

# Household spending in pharmacies: how much and on what?

Applied research in North Macedonia to improve tracking of health expenditure

North Macedonia

Tracking health spending

#### WHO Barcelona Office for Health Systems Financing

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### Abstract

Access to safe, effective, quality and affordable essential medicines is a central element of universal health coverage, and yet they are, in most countries, the main driver of out-of-pocket (OOP) spending on health and financial hardship. To address this challenge, evidence-informed decisions are required that can be tailored to the level of OOP spending on medicines and to the diseases and conditions for which people spend OOP in pharmacies.

North Macedonia has made significant progress in recent years in developing a detailed and advanced tracking health spending based on the System of Health Accounts (SHA) 2011 framework. This report is based on applied research aimed at further improving the system for tracking OOP spending on pharmaceuticals, with the potential to inform policy-makers in other countries and in similar contexts.

The research found that about one-fifth of community pharmacies' sales are non-medical goods, which may slightly increase the OOP on medicines, but in the case of North Macedonia doesn't reduce total OOP spending. Thus, it is recommended that a distribution key should be defined and applied for separating non-medical goods whenever aggregated data includes such sales.

To further inform decisions on medicines spending, when an anatomic therapeutic chemical coding of dispensed medicines is available or can be collected, it is useful to link and define pharmaceutical spending by major disease groupings based on the diseases classification of the SHA 2011 methodology.

It is recommended that similar studies are conducted in other countries of the WHO European Region to improve the tracking OOP spending on medicines.

## Contents

Acknowledgements vi Executive summary vii
Executive summary VII
Abbreviations >
1. Introduction
Pharmaceutical expenditure and overview of use
Use of non-prescribed pharmaceutical products
Purpose and objective
2. Research aim and methodology 7
Research aim
Methodology S
3. Findings and interpretation 15
Revenue structure of community pharmacies 17
Structure of OOP expenditure on medicines
with ATC code by major disease groups 22
Interpretation and conclusions: impact of research on the HA results 25
Limitations of this research 30
4. Conclusions 31
References 35
Annex 1. Methodology: data collection tools 37
Annex 2. Methodology: sample size and sampling strategy 38
Annex 3. SHA2011 codes for current health expenditures (CHE)
by disease/condition 40

### Tables

### **Figures**

Table 2.1. Data collection variables10

Table 2.2 Collected data by uniquetax ID and number of individualpharmacy outlets, 2018–202012

Table 2.3. Geographic distributionof collected data by number ofindividual pharmacy outlets andestimated population covered inmajor cities, all years13

Table 2.4. Collected data on totalsales in HA, 2018–202013

**Table 3.1.** Revenue structure of community pharmacies (million MKD), 2018–2020 17

Table 3.2. Expenditure structurein community pharmacies for OTCmedicines by type, 2018–202020

Table 3.3. Main SHA2011 codes forcurrent health expenditures (CHE)by disease/condition21

Table 3.4. Impact of researchfindings on the level of CHE andOOP expenditure in the HA for2018 and 201926

Table 3.5. Linking SHA2011 DIScodes and ATC codes28

Fig. 3.1. Structure of community pharmacy sources of revenue, 2018–2020 17

Fig. 3.2. Structure of revenues from OOP (non-HIF) sales, 2018–2020 18

**Fig. 3.3.** Structure of OOP expenditure in community pharmacies, 2018 19

**Fig. 3.4.** Structure of OOP expenditure in community pharmacies, 2019

**Fig. 3.5.** Structure of OOP expenditure in community pharmacies by major disease groups, 2018–2020 21

**Fig. 3.6.** Structure of OOP expenditure in community pharmacies by major NCDs, 2018 23

Fig. 3.7. Structure of OOP expenditure in community pharmacies by major NCDs, 2019 23

**Fig. 3.8.** Structure of OOP expenditure in community pharmacies by major IPDs, 2018–2020 24 **Fig. 3.9.** Structure of OOP expenditure in community pharmacies by ATC codes, 2018–2020 29

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### **Executive summary**

In the North Macedonian health system, 40% of current health expenditure is out-of-pocket spending, half of which is spent on pharmaceuticals. Pharmaceutical expenditure is the largest component of out-of-pocket spending and the main driver of financial hardship in many countries. Addressing this challenge requires evidence-informed decisions tailored to the specific level of out-of-pocket spending on pharmaceuticals and to the diseases and conditions for which people spend out of pocket in pharmacies. Access to safe, effective, high-quality and affordable essential medicines and rational use of them is a central element of universal health coverage.

North Macedonia has made significant progress in recent years in tracking health spending, applying an international methodology; the System of Health Accounts 2011 framework, advanced and tailored to the local context. This has allowed a much more accurate estimate of the country's health spending (including out of pocket) than most of the countries in the WHO European Region. However, despite this progress, the team tracking health spending noted that data from private providers (community pharmacies) are not sufficiently disaggregated to identify the purpose of consuming these medicines (for example, by separating health-related goods from other items purchased in pharmacies and then linking them with health conditions).

The research reported on here was conducted to address the data limitations mentioned above. More specifically, it was designed to identify and exclude the consumption of non-health commodities in community pharmacies, determine the medical use of medicines prescribed by private providers (that is, not by the national health insurance) and nonprescribed medicines (self-medication) sold by community pharmacies. This research is the first of its kind in the WHO European Region.

The main findings of the research were:

- 75% of overall out-of-pocket spending in community pharmacies is related to medical goods, with a dominant share of medical spending (94%) on pharmaceuticals;
- Out of all out-of-pocket spending on medical goods, only 57% of pharmaceutical spending is on drugs categorized in the Anatomic Therapeutic Chemical classification of medicines that can be largely coded by disease – for the rest, it was difficult to estimate the medical reason, disease or condition for purchase or use, since there was no associated Anatomic Therapeutic Chemical code or they represent other medicinal products;

 Out of all pharmaceuticals categorized by Anatomic Therapeutic Chemical code, 70% of the coded spending is on medicines used to treat noncommunicable diseases –mainly hypertensive diseases (20%), mental disorders (12%) and unspecified cardiovascular diseases (9%). Most of these medicines were purchased without any medical advice or prescription.

The research also provided more accurate exclusion of nonmedical goods, and findings showed that nonmedical spending had minimal effects on the total share of out-of-pocket spending in the country.

Finally, the research showed that available data on Anatomic Therapeutic Chemical classification can be reliably used to allocate pharmaceutical expenditure by major disease or condition groups based on the System of Health Accounts 2011 methodology. Such an exercise can be useful for predicting the use of medicines purchased out of pocket (non-prescription and self-medication) by disease, and ultimately improving estimations of out-of-pocket expenditure on pharmaceuticals by disease or condition.

Such a comprehensive tracking of pharmaceutical spending provides crucial information on how households spend in pharmacies and will serve as a further evidence based for policy-makers in other countries with a similar pharmaceutical environment (in particular in countries with a high level of irrational use of drugs resulting from ineffective prescription practices).

## Abbreviations

ATC	Anatomic Therapeutic Chemical
CHE	current health expenditures
DIS	SHA disease classification
DS-TB	drug-sensitive tuberculosis
EU	European Union
GBD	global burden of disease
HA	Health Accounts
HIF	Health Insurance Fund
HIV/AIDS	human immunodeficiency virus/auto immune deficiency syndrome
ICD	International Classification of Diseases
IPD	infectious and parasitic disease
MDR-TB	multidrug-resistant tuberculosis
NCD	noncommunicable disease
NEC	not elsewhere classified
OECD	Organisation for Economic Co-operation and Development
OI	opportunistic infection
OOP	out-of-pocket
OTC	over-the-counter
POMs	prescription-only medicines
SHA	System of Health Accounts
SSO	State Statistical Office
STD	sexually transmitted disease
ТВ	tuberculosis
XDR-TB	extensively drug-resistant tuberculosis

# 1. Introduction

## Pharmaceutical expenditure and overview of use

Pharmaceutical spending is one of the largest components of national health spending, ranking third in European Union (EU) and Organisation for Economic Co-operation and Development (OECD) countries' health budgets after inpatient and outpatient care, and rising as a percentage of gross domestic product (Kanavos et al., 2011; OECD, 2013). North Macedonia is no exception; in 2017, pharmaceutical expenditure was the second largest component of national health spending, constituting one third of total health expenditures; more than half of which was borne by households.

