

## ORIGINAL ARTICLE

**OTC market – comparing Czech Republic and Greece****Trh s volně prodejnými léčivými – porovnání Česká republika a Řecko****Božena Macešková • Marios-Panagiotis Tsadaris • Michail Machlis**

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**Summary**

Medicines for self-medication (over-the-counter, OTC) are available through pharmacies, in some countries they are also available in supermarkets and other outlets. The use of OTC in European Union countries shows some differences at national level, in pharmacies and in patients' preference. This study aimed to completing the lists of marketed OTC in Czech Republic and Greece. Next topics are: finding out the real range of OTC products offered by pharmacies, finding and evaluating number of packages sold in pharmacies in 20 particular common OTC in 2016, and identification of factors influencing the sales. Web pages of national drug authorities (Czech Republic, Greece) were searched to complete lists of marketed OTC in each country. Data on range of OTC drugs and sales of them were extracted from computer systems (Czech Republic) and other types of documents (Greece) kept in pharmacies. The percentage of the real range of OTC products in pharmacies was calculated as the ratio to the number of OTC in national lists. Numbers of sold packages were compared among pharmacies. Classification system ATC (anatomical/therapeutical/chemical) was employed to present findings in all parts of the research. The Czech list contained 1,160 of marketed OTC in 10 ATC (1<sup>st</sup> level), with the maximum in ATC R (243 drugs). The Greek list contained 1,254 OTC in 13 ATC (1<sup>st</sup> level), with the maximum in ATC D (272 drugs). In lists of both countries, there were detected 86 drugs identical in 9 ATC (1<sup>st</sup> level). At least one OTC in each of 10 listed ATC was found in Czech pharmacies as a part of range of products, the range of OTC in Greek pharmacies comprised 11 ATC. The highest sales (year 2016) were found in ATC R (drug ACC long tbl eff) in CR and in ATC A (drug: Imodium cps) in Greece. The differences in the range of OTC drugs and in their sales were found between Czech Republic and Greece, and between types of

pharmacies inside each country. Factors influencing them were detected: ownership of the pharmacy, locality (number of inhabitants).

**Key words:** OTC drugs • pharmacy • Czech Republic • Greece

**Souhrn**

Léčiva pro samoléčení (OTC přípravky) jsou dostupné v lékárnách, v některých zemích jsou k dispozici rovněž v supermarketech a na dalších místech. Problematika OTC přípravků v zemích Evropské unie vykazuje některé odlišnosti na národní úrovni, v lékárnách i v preferencích pacientů. Tato studie má za cíl sestavit seznamy obchodovaných OTC přípravků v České republice a v Řecku. Dalšími tématy jsou: zjištění skutečného spektra OTC léčiv nabízených v lékárnách, vyhodnocení počtu prodaných balení vybraných 20 běžných OTC léčiv za rok 2016 a identifikace faktorů ovlivňujících prodej OTC přípravků. Webové stránky národních lékových agentur (Česká republika, Řecko) byly použity pro sestavení seznamů obchodovaných OTC přípravků v obou zemích. Údaje o spektru OTC v lékárnách a jejich prodeji byly získány z lékárenského software (v ČR) a z jiných typů dokumentů uchovávaných v lékárně (v Řecku). Byl vypočítán podíl nalezeného spektra OTC v jednotlivých lékárnách vzhledem počtu OTC v národních seznamech. Byly porovnány počty prodaných balení. Ve všech částech práce byla pro prezentaci výsledků použita ATC (anatomicko/terapeuticko/chemická) klasifikace léčiv. Český seznam obsahoval 1160 obchodovaných OTC přípravků náležejících do 10 ATC skupin (první úroveň), s maximem v ATC R (243 přípravků). Řecký seznam obsahoval 1254 obchodovaných OTC přípravků náležejících do 13 ATC skupin, s maximem v ATC D (272 přípravků). Bylo identifikováno 86 totožných přípravků v seznamech obou zemí, náležejících do 9 ATC skupin (první úroveň). V nabídce OTC v českých lékárnách se vyskytoval alespoň jeden přípravek z každé z deseti identifikovaných ATC skupin, v nabídce řeckých lékáren byly zahrnuty OTC přípravky z 11 ATC skupin. Nejvyšší prodeje (v roce 2016) byly zjištěny v ČR v ATC skupině R (přípravek ACC long tbl eff) a v Řecku v ATC A (přípravek Imodium cps). Byly nalezeny rozdíly v nabídce OTC přípravků v lékárnách a v jejich pro-

