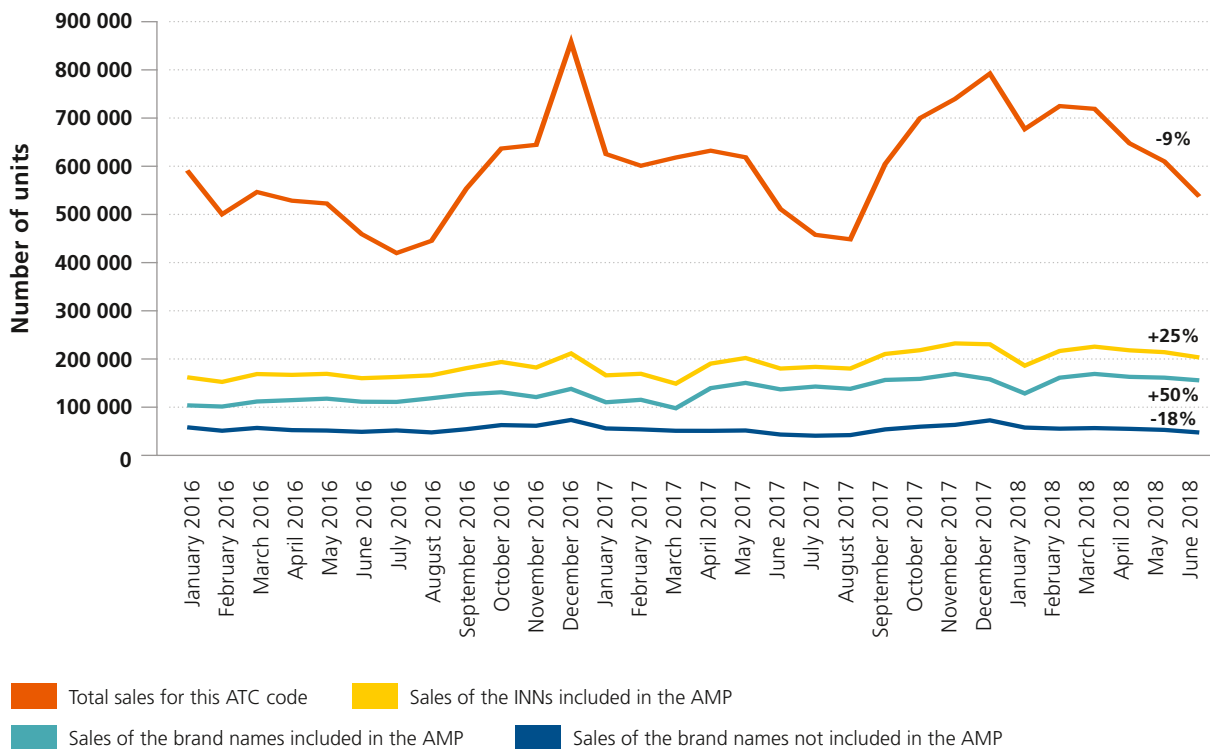
Source: data provided by Proxima Research; analysis undertaken by the authors.

Fig. A9 | Evolution of sales of ATC group C09 (agents acting on the renin-angiotensin system)



Source: data provided by Proxima Research; analysis undertaken by the authors.