Pharmaceutical expenditure includes spending on prescription and overthe-counter (OTC) medicines and products, as well as other non-durable (disposable or single-use) medical goods, the consumption of which is not integrated to the services. In North Macedonia, while pharmaceutical expenditure and use of medicines prescribed and dispensed under the health insurance system can be analysed in great detail, the remaining portion of medicinal products – including prescription-only medicines (POMs) dispensed without prescription, as well as non-prescription medicines and OTC products – is very difficult to track, disaggregate and quantify (Milevska-Kostova, 2017).

In recent years, the WHO definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" has been expanded to include another aspect, linked to cultural, economic and social factors, which suggests that the meaning of health is no longer confined to only limiting illness, but also encompasses investing in prevention of illness, improving well-being and maintaining health. This also reflects on the definition of so-called health products used in everyday life. Citizens and patients often buy from pharmacies products known as lifestyle medicines, such as supplements, as well as non-medical products such as toiletries, cosmetics, dietetics, and so on (Bernardini, Ambrogi & Perioli, 2003).

Thus, the concept of health has been broadened to include self-care. According to WHO, self-care includes "what people do for themselves to establish and maintain health, prevent and deal with illness", and concerns: hygiene (general and personal), nutrition (type and quality of food eaten), lifestyle (sporting activities, leisure), environmental factors (living conditions, social habits), socioeconomic factors (income level, cultural beliefs) and self-medication (WHO, 1998).

Part of self-care in the context of this research is also self-medication, described as a practice by individuals treating conditions and diseases that usually have not been diagnosed. Such treatment commonly involves medicines that are approved and available without prescription, and which are safe and effective when used as directed – for example, use of anti-inflammatory medicines for treating headache, back pain or toothache (Bernardini, Ambrogi & Perioli, 2003). However, self-medication is also reported for medicines that are approved for use only with medical advice or prescription; that is, POMs. From both aspects, self-medication

is becoming increasingly important and is recognized today as part of health care systems and health financing. Several studies confirm that supplements and OTC pharmaceuticals – the use of which represents a significant part of self-medication – have an increasing share of the pharmaceutical market (Masumoto et al., 2018).

# Use of non-prescribed pharmaceutical products

It is well known that it is hard to assess the actual use of medicines and medicinal products purchased without prescription or any other medical advice or indication. Moreover, diagnoses are one of the essential key features for assessment of cost-effectiveness and guality monitoring of any health care services, and, more importantly, for effective use of health resources on pharmaceuticals (Filzmoser, Eisl & Endel, 2009). In both outpatient and inpatient health service delivery, a standardized, internationally recognized and reliable diagnosis system exists; namely, the WHO-published International Classification of Diseases (ICD), the use of which is becoming more commonplace in increasingly more countries worldwide (WHO, 2022c). The ICD classification is used for indicating the medical need for a specific medicine or therapy, and these codes are used by medical doctors and prescribers. However, for medicines that are purchased without any prescription or medical indication and advice, it is impossible to define the actual use from the pharmacy records based on the ICD. As a result, and in a similar vein to the classification of diseases, an internationally standardized Anatomic Therapeutic Chemical (ATC) classification of medicines was introduced. Since under ATC medicinal products are classified according to the main therapeutic use of the main active ingredient this was used as one of the methods to identify which medicines have been dispensed, and in addition to attempt to understand and estimate what these medicines were used for; that is, for prognosis diagnoses through the use of the ATC codes for pharmaceutical products that have been prescribed (WHO, 2022). However, the ATC system does not in general include complementary and herbal traditional medicinal products, including supplements (WHO, 2022).

Some attempts to predict medicine use through different data sources have been made in the past, for example using pharmacy data, which was found to be highly reliable to predict the prevalence of some chronic conditions (Chini et al., 2011). On a wider systemic scale, several scholar groups linked ATC codes to the ICD classification for the same purpose (Endel & Weibrecht, 2019; Filzmoser, Eisl & Endel, 2009; Weisser et al., 2008) and established a reliable system for predicting use of non-prescribed medicines for the closest possible diagnosis.

The ICD and ATC are standardized classifications primarily for medical and clinical use to ensure optimal and standardized care for individual patients, and are also used for epidemiological as well as economic purposes.

The internationally accepted standard for classifying diseases is the ICD, which is regularly revised and published by WHO. There is a new version available (ICD11); however, many countries are still using the previous versions at the time of writing (ICD10, and to a lesser extent, ICD9). With that in mind, all recent work on identifying expenditure by disease uses disease categorizations based on the ICD-10 (or the earlier ICD-9) classifications. The ICD was developed to categorize diseases by diagnosis in order to collect mortality and morbidity information (e.g. on prevalence, incidence, and so on), which is used in a wide range of public health policy areas. This information supports decision-makers with regard to disease prevention, public health programmes, treatment and reimbursement schemes.

However, the ICD-10 system in its full implementation defines more than 30 000 different disease classes and about 1000 agreed levels of classes for international reporting. The production of estimates according to this agreed level is impractical in terms of actual final presentation and is often not feasible given the sample sizes and level of disease coding of many primary data sources. These constraints necessitate the use of a more aggregated grouping of ICD classes. Countries that analyse expenditure by disease have restricted themselves to broad ICD-10 chapters (BASYS, CEPS & IGSS, 2006), or have adopted country-specific groupings of ICD codes, as in the United States (Roehrig et al., 2009). Some have used the same categories used in the WHO Global Burden of Disease (GBD) study (or a modified version), as is the case in Australia and Sri Lanka. The GBD study has its own disease classification that represents a grouping or meta-classification of ICD classes (IHME, 2018). In the absence of a single international standard classification for collecting data, the System of Health Accounts methodology of 2011 (SHA2011) proposed its own specific disease classification (DIS) based on the GBD classification, adapted at a high level of aggregation, and the ICD-10 main chapters (OECD, Eurostat & WHO, 2011). In other words, the SHA2011 DIS classification is an aggregated grouping of ICD classes, and so can be fully mapped to ICD classes. According to the SHA2011 methodology, categorization of diseases based on the GBD classification system was found to be most appropriate for international comparisons of expenditure by disease. The SHA2011 methodology also acknowledges the existence and potential use of the ATC classification; however, it does not provide guidance on its use to estimate health expenditures by disease. To this end, only limited literature was found on using ATC codes to predict the diagnosis and use of medicines issued without prescription, as categorized in the SHA2011 DIS classification. Such an exercise can be useful for predicting the use of medicines paid for out of pocket (non-prescription and self-medication) by disease, and to that end, estimating out-of-pocket (OOP) expenditure on pharmaceuticals by disease or condition.

## Purpose and objective

In 2017 North Macedonia requested technical assistance from WHO to establish and institutionalize health accounts (HA) as part of its commitments to the EU accession process.<sup>1</sup> Within this process, and as part of the six key areas of the *EU acquis* in statistics, establishing and institutionalizing a system of national accounts (including HA) is an imperative.

1. The *EU* acquis (Chapter 18: Statistics) defines the harmonization of statistics with EU standards and rules which must be achieved in the pre-accession period. This chapter covers six areas, one of which is the system of national accounts (Eurostat, 2022). During 2018–2019, WHO provided technical assistance to the Ministry of Health and the State Statistical Office (SSO) in conducting the first HA study for 2017) (HA 2017). The results from HA 2017 were discussed and adopted in a consultative manner and were submitted by the country for publishing in the Global Health Expenditure Database in 2020 (WHO, 2022b).