dejích, a to jak mezi Českou republikou a Řeckem, tak mezi jednotlivými typy lékáren uvnitř každé země. Jako faktory těchto rozdílů byly identifikovány: vlastnictví lékárny, lokalita (počet obyvatel).

**Klíčová slova:** OTC léčiva • lékárna • Česká republika • Řecko

## Introduction

Medicines for self-medication are often called „nonprescription“ or „over-the-counter“ (OTC) and are available through pharmacies. In some countries OTC products are also available in supermarkets and other outlets. Responsible self-medication has been identified as an important element in long-term health policy by the institutions of the European Community<sup>1)</sup>. Research shows that 81 percent of adults use OTC medicines as a first response to minor ailments<sup>2)</sup>.

Harmonization between countries' regulatory agencies is a positive development<sup>3)</sup>. Even if a specific directive<sup>4)</sup> has been approved, the situation of self-medication products in European Union (EU) countries is still far from being harmonized<sup>5)</sup>. The final EU Medicines Agencies Network Strategy 2020 emphasises that this strategy has a key role in improving patients access to well-established medicines including the nonprescription ones. Multi Annual Work Plan (MAWP) incorporates the same objective: enhancement and improvement of existing tools such as the mutual recognition/decentralized procedures (MRC/DCP) and achievement of agreements on common criteria for the authorisation of OTC products. It recommends to explore ways how to facilitate the greater number of product switches which should result in improving the availability of nonprescription medicines through simplified regulatory requirements<sup>6)</sup>. It is often expected that through deregulation in the community pharmacy sector the prices of OTC medicines will go down. In reality these expectations could not be fully met. Deregulation has led to the opening of new pharmacies and of OTC dispensaries, since OTC sale outside pharmacies is usually permitted<sup>7)</sup>.

## Situation in Czech Republic

Though one of the smallest markets, the Czech Republic has a strict control of a drug on its launch and a rigorous system of drug registration<sup>8)</sup>. Any proprietary medicinal product is subject to marketing authorisation prior to its placement on the market in the Czech Republic. The marketing authorisation procedure is the responsibility of State Institute for Drug Control and it includes an assessment of a dossier, in which the future marketing authorisation holder evidences the safety, efficacy, and quality of the product<sup>9)</sup>. Patients can have access to a small amount of OTC drugs subcategory „selected drugs“ in many points except pharmacies<sup>10)</sup>. Spending on retail pharmaceuticals as a share of GDP (2013): total 1.3%, private 0.5%<sup>11)</sup>. The

expenditure per capita (2015): 404 USD<sup>12)</sup>, OTC 83 USD (2013)<sup>11)</sup>. OTC share in total pharmaceutical market not listed in<sup>10)</sup>, estimation: nearly 5%.

## Situation in Greece

Accessing the market requires manufacturers to obtain necessary approvals from The National Organization for Medicines (EOF), an entity of Ministry of Health and Social Solidarity. Right from informing the EOF, manufacturers might have to cope with other complex Regulatory procedures for registrations and licensing<sup>13)</sup>. Price liberalization and market opening (since 2016) allows for the ability of Greek consumers to buy more OTC products while creating increased competition from new outlets will press prices down. Negotiations are currently taking place regarding the sale of OTC via channels (i.e. supermarkets) other than just pharmacies<sup>14)</sup>. The main aim of the reform is to provide to patients all necessary knowledge, advice and convenience in order to be healthier, by choosing the ideal drug for their condition. A base alignment and agreement between the state, the industry and the pharmacy with the patient in the core will create a huge evolution with increasing satisfaction for consumers<sup>15)</sup>. OTC that can be bought outside the pharmacies as well create the subcategory „drugs for general distribution“<sup>16, 18)</sup>.