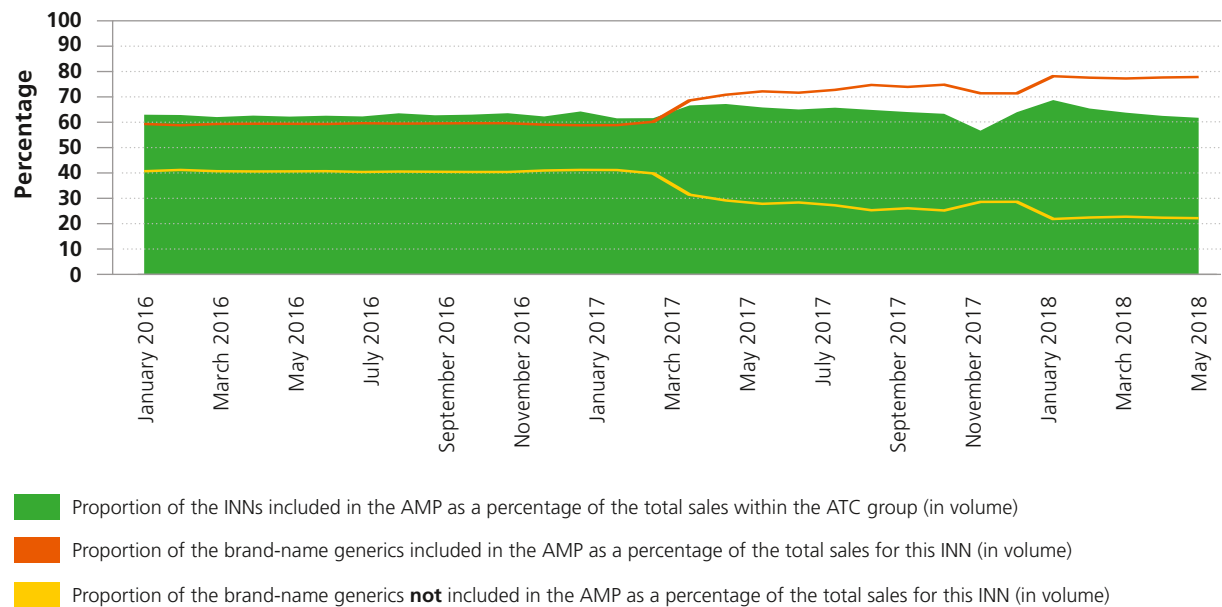
Fig. A10 | Evolution of sales of ATC group R03 (drugs for obstructive airway diseases)



Source: data provided by Proxima Research; analysis undertaken by the authors.

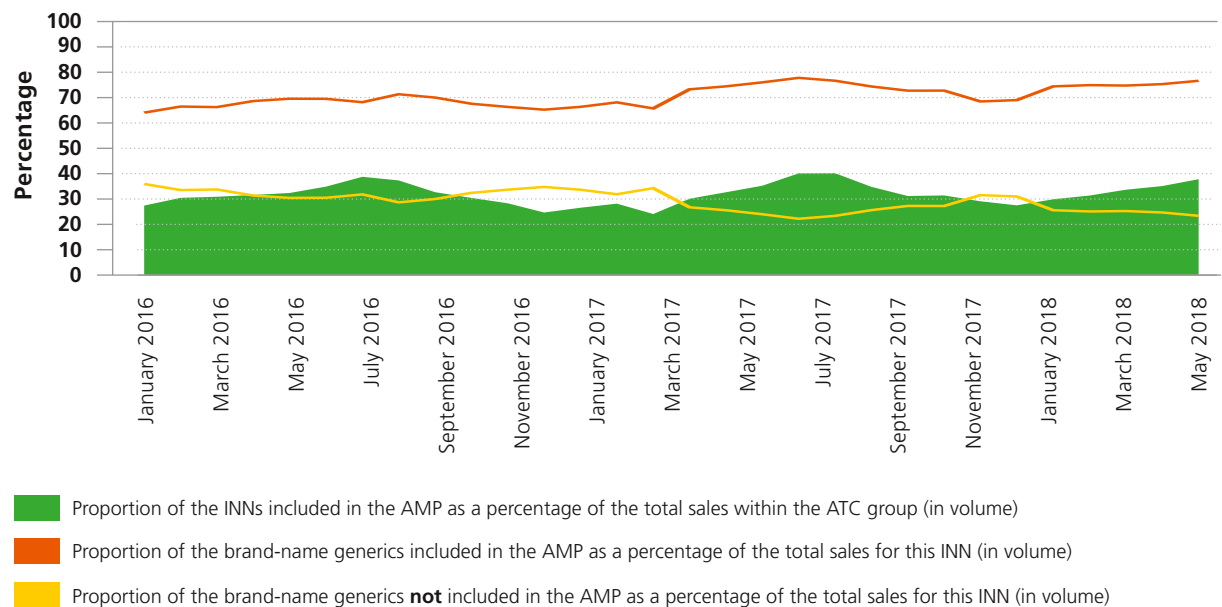
Figures A11 and A12 show the evolution of the structure of consumption within each ATC group included in the AMP.

Fig. A11 | Evolution of the structure of consumption in ATC group A10 (diabetes medicines)



Source: data provided by Proxima Research; analysis undertaken by the authors.

Fig. A12 | Evolution of the structure of consumption in ATC group R03 (drugs for obstructive airway diseases)



Source: data provided by Proxima Research; analysis undertaken by the authors.



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ISBN 9789289054003



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