One of the main findings of the HA 2017 study was that pharmaceutical expenditure constitutes the second largest share of health spending, more than half of which is borne by households.

It was also identified that, while the country has a very elaborate and reliable data collection system, most of the data relate to health expenditures in the public domain, and regularly gathered data from private health providers are not sufficiently disaggregated to enable analysis of health expenditures occurring in this sector.

From a methodological point of view it was concluded that this data limitation hampers:

- identifying and excluding the consumption of non-health commodities in outpatient (community) pharmacies; and
- determining the purpose of medicines dispensed with a prescription from private providers not covered by the national Health Insurance Fund (HIF)), as well as medicines without any prescription (private purchases and self-medication).

This data limitation at a community pharmacy level skews the entire landscape of pharmaceutical expenditure in North Macedonia.

With the above factors in mind, the main objective of the proposed study is to gather and analyse data from individual community pharmacies, in order to: (i) respond to the above problem appropriately; (ii) explore the possibility of creating a distribution key for the structure of consumption at community pharmacy level; and (iii) explore the possibility of institutionalizing this data collection process as part of the health expenditure tracking mechanism in North Macedonia.

# 2. Research aim and methodology

## Research aim

With the currently available data it is impossible to distinguish the medical and pharmaceutical from non-medical sales in pharmacies, which unintentionally inflates the OOP expenditure on pharmaceuticals in the HA. This research is concerned with understanding the scope of OOP expenditure on medical/pharmaceutical goods, and therefore aims to produce two main outcomes:

- create a model to assess the distribution of costs at community level, which would allow an estimation of expenditure on non-health commodities purchased in community pharmacies, for the purpose of adjusting OOP expenditure on pharmaceuticals; and
- create a distribution key for the disease indication/use of pharmaceutical products with medical indication, which are dispensed without prescription or with a prescription that is not part of the mandatory health insurance scheme.

## Methodology

As part of the SHA annual data collection, most OECD and EU countries provide information on retail pharmaceutical expenditure; that is, consumption of medical goods in outpatient or community pharmacies, including prescribed, non-prescribed and OTC medicines (OECD, 2019a). The data are collected routinely both from reimbursement databases and directly from community pharmacies (OECD, 2019b).

The Methods to analyse medicine utilization and expenditure to support pharmaceutical policy implementation published by WHO (WHO, 2018) proposes use of pharmacy records on dispensed medicines and medical products; the data should include at least a patient identifier, the name of the medicine, along with the dosage form, strength, quantity and cost of each medicine dispensed.

#### Data sources and collection tools

Regarding data collection, since this research aims to provide better disaggregation and more detailed coding for the HA, and at the same time HA are part of the mandate and activities of the SSO, it was decided to collect the data through the SSO's already-established communication channels with all legal entities (including pharmacies). Furthermore, the SSO is authorized to collect and analyse microdata for statistical purposes.

The data collection process was based on the respective SSO bylaws and data collection protocols, including: (i) developing a special template for data collection, based on SSO data requirements; and (ii) obtaining contacts from the official contact list at the Central Registry Office database for all entities registered as pharmacies.

The template, developed in Microsoft Excel table format, requires disaggregated data to be inserted according to four main categories of products:

- pharmaceuticals for which the name or ATC code is known dispensed either under prescription that is not covered by the mandatory health insurance (so-called non-HIF prescription) or without any prescription;
- other medical and non-medical products (durable and non-durable);
- medical (orthopaedic) devices, by type of device; and
- individual products that could not be categorized by the pharmacies in the above predefined tables.

The required variables included name and type, value or amount of dispensed/sold products and the location of the pharmacy where it was sold/dispensed. To ensure uniformity, detailed instructions for data collection were prepared, as shown in Annex 1.

To simplify the process and ensure a higher response rate, the template did not include collecting data for pharmaceuticals covered by the HIF through the mandatory health insurance scheme. Such data are already regularly obtained for the HA process from the HIF data system and, due to the very high level of data disaggregation and accuracy resulting from that system, it was considered unnecessary to gather the same data again for validation purposes.

Data were collected for three consecutive years (2018, 2019 and 2020) and included the variables listed in Table 2.1.

#### Table 2.1. Data collection variables

Category	Location	Name (generic)	ATC (if available)	Quantity dispensed	Cost
a. Pharmaceuticals issued with non-HIF prescription or without prescription	•	•	•	•	•
b. Other medical and non-medical products (durable and non-durable)	•	•	•	•	•
c. Medical (orthopaedic) devices by type	•			•	•
d. Non-medical goods	•				•

#### Sample size and sampling

As of 1 February 2021, according to the database held by the Ministry of Health, 1067 pharmacies were registered; of which, after filtering the data (removing hospital pharmacies, closed outlets and other types of pharmacy), 994 were identified as **community** pharmacies. According to HIF data, at the time of data collection, 791 community pharmacies were contracted to dispense medicines under the mandatory health insurance scheme. Online sales/dispensing of POMs or medicines with any pharmacological ingredient is not allowed in the country; therefore, no online pharmacies were considered or included in the sample.

To determine the sampling strategy, analysis was undertaken of the number of pharmacies and structure of the community pharmacy market by ownership and insurance coverage (see Annex 2).

As described in Annex 2, community pharmacies in North Macedonia are registered as private trade (commercial) entities and, by law, those having more outlets are registered under the same taxpayer identification number (taxID), unique for each company, including pharmaceutical retailers.

To align data collection, analysis and interpretation to the needs of the HA development process, data were collected and presented by unique taxID of the pharmaceutical retailers, as well as by number of pharmacies/outlets represented in the sample.

The sampling strategy included all 994 community pharmacies, reached by contacting 487 pharmaceutical retailers.

#### Data collection and checking inclusion criteria

On 2 July 2021, the invitation for data collection was sent by the SSO to all 487 pharmaceutical retailers with a registered unique taxID number to their official e-mail addresses, as retrieved from the Central Registry Office database. To ensure comparability of data across the analysed time period, only the 487 unique taxID retailers with active status in all three years of data collection and with valid e-mail addresses were included in the sample.

The invitation included information on the research, the template for data collection and instructions for completing the template, as well as contact details for any clarifications or further information required. Initially, the data collection period was set between 2 and 23 July 2021 but, due to the holiday season and feedback from some pharmacies that they needed more time (either the responsible person was not available or retrieving the data required longer), the data collection period was extended until 17 August 2021.

In order to be included in the analysis, the collected data went through several rounds of criteria checks, ensuring:

- presence of the minimum variables needed for the research; and
- disaggregation of the data by product (for pharmaceuticals).

In order to validate the accuracy of the data, an additional criterion was applied; the total sales value data had to be in line with the total revenues reported to the Public Revenue Office for the corresponding year. Data on the total revenue for each taxID were available from the regular data collection for HA development process. After checking compliance with the inclusion criteria, 34 pharmacies were excluded due to lack of minimum variables in the dataset, especially for pharmaceutical products. In these, the data for pharmaceuticals were provided as aggregated total costs, which was considered inappropriate for further analysis, mainly because it would affect the outcome with regards to the distribution of OOP expenditure by disease, which was one of the key outputs of this research.

As already mentioned, to align data collection, analysis and interpretation to the needs of the HA development process, data were collected and presented according to specific criteria (see Table 2.2).

It is significant that all three of the largest pharmaceutical retailers (Eurofarm, Zegin and Moja Apteka) provided their data for analysis; together they own 247 individual outlets.

In terms of geographic representation, the sample was relatively well distributed across the country, with estimated coverage of approximately 42% of the entire population (Table 2.3).