Spending on retail pharmaceuticals as a share of GDP (2013): total 2.8%, private 0.9%<sup>11)</sup>, per capita (2015): 572 USD<sup>12)</sup>, OTC share in total pharmaceutical market 5%<sup>10)</sup>.

Advertising of OTC medicines is allowed in many countries in EU, including both CR<sup>19)</sup> and Greece<sup>17)</sup>.

The aim of this study was to complete the list of all marketed OTC in Czech Republic and Greece, to compare them, to ascertain the real range of OTC drugs offered by selected pharmacies (3 in each country) and to analyse the sales of twenty chosen OTC in these pharmacies in one-year period (2016).

## Experimental part

### Methodology

OTC marketed in CR and Greece were the subject of this research. This group presents the sub-group of authorized OTC, and the drug was included in the list of marketed OTC if it was really marketed by wholesalers and pharmacies. Analysis of national lists of OTC in CR<sup>20)</sup> and Greece<sup>21, 22)</sup> was the first step of the research. Drugs marketed in 2016 were sorted using the ATC (anatomical/therapeutic/chemical) system (5<sup>th</sup> level) and the identical drugs (the same name, dosage form, strength and size of package) were identified comparing both lists. Six pharmacies (3 in each country) were chosen to take part in data gathering. Different types of ownership and different localities were the parameters for the selection (Table 1). Finding out the range of marketed OTC drugs in pharmacies followed. The range of OTC is the aggre-

gate of particular drugs that used to be in the stock of the pharmacy, it means they have been at least once ordered by the pharmacy, regardless of their real presence in the stock of the pharmacy in the moment of researching. To complete the range of products, the documentation of stocking drugs in chosen pharmacies was analysed in the end of 2016. There are substantial differences between CR and Greece in the methods of stock inventory – the Czech ones are more complex due to use of sophisticated computer systems. Authors performed the search under the supervision of the head of the pharmacy. Documents in Greek pharmacies showed the large variety and lack of uniformity, using different kinds of software to keep records of various structure and content. The cooperation of the pharmacist with the researcher was necessary to find corresponding data. The ratio between the real range of OTC found in pharmacies and the total number of marketed OTC included in national lists was calculated in ATC groups (1<sup>st</sup> level) in both countries and expressed in percentage. Finally, analysing the sales of 20 particular common OTC in chosen pharmacies was performed (January 1, 2016 – December 31, 2016). The sample of OTC was based on 18 OTC identified as identical in both countries, the next two were of different size of package comparing CR and Greece (Table 4). Basic condition for the choice was the presence of the drug in the range of OTC products in pharmacies. The next condition was to include maximal number of ATC groups – eight ATC

groups (1<sup>st</sup> level) from the nine ones found in the group of identical OTC can be found in the sample. Completing this part of research was finished in spring 2017.

Pharmacy I. (CR) was owned by corporation, it was the only one run by this legal body, pharmacy III. (CR) was a member of the chain operating several hundreds pharmacies. The number of inhabitants in the city where the chain pharmacy was established is not mentioned because all pharmacies of the chain have the same business strategy and the range of OTC products is quite the same in all of them, not dependent on the population. All community pharmacies were owned exclusively by pharmacist in Greece in the time of research. The influence of pharmacys' characteristics on the range of OTC drugs and on the number of sold packages is mentioned in discussion.

## Results

ATC with no OTC in both countries are not included in Figure 1.