Table 2.2 Collected data by unique tax ID and number of individual pharmacy outlets, 2018–2020

Year	No. of unique taxpayers	Verified e-mails contacted	Datasets received	Datasets passing inclusion criteria	No. of pharmacy outlets
2018	489	487	134	117	381 (44.82%)
2019	493	487	150	117	381 (44.82%)
2020	507	487	151	117	381 (44.82%)

Table 2.3. Geographic distribution of collected data by number of individual pharmacy outlets and estimated population covered in major cities, all years

16

152

29

19

29

13

%

pharmacies

analysed

72.7

59.1

50.0

50.0

48.3

48.1

Estimated

total

population\*

52 575

630 686

94 651

85 136

121 029

57 783

Estimated

population

covered

38 236

373 013

47 326

42 568

58 497

27 821

Pharmacies

in sample

City

Shtip

Skopje

Bitola

Prilep

Veles

Kumanovo

Registered

pharmacies

22

257

58

38

60

27

\* Based on the number of individuals insured by the HIF.

Onna	39	17	43.6	55 698	24 279
Kochani	21	9	42.9	38 681	16 578
Gostivar	38	16	42.1	87 366	36 786
Kavadarci	26	10	38.5	43 749	16 827
Strumica	37	12	32.4	83 230	26 994
Gevgelija	18	5	27.8	30 620	8 506
Struga	32	7	21.9	52 714	11 531
Tetovo	67	4	6.0	170 503	10 179
Kichevo	24	1	4.2	43 144	1 798
Other cities	230	42	18.3	221 944	40 529
Total	994	381	38.3	1 869 509	781 466 (42%)

of collected data according to the total volume of sales for the three respective years.

Table 2.4. Collected data on total sales in HA, 2018–2020

Year	Total amount of sales	Sales by pharmacies	s (all collected data)	Sales by pharmacies with complete data		
	(in million MKD)	(in million MKD)	(%)	(in million MKD)	(%)	
2018	13 775	8 336	60.52	7 835	56.88	
2019	14 885	8 997	60.45	8 459	56.83	
2020	16 399	10 076	61.44	9 459	57.68	

# 3. Findings and interpretation

# Revenue structure of community pharmacies

The analysed data collected from community pharmacies showed that in 2018 their total revenue was MKD 7.8 billion, which increased to MKD 8.5 billion and to MKD 9.5 billion in 2019 and 2020, respectively. Around 20% of the revenue for these pharmacies came from providing medical goods to the insured population covered by the HIF (Fig. 3.1).

The revenues in absolute amounts (million MKD) are given in Table 3.1.



## Table 3.1. Revenue structure of community pharmacies (million MKD), 2018–2020

Year	2018	2019	2020
Total revenue from sales (million MKD)	7 834.58	8 458.85	9 459.15
From HIF*	1 622.26	1 485.65	1 615.58
Revenues from private (OOP) sales of medical products non-medical products	4 519.75	5 154.42	6 035.36
Additional payments	89.79	102.62	105.94

\*The decrease in HIF revenue in 2019 is due to liquidity management by the HIF.

#### Defining the share of OOP expenditure on non-medical goods

One of the important aims of this research was to define the share and understand the structure of non-HIF revenues of community pharmacies, with the aim of understanding (i) the share of OOP health expenditure by this group/level of health care providers; and (ii) the share of community pharmacy revenue from non-medical (or non-health) goods.

Based on the surveyed sample, the share of revenue from non-medical goods sales was 26% and 25% in 2018 and 2019, respectively, while in 2020 it dropped to 22% (Fig. 3.2). Or, in other words – and as anticipated at the conceptualization stage of the research – OOP expenditure on medical products increased during 2020, as a result of the ongoing pandemic. For this reason, the year 2020 was not included when defining the distribution keys for OOP payments for pharmaceuticals and other medical goods obtained in community pharmacies, as the year was considered an outlier, and its data would significantly distort the resulting distribution keys.





#### Structure of OOP expenditure on medical goods

Most of the OOP payments in community pharmacies were for OTC medicines, accounting for 94% in both 2018 (Fig. 3.3) and 2019 (Fig. 3.4), followed by around 4% for other non-durable medical goods and 2% for all other durable medical goods. Eyeglasses and other vision products and orthopaedic devices are also sold by community pharmacies, but their share was insignificant in the years analysed (<1% combined).



#### **OTC** medicines

According to the SHA2011 methodology, OTC medicines (OTC code HC.5.1.2) comprise all pharmaceuticals, including branded and generic pharmaceutical products which may or may not be available without prescription but have been purchased independently (OECD, Eurostat & WHO, 2011).

For the purpose of this analysis, OTC medicines were divided into two groups: medicines that are categorized in the ATC classification of medicines; and all others. For 2018 and 2019, medicines with an ATC code accounted for 57% and 56%, respectively (Table 3.2). Medicines with an ATC code were further analysed to determine their dominant use by disease code (DIS), whereas this was not possible for medicinal products without ATC classification (e.g. ancillary and borderline products). As Table 3.2 shows, for 2020 this figure was significantly lower than the other two years (49%), contributing to the conclusion that data for 2020 are not suitable for generalization of findings or inclusion in the distribution key calculations.

Table 3.2. Expenditure structure in community pharmacies for OTC medicines by type, 2018–2020

	2018	2019	2020
Medicines with ATC (%)	57	56	49
Medicinal products without ATC (%)	43	44	51

#### Structure of OOP expenditure by major disease groups

According to the SHA2011 methodology, information on expenditures by disease can serve several purposes, such as monitoring and providing information about resource allocation by disease or defined priority area. Linked with HAs, such information can feed into the policy-making process by addressing certain important questions, including which diseases or conditions consume the most health care resources, which financing scheme is funding the related services and how expenditures are distributed across levels of care. In this way, HAs provide useful inputs for resource planning and allocation.

Bearing in mind the scale of pharmaceutical expenditure as a proportion of total health care spending, it is important to understand the structure of OOP spending on pharmaceutical products by disease/condition. Although SHA2011 coding for diseases/conditions (DIS codes) is not very nuanced, it can provide a sound overview of health expenditures by major disease groups (Table 3.3), which is sufficient for high-level policy-making, resource planning and allocation. Annex 3 provides more detail on the main SHA2011 DIS codes. Table 3.3. Main SHA2011 codes for current health expenditures (CHE) by disease/condition

DIS code	CHE by disease/condition
DIS.1	Infectious and parasitic diseases (IPDs)
DIS.2	Reproductive health
DIS.3	Nutritional deficiencies
DIS.4	Noncommunicable diseases (NCDs)
DIS.5	Injuries
DIS.6	Non-disease-specific
DIS.NEC	Other and unspecified diseases and conditions (not elsewhere classified)

The analysis of data by main SHA2011 disease categories showed that a dominant share of 70% and 71% (in 2018 and 2019, respectively) was used to treat NCDs (DIS 4) (Fig. 3.5), followed by 16% in both years for IPDs (DIS 1). Further, 11% and 10% (in 2018 and 2019, respectively) was spent on medicines not specific to any disease and medicines with ATC for unspecified diseases/conditions (DIS 6). Nutritional deficiencies, reproductive health and injuries were found to be insignificant in the total structure.



Similarly to 2018–2019, OOP expenditure on pharmaceuticals in 2020 was mostly spent on treating NCDs (71%), IPDs (16%) and medicines that were not specific to any disease (11%) (see Fig. 3.5).

# Structure of OOP expenditure on medicines with ATC code by major disease groups

In addition to an overview of the OOP expenditure structure by major disease groups described above, it is useful to understand the structure of the OOP payments for different diseases and conditions within each of the major disease groups that constitute the majority of the OOP payments; namely, NCDs (DIS 4) and IDPs (DIS 1). Given the limitation of the granularity of SHA2011 codes for the non-disease specific code (DIS 6), although nearly one tenth of the expenditure occurs for this category, it is not possible to present a more detailed analysis of expenditure on these groups of pharmaceuticals.