The list of OTC chosen for sales evaluation was completed by the column „number of OTC in national list ATC (5<sup>th</sup> level)“ in order to be able to assess the influence of other OTC drugs with the same active substance on the patients' choice and on the sale of the particular drug included in analysis. The data in columns (CR, Greece) present the number of marketed OTC in the same ATC (5<sup>th</sup> level) (Table 4).

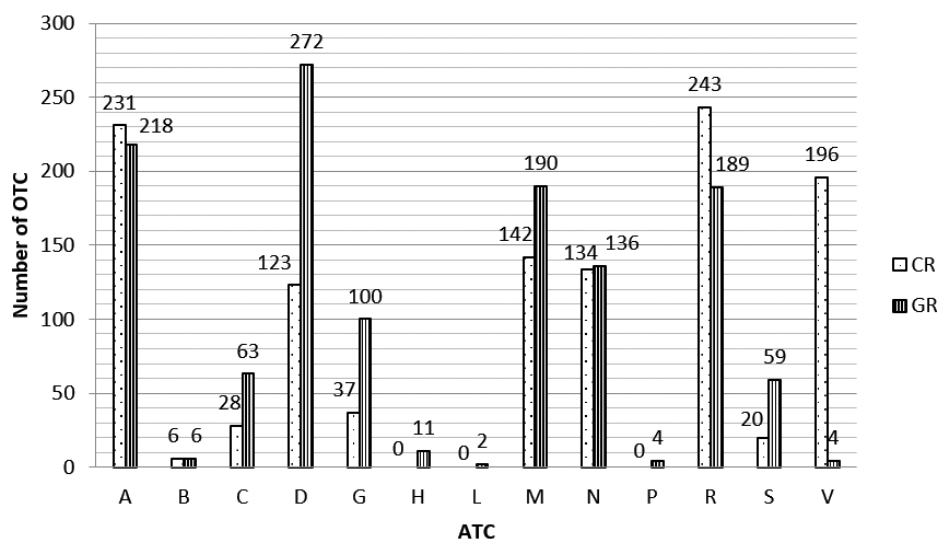


Fig. 1. Number of marketed OTC medicines in ATC: comparing CR and Greece

Table 1. Description of pharmacies that took part in the research

	CR			Greece		
	Pharmacy I	Pharmacy II	Pharmacy III	Pharmacy I	Pharmacy II	Pharmacy III
Locality	Big city	Town	City	Big city	Town	Village
Inhabitants	500,000	2,000	–	3,500,000	20,000	1,000
Owner/type	corporation	pharmacist	chain	pharmacist	pharmacist	pharmacist

Table 2. Identical OTC-ATC classification

Country	Number of marketed OTC in national list	Number of identical OTC	Number of identical OTC in particular ATC (1 <sup>st</sup> level)												
			A	B	C	D	G	H	L	M	N	P	R	S	V
CR	1,160	86	18	1	1	16	2	0	0	6	14	0	26	2	0
Greece	1,254														

Table 3. Comparing the range of OTC products in pharmacies with the number of marketed OTC in CR and Greece

	CR			Greece		
	range of products as a share of the list of marketed OTC			range of products as a share of the list of marketed OTC		
ATC	Pharmacy I	Pharmacy II	Pharmacy III	Pharmacy I	Pharmacy II	Pharmacy III
A	27.27%	57.14%	44.58%	32.11%	16.97%	19.72%
B	50.00%	83.33%	100.00%	16.67%	16.67%	16.67%
C	42.85%	82.14%	71.43%	41.27%	12.70%	17.46%
D	31.71%	60.98%	46.34%	47.43%	28.68%	33.09%
G	43.24%	56.76%	54.05%	5.00%	8.00%	5.00%
H	*	*	*	0.00%	0.00%	0.00%
L	*	*	*	50.00%	50.00%	50.00%
M	25.35%	50.70%	47.89%	44.74%	25.26%	33.68%
N	23.88%	50.00%	54.48%	46.32%	33.09%	32.35%
P	*	*	*	50.00%	50.00%	50.00%
R	35.80%	56.38%	59.26%	55.02%	36.51%	43.39%
S	45.00%	75.00%	35.00%	27.12%	22.03%	25.42%
V	8.16%	39.80%	15.82%	0.00%	0.00%	0.00%
Total	26.98%	53.88%	45.60%	40.03%	24.72%	28.55%

(\*) no marketed OTC in the ATC group in the national list, 0.00% means that there was at least one marketed OTC in the national list in the particular ATC group, but none was found in the range of products in the particular pharmacy. „Total“ means the percentage of the complete range of products in the pharmacy expressed as a share of the national list of marketed OTC.