#### OOP payments for medicines with ATC code used for NCDs (DIS 4)

The largest share of OOP payments in community pharmacies could not be attributed to any specific group of NCDs (i.e. 23% in 2018 and 25% in 2019; see Fig, 3.6 and Fig, 3.7) – understandably so, since these medicines and pharmaceutical products were dispensed either without a prescription, or with a prescription from a private provider, for which diagnosis or purpose for the prescription were not necessarily noted. The largest share of pharmaceuticals attributable to a specific NCD group were dispensed for cardiovascular diseases or hypertension, and in particular antihypertensive medicines (20% and 19% in 2018 and 2019, respectively), followed by medicines for mental health and associated disorders (12% and 11%), and other unspecified cardiovascular diseases (9% in both years). The share of pharmaceuticals purchased privately for other NCDs are shown in detail in Fig. 3.6 and Fig 3.7.



#### Fig. 3.6. Structure of OOP expenditure in community pharmacies by major NCDs, 2018



#### Fig. 3.7. Structure of OOP expenditure in community pharmacies by major NCDs, 2019

#### OOP payments for medicines with ATC code used for IPDs (DIS 1)

Within the IPDs group, the largest share of OOP payments occurred for other and unspecified IPDs (71% and 70% in 2018 and 2019, respectively) (Fig. 3.8), followed by diarrhoeal diseases (18% and 19%), and respiratory infections (11% in both years). Tuberculosis (TB), HIV and other infectious diseases for which the SHA2011 has distinct codes are neither endemic nor present significant morbidity burden and thus contribute insignificantly to overall health expenditures as well as to the OOP payments on pharmaceuticals.



## Interpretation and conclusions: impact of research on the HA results

## Adjusting OOP payments for pharmaceuticals by excluding non-medical goods

One of the main purposes of this research was to define the share and structure of medical and non-medical expenditures by analysing revenue data from community pharmacies, with the ultimate goal of identifying the share of expenditures that did not occur as a result of medical or health need but was instead of a non-medical nature. This is important in order to produce a more accurate estimation of OOP payments in health expenditure tracking by excluding any spending on non-medical products and goods.

The methodology used to estimate the level of OOP payments within health expenditures in North Macedonia is based on a bottom-up approach, using administrative data. However, bearing in mind that at community level purchases are made directly by the population, the residual method for pharmacies (HP.5.1) is adjusted based on the information on spending on drugs and devices from the Household Budget Survey and the share of this in overall household consumption.

In addition, analysing the primary data collected through this research enabled OOP payments for both medical and non-medical goods in community pharmacies to be distinguished from each other, and OOP payments for pharmaceuticals within the HA to be further adjusted as a result. As described earlier, in 2018 and 2019 on average one fifth (20%) of total revenue in community pharmacies was from non-medical goods. This had the effect of decreasing the actual figures for total OOP expenditure on pharmaceuticals by 8% and 13% in 2018 and 2019, respectively (Table 3.4).

#### Extrapolating adjusted OOP payments for pharmaceuticals to CHE

The next step in the analysis was to determine the impact of the excluded revenues from non-medical goods in community pharmacies on the total CHE within the HA.

Table 3.4 presents the difference between the HA results obtained by analysing the original datasets; that is, total revenues of community pharmacies from private OOP sales, which include both medical and nonmedical goods, and the adjusted HA results after applying the derived distribution key for OOP expenditure.

## Table 3.4. Impact of research findings on the level of CHE and OOP expenditure in the HA for 2018 and 2019

HA results	Using original	datasets	Adjusted for by research results		
	2018	2019	2018	2019	
Total CHE (in million MKD)	43 318.90	50 011.58	42 672.85	48 948.73	
Total OOP (in million MKD)	18 241.43	20 195.96	17 595.37	19 133.11	
as % of total CHE	42.11	40.38	41.23	39.09	
Total OOP in pharmacies (HF.3.1) (in million MKD)	8 431.29	9 652.56	7 785.24	8 667.07	
as % of total CHE	19.46	19.30	18.24	17.71	
Absolute and relative difference	2018	2018 (%)	2019	2019 (%)	
Total CHE (in million MKD)	646.05	1.49%	1 062.85	2.49%	
Total OOP (in million MKD)	646.05	3.54%	1 062.85	6.04%	
as % of total CHE	0.88	2.09%	1.29	3.13%	
Total OOP in pharmacies (HF.3.1) (in million MKD)	646.05	7.66%	985.49	12.66%	
as % of total CHE	1.22	6.27%	1.59	8.72%	

Extrapolation of the analysed sample results for the entire OOP spending on pharmaceuticals in the HA shows a decline in total CHE – this is understandable, since the total OOP expenditure decreased by the amount not used for medical and health-related needs. In other words, if the average percentage of revenue from non-medical goods in the analysed pharmacies (26% in 2018 and 25% in 2019) is applied across all pharmacies in the country, the total CHE and OOP decreases by MKD 0.6 billion in 2018 and by MKD 1.1 billion in 2019. This, in turn, reflects on the HA results as a decrease in the share of OOP in the total CHE from 42.1% to 41.2% in 2018 and from 40.4% to 39.1% in 2019.

It is worth noting that this exercise is indicative and intended to prove the hypothesis on the significant impact of non-medical expenditure at community pharmacy level on the accuracy of overall HA results. Proving the hypothesis with this research provides grounds for further applying the results of this research directly into the HA production system, where more precise and accurate calculations can be made using the exact values and level of CHE and OOP spending for any given year.

The above calculations relate to the applicability of the model and distribution key for 2018 and 2019, specifically; however, it will be important to consider its applicability on other years, both retrospectively and prospectively. Given the fact that prior to 2018, there were no significant policy changes with regards to access, prices or availability of POMs, other pharmaceuticals, medical and non-medical goods, and there were no medical emergencies of the scope and magnitude of the COVID-19 pandemic, it is acceptable to assume that for the years prior to 2018 (e.g. 2017) the results of this research could be applied to adjust the CHE and OOP spending figures. A suggested precondition would be to compare the relative values of CHE and OOP spending for 2017 to the analysed years, as a checkpoint for validating the applicability of the defined distribution key.

The significant distortion of results for the year 2020, due to the COVID-19 pandemic, demonstrate that there is a level of uncertainty for repetitive use of the model in outlier years. As similar effects on the HA results (from the pandemic) can reasonably be expected for 2021 as well, it might be of some value to consider the 2020 results as a special distribution key for cases of medical emergencies. However, such application would require additional prerequisites to be satisfied, including (for example) level and magnitude of the pandemic/emergency, similarity of patterns of use of medical and non-medical goods during the pandemic, and so on.

#### Linking SHA2011 DIS codes to ATC classification of medicines

In addition to being important for standardizing individual care, diagnoses represent critical and particularly relevant data in the field of epidemiology, as well as in assessing health status and other populationbased health indicators. While being used across all levels of care (from prevention and primary care to tertiary and rehabilitation care) in a very systematic and standardized way, diagnoses are not available for medicines purchased out of pocket (without prescription or other medical advice) in community pharmacies. Having such information would allow OOP expenditure on pharmaceuticals to be allocated by disease/ condition, and thereby to understand the purpose for which these medicines have potentially been used.

In order to assess the purpose for which these medicines have potentially been used, and to allocate OOP expenditure on pharmaceuticals within a DIS classification system, one possible approach identified in this research is to link the SHA 2011 DIS codes to specific standardized codes for medicines; namely, the ATC classification of medicines. The ATC classification is a methodology for assigning a unique ATC code to active substances in medicines, according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties (WHO, 2022a). However, as there are multiple indications for which a medicine can be used, this approach requires some adjustments, such as: (i) each ATC code is linked to the DIS code based on the primary or most frequent indication for which the medicine is used; (ii) medicines such as anti-infectives are assigned to the infectious diseases category, despite their potential use for other medical indications (such as cancer, surgical prophylaxis or immunocompromised patients); and (iii) non-steroid antiinflammatory and pain-relief medicines are allocated to the non-diseasespecific code, as these medicines can be used for a very wide range of medical indications.