Table 4. List of OTC chosen for analysis of sales in the pharmacies (CR, Greece)

Code		Name of Drug	Dosage Form	Strenght	Size of Package	Name of Substance	ATC 5 <sup>th</sup> level	Number of OTC in national list (ATC 5 <sup>th</sup> level)	
CR	Greece							CR	Greece
45989	7549	TALCID	tbl mnd	500 mg/tbl	20 tbl	Hydrotalcit	A02AD04	1	1
151579	103599	DULCOLAX	tbl ent	5 mg/tbl	40 tbl	Bisacodyl	A06AB02	3	2
146257	110129	IMODIUM	cps dur	2 mg/cps	8 cps	Loperamid	A07DA03	10	3
162858	204	ASPIRIN PROTECT 100	tbl ent	100 mg/tbl	28(**20) tbl	Acetylsalic. acid	B01AC06	5	1
15892	6344	LAMISIL	crm	10 mg/1 g	15 g	Terbinafin	D01AE15	4	20

Table 4. List of OTC chosen for analysis of sales in the pharmacies (CR, Greece) - continuing

Code		Name of Drug	Dosage Form	Strenght	Size of Package	Name of Substance	ATC 5 <sup>th</sup> level	Number of OTC in national list (ATC 5 <sup>th</sup> level)	
CR	Greece							CR	Greece
15391	5862	FENISTIL ROLL-ON	drm eml	1 mg/1 g	1 × 8 ml	Dimetinden	D04AA13	3	2
103065	2820	ZOVIRAX	crm	5 g/100 g	2 g	Aciclovir	D06BB03	5	4
62320	285	BETADINE	ung	100 mg/1 g	20(**30)g	Povidone iodine	D08AG02	18	14
149198	107818	ELLAONE	tbl nob	30 mg/tbl	1 tbl	Ulipristal acetate	G03AD02	1	1
62543	19071	NUROFEN	tbl obd	200 mg/tbl	24 tbl	Ibuprofen	M01AE01	49	20
100097	6330	VOLTAREN EMULGEL	gel	10 mg/1 g	100 g	Diclofenac	M02AA15	30	44
46213	8448	ASPIRIN-C	tbl eff	400 mg/ 240 mg/tbl	10 tbl	Acetylsal. acid, comb.	N02BA51	5	15
13802	17619	PANADOL EXTRA	tbl flm	500 mg/ 65 mg/tbl	30 tbl	Paracetamol, comb.	N02BE51	58	11
188194	112872	NICORETTE SPRAY 1 mg/DOSE	orm spr sol	1 mg/dose	1 × 13.2 ml	Nicotin	N07BA01	22	30
189464	8411	OTRIVIN MENTHOL 1 mg/ml	nas spr sol	1 mg/1 ml	1 × 10 ml	Xylometazolin	R01AA07	27	11
119924	3983	LIVOSTIN	nas spr sus	5 mg/10 ml	1 × 10 ml	Levocabastin	R01AC02	1	1
64907	109150	STREPFEN	pas	8.75 mg/pas	16 pas	Flurbiprofen	R02AX01	4	3
57395	114588	ACC LONG	tbl eff	600 mg/tbl	10 tbl	Acetylcystein	R05CB01	17	12
23739 (*)	101332	PROSPAN	sir	7 mg/1 ml	100 ml	Hedera leaf	R05CA12	9	2
49629	2405	TEARS NATURALE II	oph gtt sol	1 mg/1 ml + 3 mg/1 ml	15 ml	Hypromelose + Dextran	S01XA20	10	17