While such analysis is useful and even more detailed than the one based on current DIS coding, it cannot be directly used with the SHA2011 methodology for health expenditure tracking. For that reason, it is important to find a link through which the medicines purchased out of pocket can be associated to the disease for which they have potentially been used. The most obvious method is to link a standardized medicine classification – such as the ATC classification – to a standardized disease classification, such as the WHO ICD or, specifically for HA, the SHA2011 DIS classification of diseases. Some attempts to predict medicine use by linking ATC codes to the ICD classification have been made (Filzmoser, Eisl & Endel, 2009; Weisser et al., 2008), but to date no literature was found on any attempt for using ATC codes to predict use of medicines for diseases as classified by the SHA2011 DIS methodology. Using the data obtained from the community pharmacies for this research, a summary of the attempt to link the SHA2011 major DIS codes with the ATC codes by ATC Level 2 is given in Table 3.5.

#### Table 3.5. Linking SHA2011 DIS codes and ATC codes

DIS codes	ATC codes
1.2.NEC Unspecified tuberculosis (NEC)	J04
1.4 Respiratory infections	R05
1.5 Diarrhoeal diseases	A07
1.NEC Other and unspecified IPDs (NEC)	D01, D06, D07, D08, J01, J02, J06, J07, P01, P02, P03
2.3 Contraceptive management (family planning)	G02
3 Nutritional deficiencies	A11, A12, B03
4.1 Neoplasms	L01, L02, L03, L04
4.2.1 Diabetes	A10
4.2.NEC Other and unspecified endocrine and metabolic disorders (NEC)	H01, H02, H03, H04
4.3.1 Hypertensive diseases	C02, C03, C04, C08, C09
4.3.NEC Other and unspecified cardiovascular diseases (NEC)	C01, C05, C07, C10
4.4.1 Mental (psychiatric) disorders	N05, N06
4.4.3 Neurological conditions	N03, N04, N07
4.5 Respiratory diseases	R01, R02, R03, R06, R07
4.6 Diseases of the digestive system	A02, A03, A04, A05, A06, A08, A09, A14, A16
4.7 Diseases of the genitourinary system	G01, G02, G03, G04
4.8 Sense organ disorders	501, 502, 503
4.9 Oral diseases	A01
4.NEC Other and unspecified NCDs (NEC)	B01, B02, B06, D04, D05, D07, D11, M01, M02, M03, M04, M05, M09
6 Non-disease specific	B05, D02, D03, D10, N01, N02
NEC Other and unspecified diseases/conditions (NEC)	V03, V06, V07, V08

## After linking the ATC codes to the main SHA2011 DIS codes (Table 3.5), the collected data was filtered for medicines with ATC codes and analysed (Fig. 3.9).



The analysis showed that 20% of expenditure could be allocated to each nervous (N) and cardiovascular (C) system group of medicines, followed by alimentary tract (A), blood and blood-forming organs (B), anti-infectives (J), and medicines for musculoskeletal (M) and respiratory (R) systems. These findings are consistent with the data presented earlier on the high proportion of OOP expenditure on NCDs and IPDs.

## Limitations of this research

This research also has its limitations, including the data collection process, the data completeness and the sample size.

Since the HA process has been already institutionalized in the SSO, the data collection process was conducted jointly by the research team and the SSO, whereby certain rules of data gathering for statistical purposes had to be observed. This to a certain extent limited the speed and comprehensiveness of the data collection exercise. In addition, since all community pharmacies operate their business using elaborate software applications, most of them submitted the data in standard Excel files, rather than using the template. Whereas all of those that passed the inclusion criteria check had all the necessary variables, some variances were observed, which required the datasets to be thoroughly inspected. Second, in some of the datasets, while all values were present, for some products it was difficult to identify the product group to which they belonged, necessitating additional thorough data inspection and cleaning. While the number of such products was less than 0.5% of the entire dataset for all pharmacies, it is possible to anticipate that some of these products may have been placed in a wrong category; most of these, however, were from the non-medical group, which was in any case not analysed to the same level of detail as the group of pharmaceuticals.

Finally, the response rate was not as high as expected, for two principal anticipated reasons: first, it is difficult for pharmacies (especially smaller ones) to answer a request to prepare and submit data in a specified format, which would require additional staff to manually compile data. Second – and possibly more important – is the fact that, until this research, no authority in the country had asked community pharmacies to provide data on their revenues from private (OOP) sales, and as such the request was received with scepticism about its intention and purpose. This resulted in some pharmacies refusing to provide data, or simply not responding to the SSO's request. Despite the above limitations, the sample of participating pharmacies can be considered representative of the entire country, in terms of geographic distribution, volume of sales analysed, and representation of both large and small retailers, allowing further use of the data and their application to the process of producing the HA.

# 4. Conclusions

It is a common fact that it is hard to assess actual use of medicines and medical products purchased without prescription or any recorded medical advice or indication. Furthermore, community pharmacies also sell and dispense non-medical goods, which, unless specifically coded, are impossible to distinguish through commonly used accounting codes. This often inflates the OOP expenditures on pharmaceuticals at community (outpatient care) level, skewing the picture of health expenditures tracking.

To overcome this methodological issue related to the lack of regular collection of community pharmacy data, an applied research was conducted with two objectives: 1) to assess the revenue structure of community pharmacies and to develop a distribution key for medical and non-medical goods, that can be applied to the OOPs on pharmaceuticals within the overall health expenditures tracking process; and 2) to predict for which disease/condition non-prescribed and OTC medicines were used, by linking specific standardized medicine coding (ATC) with the diagnosis coding system (SHA2011 DIS based on GBD/ICD-10).

Regarding the first objective, the research has shown that a significant portion of revenues (20% in 2018 and 2019) in community pharmacies come from non-medical goods, which inflates the OOPs on pharmaceuticals and skews the overall picture of total OOPs and OOPs on pharmaceuticals. In the case of North Macedonia, although the existing OOPs estimation methodology applies an adjustment on expenditures in pharmacies, the applied research resulted a relatively small decrease of total CHE and total OOP expenditures (from 42.1% to 41.2% in 2018 and from 40.4% to 39.1% in 2019). In other words, in the case of North Macedonia, while there is an evident high proportion of revenues from non-medical goods in community pharmacies, this does not significantly impact the overall trend of OOP spending consequently the overall HA results. The similar studies in other countries will have the different results, it is therefore recommended that similar studies are conducted in other countries of the WHO European Region.

Regarding the second objective, and based on the literature, it was confirmed that ATC classification can be reliably used to predict ICD diagnoses, i.e. to distribute the pharmaceutical expenditure by major groups of diseases/conditions.

From the methodological point of view, it was observed that data at community pharmacy level is available in very different formats, which makes it difficult for pharmacies – especially smaller ones – to provide data in a specified format. On the other hand, when data is requested in the native raw format – as available in the pharmacies' systems – the process of data collection, cleaning and analysis becomes was very labour-intensive, and rather impractical to conduct on an annual basis.

To this end, and to resolve this methodological issue, two possibilities can be envisaged: 1) to introduce standard data collection format in the software of all pharmacies, that would enable fast retrieval of unified data in a standardized template; or 2) to conduct the applied research every 4–5 years for a 3-year period data, that would likely enable application of the distribution keys for the years between two studies.

Implementation of the first option involves modifications in pharmacy software, which might be possible to implement as a module within the mandatory reporting/connection between the pharmacies and the existing health information systems in E-health directorate (MojTermin) or HIF (for reimbursement purposes). The implementation of the second option requires establishment of a team and practice for conducting the applied research within the SSO, as the responsible institution for HA production.

Besides the defined objectives, the research highlights several additional noteworthy findings relevant to the OOP spending on pharmaceuticals, namely:

- Large portion of the pharmaceuticals consumed in the country is purchased without any medical advice or prescription for conditions that require medical advice (medicines with ATC codes purchased OOP are 30% of total sales of community pharmacies). The main diseases for which people spend out-of-pocket, like hypertension, cardiovascular and mental and psychiatric disorders are conditions which should be under regular professional medical supervision.
- For about a half of the pharmaceuticals purchased OOP it was difficult to estimate the medical reason, disease or condition for purchase or use, since there was no ATC code associated with them. Majority of these pharmaceuticals fall into the category of supplements and products without proven active ingredient, but determining their use alone or in combination with other pharmaceuticals is important due to possible (un)desired interactions and health effects.
- Apart from the health insurance-related sales, community pharmacies do not report in detail on their other medical or nonmedical sales. This kind of reporting is not mandatory in the regulation covering the pharmaceutical care in North Macedonia, and also missing in other countries in the region. The lack of data makes impossible to analyse the biggest portion of the OOP spending in the countries and not having information may defocus policy makers from taking actions to address issues that can potentially have the biggest impact on the level of OOP spending in the system.

## References<sup>2</sup>

2. All references accessed on 07 November 2022

BASYS, CEPS, IGSS (2006). Feasibility study of health expenditures by patient characteristics. Augsburg: BASYS Consulting Society for Applied Systems Research.

Bernardini C, Ambrogi V, Perioli L (2003). Drugs and non-medical products sold in pharmacy: information and advertising. Pharmacol Res. 47(6):501–508 (https://doi.org/10.1016/S1043-6618(03)00044-6).

Chini F, Pezzotti P, Orzella L, Borgia P, Guasticchi G (2011). Can we use the pharmacy data to estimate the prevalence of chronic conditions? a comparison of multiple data sources. BMC Public Health, 11(688):1–8 (https://doi.org/10.1186/1471-2458-11-688).

Endel F, Weibrecht N (2019). ATC-ICD: enabling domain experts to explore and evaluate machine learning models estimating diagnoses from filled predictions. IJPDS 4(3):150 (https://doi.org/10.23889/ijpds.v4i3.1314).

Eurostat (2022). Enlargement policy and the acquis in statistics. In: Eurostat statistics explained [website]. Brussels: European Commission (https://ec.europa.eu/eurostat/statistics-explained/index. php?title=Enlargement\_policy\_and\_the\_acquis\_in\_statistics#The\_EU\_ acquis\_in\_the\_field\_of\_statistics).

IHME (2018). Protocol for the global burden of diseases, injuries, and risk factors study (GBD). Version 3.0. Seattle (WA): Institute for Health Metrics and Evaluation (https://www.healthdata.org/sites/default/files/files/ Projects/GBD/GBD\_Protocol.pdf).

Filzmoser P, Eisl A, Endel F (2009). ATC  $\rightarrow$  ICD: determination of the reliability for predicting the ICD code from the ATC code. Vienna: Vienna University of Technology Department of Statistics and Probability Theory (https://www.researchgate.net/publication/267772618\_ATC\_-\_ICD\_Determination\_of\_the\_reliability\_for\_predicting\_the\_ICD\_code\_from\_the\_ATC\_code).

Kanavos P, Vandoros S, Irwin R, Nicod E, Casson M (2011). Differences in costs of and access to pharmaceutical products in the EU. Brussels: European Parliament (https://www.europarl.europa.eu/RegData/etudes/ etudes/join/2011/451481/IPOL-ENVI\_ET(2011)451481\_EN.pdf).

Masumoto S, Sato M, Maeno T, Ichinohe Y, Maeno T (2018). Factors associated with the use of dietary supplements and over-the-counter medications in Japanese elderly patients. BMC Fam Pract. 19(20):1–7 (https://doi.org/10.1186/s12875-017-0699-9).

Milevska-Kostova N (2017). Policy change and regulation of primary care prescribing and dispensing in Macedonia – a qualitative study [PhD thesis]. Sheffield: University of Sheffield (http://etheses.whiterose.ac.uk/19424/).

OECD (2019a). Improving forecasting of pharmaceutical spending insights from 23 OECD and EU countries. Analytical report. Paris: OECD Publishing (https://www.oecd.org/health/health-systems/Improving-Forecasting-of-Pharmaceutical-Spending-Report.pdf).

OECD (2019b). Using routinely collected data to inform pharmaceutical policies. Analytical report for OECD and EU countries. Paris: OECD Publishing (http://www.oecd.org/health/health-systems/Using-Routinely-Collected-Data-to-Inform-Pharmaceutical-Policies-Analytical-Report-2019.pdf).

OECD (2013). Pharmaceutical expenditures. In: Health at a glance 2013: OECD Indicators. Paris: OECD Publishing (https://doi.org/https://doi.org/10.1787/health\_glance-2013-67-en).

OECD, Eurostat, WHO (2011). A system of health accounts 2011: revised edition. Paris: OECD Publishing (https://doi.org/10.1787/9789264270985-en).

Roehrig C, Miller G, Lake C, Bryant J (2009). National health spending by medical condition, 1996–2005: mental disorders and heart conditions were found to be the most costly. Health Aff. 28(Suppl1):w358-w367 (https://doi.org/10.1377/hlthaff.28.2.w358).

Weisser A, Endel G, Filzmoser P, Gyimesi M (2008). ATC  $\rightarrow$  ICD – evaluating the reliability of prognoses for ICD-10 diagnoses derived from the ATC-Code of prescriptions. BMC Health Serv Res. 8(Suppl. 1):A10 (https://doi.org/10.1186/1472-6963-8-51-A10).

WHO (2022a). Anatomical therapeutic chemical (ATC) classification [website]. Geneva: World Health Organization (https://www.who.int/tools/atc-ddd-toolkit/atc-classification).

WHO (2022b) Global health expenditure database [online database]. Geneva: World Health Organization (https://apps.who.int/nha/database/Home/Index/en).

WHO (2022c). International Statistical Classification of Diseases and Related Health Problems (ICD) [website]. Geneva: World Health Organization (https://www.who.int/standards/classifications/classification-of-diseases).

WHO (2018). Methods to analyse medicine utilization and expenditure to support pharmaceutical policy implementation. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/274282).

WHO (1998). The role of the pharmacist in self-care and self-medication: report of the 4th WHO Consultative Group on the Role of the Pharmacist, The Hague, The Netherlands, 26–28 August 1998. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/65860).

# Annex 1. Methodology: data collection tools

Instructions provided to community pharmacies for completing data collection template

Table 1. Consumption of medicines and over-the-counter (OTC) medicinespurchased out of pocket (privately), by location

This group "Medicines and OTC medicines" includes all medicines that have been dispensed with or without prescription; e.g. with private prescription, as well as supplements, OTC, herbal and other, similar products.

If an ATC classification is not available for a specific medicine, please list the trade name or the generic name of the medicine.

If the data on quantities and/or price of the individual package or medicine are not available, the total amount of medicine dispensed/sold can be provided, by type of medicine, and by location.

Table 2. Consumption of therapeutic and medical aids, purchased out of pocket (privately), by location

Please add the total amount of purchased therapeutic and medical aids by group of aids (annually). Please list only the therapeutic and medical aids that have been fully paid for out of pocket (privately); that is, do not list any therapeutic or medical aid that is covered by the mandatory health insurance or for which a co-payment is required.

Table 3. Consumption of other products purchased out of pocket, by location

Within this category, two subcategories are envisaged:

(1) other medical products and (2) non-medical products.

In group (1) "Other medical products", please list all other medical products that are for health use but do not belong to any other of the above categories, e.g. pregnancy tests, blood pressure meters, glucometers, bandages, plasters, etc.