(\*) code cancelled at May 1, 2017, replaced by 202353

(\*\*) size of package in Greece (difference from CR)

## Discussion

There were 1,160 marketed OTC in CR and 1,254 ones in Greece in 2016 (Table 2). There were 86 of them identical in both lists, it means having the same name, dosage form, strength and size of package. They were classified in 9 ATC (1<sup>st</sup> level). No identic OTC was found in ATC H, L, P and V. The only one drug (Ellaone tbl 30 mg 1 tbl) has been authorized by European Medicines Agency, the rest of them by national medicines agencies.

As for the variety of marketed OTC drugs in national lists: it was more extensive in Greece, comprising 13 ATC 1<sup>st</sup> level (Fig. 1), but OTC listed in ATC H and V were not found as a part of range of products in any of researched pharmacies (Table 3). The list of marketed OTC in Czech Republic was ranked in 10 ATC 1<sup>st</sup> level (Fig. 1) and at least one drug of each of these 10 ATC groups was really the part of range of products in pharmacies (Table 3).

The range of OTC in pharmacies (Table 3) seemed to be independent of the size of the settlement whe-

Table 5. Sales of chosen OTC in pharmacies in 2016 (CR, Greece)

Name of drug (*)	CR				Greece			
	Number of packages				Number of packages			
	Pharmacy			Total	Pharmacy			Total
	I	II	III		I	II	III	
TALCID	1	0	37	38	3	7	5	15
DULCOLAX	0	1	35	36	146	170	100	416
IMODIUM	22	22	103	147	300	425	125	850
ASPIRIN PROTECT 100	7	6	5	18	75	83	50	208
LAMISIL	6	2	24	32	38	49	23	110
FENISTIL ROLL-ON	0	0	8	8	57	50	49	156
ZOVIRAX	9	6	19	34	74	68	52	194
BETADINE	64	33	162	259	10	39	21	70
ELLAONE	0	0	14	14	6	11	8	25
NUROFEN	0	0	11	11	6	25	5	36
VOLTAREN EMULGEL	12	5	48	65	197	320	147	664
ASPIRIN-C	0	0	23	23	29	120	21	170
PANADOL EXTRA	30	17	269	316	363	250	170	783
NICORETTE SPRAY 1 mg/DOSE	1	0	61	62	8	15	11	34
OTRIVIN MENTHOL 1 mg/ml	215	15	174	404	10	8	1	19
LIVOSTIN	0	7	33	40	29	32	18	79
STREPFEN	3	14	62	79	76	82	52	210
ACC LONG	14	49	556	619	5	11	2	18
PROSPAN	13	4	15	32	29	40	18	87
TEARS NATURALE II	1	17	21	39	53	72	39	164
Total	398	198	1,680	2,276	1,514	1,877	917	4,358

(\*) dosage form, strength and size of package: see Table 4

re the pharmacy was located in Greece. This was not confirmed in CR. The pharmacy in the small town offered the biggest range of products in 70.00% of ATC (1<sup>st</sup> level) comparing to pharmacies in other localities. There were found 53.88% of all marketed OTC in the range of products in this small pharmacy. The pharmacy in the big city (CR) had the smallest range of products in 90.00% of ATC (1<sup>st</sup> level), in total: 26.98% of the marketed ones. It could be deduced that the pharmacy in the small town (the only one in this town) made efforts to meet the maximum of patients' needs in order to prevent the patients to buy their OTC in other pharmacies. The next reason could be the difference in the ownership of the pharmacies: because of the big competition the pharmacist as the owner had to supply the patients' demands as much as possible to be attractive for clients and to stack up to the competition. The results in pharmacies in big cities

were opposite: the range of products offered to patients was 26.98% in CR (minimum of the researched Czech pharmacies) versus 40.03% in Greece (maximum of the researched Greek pharmacies). Similar range of products in pharmacies in smaller settlements (24.72% town, 28.55% village) was found in Greece. Chain (CR) seemed to offer the wide range of OTC products (45.60%) comparing to the independent pharmacy in the big city (26.98%).