In group (2) "Non-medical products", please add the total amount of the products in this category that are not intended for medical or direct health need, e.g. hygienic products, cosmetics, food and nutrition products, etc.

Table 4. Other products that were not classified in tables 1, 2 or 3 (that is, products for which you are not sure where to classify them), purchased out of pocket (privately), by location

In this table please add all products for which you are not sure where to classify them or cannot put them in any of the previous tables. Please add only the total annual amount of all products, by location.

## Annex 2. Methodology: sample size and sampling strategy

To determine the sampling strategy, analysis was undertaken of the number of pharmacies and the structure of the community pharmacy market by ownership and insurance coverage (Table A2.1, Table A2.2 and Table A2.3).

## Table A2.1. Community pharmacies in North Macedonia by type of insurance coverage

Note. Data correct as at 1 Feb 2021.

City	Total no.	% of total	No. HIF-contracted	% HIF-contracted	No. not in insurance scheme	% not in insurance scheme
Skopje	257	25.9	199	77.4	58	22.6
Bitola	58	5.8	52	89.7	6	10.3
Tetovo	67	6.7	39	58.2	28	41.8
Kumanovo	60	6.0	41	68.3	19	31.7
Gostivar		3.8	22	57.9	16	42.1
Ohrid		3.9	29	74.4	10	25.6
Strumica	37	3.7	33	89.2	4	10.8
Prilep	38	3.8	38	100.0	0	0.0
Veles	27	2.7	25	92.6	2	7.4
Gevgelija	18	1.8	11	61.1	7	38.9
Kavadarci	26	2.6	21	80.8	5	19.2
Struga	32	3.2	17	53.1	15	46.9
Shtip	22	2.2	17	77.3	5	22.7
Kochani	21	2.1	20	95.2	1	4.8
Kichevo	24	2.4	15	62.5	9	37.5
Other cities	230	23.1	212	92.2	18	7.8
TOTAL (%)	994 (100%)	100%	791 (79.6%)		203 (20.4%)	

## Table A2.2. Structure of community pharmacy market by ownership (group/individual)

% of total No. of pharmacies/ No. of groups Total no. of outlets in a group pharmacies/outlets 3 24.8 >50 247 0 20-49 0 0.0 5–19 12 90 9.1 4 8 32 3.2 3 25 75 7.5 2 45 90 9.1 46.3 Individual pharmacies n/a 460 TOTAL 994

Note. Data correct as at 1 Feb 2021.

## Table A2.3. Number and share of pharmacies belonging to a group of 5 or more

Note. Data correct as at 1 Feb 2021.

	Name	All pharmacies	HIF-contracted pharmacies	% not in insurance scheme
1	Eurofarm	105	104	1.0
2	Zegin	78	69	11.5
3	Moja Apteka	64	40	37.5
4	Alpi farm	14	14	0.0
5	Viola	11	10	9.1
6	Galenium farm	10	8	20.0
7	Gold moon	8	5	37.5
8	Flos farm	7	3	57.1
9	Zhiva farm	7	7	0.0
10	Herba	6	6	0.0
11	Vera	6	6	0.0
12	Sara Farm	6	6	0.0
13	Ble-farm	5	5	0.0
14	Rosa Vita	5	5	0.0
15	Biofarm	5	4	20.0
	No. of pharms in group	337	292	
	% of total	33.9%	36.9%	13.4

Nearly half of the pharmacies (46.3%) are individual outlets, and more than one third (36.9%) belong to a chain/group of five or more outlets – of these, the majority (24.8%) belong to the three biggest chains (Eurofarm, Zegin, Moja Apteka). It is important to highlight that the chain pharmacies in the country have single taxpayer identification numbers (taxID), and report as single entities to the tax authorities. This suggests that data are available from a centralized inventory/dataset, and it can be assumed that the data for over one third of the market can be provided from 15 entities (Table A1.3).

It is important to note that among the entire market, 20.4% are pharmacies without a contract with the HIF. It is important to obtain data from these outlets, since the structure of their expenditures will significantly differ from the HIF-contracted pharmacies. In this sense, it is also important to verify the software and level of detail captured in their databases, as HIF-contracted pharmacies have pre-set requirements for their contracts, and the level of data collected is already known and used in the country's HA produced.

# Annex 3. SHA2011 codes for current health expenditures (CHE) by disease/condition

#### Table A3.1. SHA2011 codes for CHE by disease/condition

DIS	CHE by disease / condition		
DIS.1	Infectious and parasitic diseases (IPDs)		
DIS.1.1	HIV/AIDS and other Sexually Transmitted Diseases (STDs)		
DIS.1.1.1	HIV/AIDS and Opportunistic Infections (OIs)		
DIS.1.1.1.1	HIV/AIDS		
DIS.1.1.1.2	TB/HIV		
DIS.1.1.1.3	Other OIs due to AIDS		
DIS.1.1.1.NEC	Unspecified HIV/AIDS and OIs (NEC)		
DIS.1.1.2	STDs other than HIV/AIDS		
DIS.1.1.NEC	Unspecified HIV/AIDS and other STDs (NEC)		
DIS.1.2	Tuberculosis (TB)		
DIS.1.2.1	Pulmonary TB		
DIS.1.2.1.1	Drug-Sensitive Tuberculosis (DS-TB)		
DIS.1.2.1.2	Multidrug-resistant Tuberculosis (MDR-TB)		
DIS.1.2.1.3	Extensively drug-resistant Tuberculosis (XDR-TB)		
DIS.1.2.1.NEC	Unspecified pulmonary Tuberculosis (NEC)		
DIS.1.2.2	Extra pulmonary TB		
DIS.1.2.NEC	Unspecified tuberculosis (NEC)		
DIS.1.3	Malaria		
DIS.1.4	Respiratory infections		
DIS.1.5	Diarrhoeal diseases		
DIS.1.6	Neglected tropical diseases		
DIS.1.7	Vaccine preventable diseases		
DIS.1.8	Hepatitis		
DIS.1.NEC	Other and unspecified infectious and parasitic diseases (NEC)		
DIS.2	Reproductive health		
DIS.2.1	Maternal conditions		
DIS.2.2	Perinatal conditions		
DIS.2.3	Contraceptive management (family planning)		
DIS.2.NEC	Unspecified reproductive health conditions (NEC)		
DIS.3	Nutritional deficiencies		

#### Table A3.1. contd

DIS	CHE by disease / condition		
DIS.4	Noncommunicable diseases (NCDs)		
DIS.4.1	Neoplasms		
DIS.4.2	Endocrine and metabolic disorders		
DIS.4.2.1	Diabetes		
DIS.4.2.NEC	Other and unspecified endocrine and metabolic disorders (NEC)		
DIS.4.3	Cardiovascular diseases		
DIS.4.3.1	Hypertensive diseases		
DIS.4.3.NEC	Other and unspecified cardiovascular diseases (NEC)		
DIS.4.4	Mental and behavioural disorders, and neurological conditions		
DIS.4.4.1	Mental (psychiatric) disorders		
DIS.4.4.2	Behavioural disorders		
DIS.4.4.3	Neurological conditions		
DIS.4.4.NEC	Unspecified mental and behavioural disorders and neurological conditions (NEC)		
DIS.4.5	Respiratory diseases		
DIS.4.6	Diseases of the digestive system		
DIS.4.7	Diseases of the genitourinary system		
DIS.4.8	Sense organ disorders		
DIS.4.9	Oral diseases		
DIS.4.NEC	Other and unspecified NCDs (NEC)		
DIS.5	Injuries		
DIS.5.1	Road traffic accidents		
DIS.5.NEC	Other and unspecified injuries (NEC)		
DIS.6	Non-disease specific		
DIS.NEC	Other and unspecified diseases/conditions (NEC)		

#### The WHO Regional Office for Europe

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