Sales of 20 common OTC (Table 4) in chosen pharmacies (Table 5) showed big differences. They were nearly twice as high (191.48%) in Greece as in CR in 2016. Despite of the similar OTC share in total pharmaceutical market (approx. 5% in 2015<sup>10)</sup>) the changes that started in 2016 (non- restrictive environment, new businesses or new products<sup>14)</sup>) in Greece seemed to bring out new patterns in pharmacists' and patients' habitual practice. The extent of OTC sales



Table 6. Top ATC groups sold in chosen pharmacies

CR		Greece	
ATC 1 <sup>st</sup> level	Number of packages	ATC 1 <sup>st</sup> level	Number of packages
R	1,174	A	1,281
N	330	N	817
A	181	M	700
D	140	D	530
M	76	R	413

Table 7. Top OTC drugs sold in chosen pharmacies

CR			Greece		
ATC 5 <sup>th</sup> level	Name of drug (*)	Number of packages	ATC 5 <sup>th</sup> level	Name of drug (*)	Number of packages
R05CB01	ACC long	619	A07DA03	Imodium	850
R01AA07	Otrivin Menthol	404	N02BE51	Panadol Extra	783
N02BE51	Panadol Extra	316	M02AA15	Voltaren Emulgel	664
D08AG02	Betadine	259	A06AB02	Dulcolax	416
A07DA03	Imodium	147	R02AX01	Streptfen	210

(\*) dosage form, strength and size of package: see Table 4

did not rely on the extent of range of OTC in pharmacies (Table 3, 5): there were biggest sales (1,877 packages) in the pharmacy with the least range of products in Greece (locality: town). On the contrary, the sales seemed to be dependent on the ownership of the pharmacy in CR: the chain-pharmacy had the highest sales (1,680 packages) even if it did not have the broadest range of products. The pharmacies located in small town (CR) and village (Greece) showed lower sales regardless of not having the least range of OTC drugs. When detecting the highest sales in ATC groups (Table 5, 6) in Greece, the most frequently sold group was ATC A (Alimentary tract – 1,281 packages) and the most frequently sold OTC was IMODIUM cps dur 2 mg/cps 8 cps (A07DA03, 850 packages) (Table 7). The number of OTC marketed in ATC A (218 OTC) was the second highest in Greece (Fig. 1 – ATC D with 272 OTC was the first one) and the range of products in the pharmacies oscillated between 32.11% and 16.97% (Table 3). In Czech pharmacies, the most frequently sold ATC group was R (Respiratory tract – 1,174 packages) (Table 5, 6) and the most frequently sold OTC was ACC long tbl eff 600 mg/tbl 10 tbl (R05CB01, 619 packages) (Table 7). The number of OTC marketed in ATC R was the highest one in CR (Fig. 1 – 243 OTC) and the range of products in the pharmacies oscillated between 59.26% and 35.80% (Table 3).

This research brings the simplified and non-representative look into the OTC market in Czech Republic and Greece. There are some factors impeding the generalization of results: the small number of pharmacies taking part in the research, impossibility of drawing a comparison between data on sales in pharmacies and international<sup>11, 12)</sup> and national statistics on OTC drug consumption (in Czech Republic at wholesalers' level)<sup>23)</sup>. Last but not least, the Czech OTC market has been stabilized since the changes in the health care system in nineties, while the Greek one is expected to undergo big changes in the near future due to starting liberalization and market opening. On the other hand, some factors not taken in consideration in this research might modify what was found up: the climatic differences between the two countries could determine what are the most common patients' symptoms treated by self-medication and what are the most frequently sold OTC drugs.

**Conflicts of interest:** none.

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