ANALYTICAL REVIEW OF THE PHARMACEUTICAL INDUSTRY IN ROMANIA

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Abstract. *The paper aims to analyze the medicines' consumption by taking into consideration the Anatomical Therapeutic Chemical Classification System (ATCCS) and the evolution of the pharmaceutical products` prices in Romania. The analysis brings to the forefront the relationship between the main "allies" in the pharmaceutical supply chain (supplier–distributor–drugstore). Innovation in the pharmaceutical industry had an upward progress in the recent years. Pharmaceutical companies have kept their loyalty to consumers' needs and invested huge amounts of money in the research and development field. In Romania, one of the main regulatory measures refers to imposing maximum limit prices lists for prescription pharma products, called CaNaMed report (The national catalog of prices for human use medicines issued by medical prescription). The report is issued three times a year, and it shows maximum limit prices for suppliers, distributors, and drugstores. Ever since the introduction of regulations on the pharma market, suppliers have tended to channel their efforts on their main activity object. Consumers could benefit from the regulation for prescription pharma products this could be a coercive measure for suppliers. The final consumer`s access to pharma products remains essential and R&D should keep pace with the consumer's needs. Huge budgets are annually allocated for more advanced and innovative products; these high amounts can lead to bad debts for the pharma companies. The channels of the product distribution terminals within a commercial chain are passed from one firm to another in accordance with their proper specialization. Pharma companies could benefit in many ways from transferring certain tasks' costs to other specialized companies. However, the Romanian pharmaceutical market remains a booming industry, being full of opportunities and attractiveness for foreign suppliers. Furthermore, the dismissal of the clawback tax could greatly stimulate research and development in Romania, taking into consideration that this tax affects the suppliers' budgets. As a conclusion related to the drugs consumption value in 2016, the total value decreased from one quarter to another. The increases in RON were generated by increasing prices and not by the quantities of consumed units. Regionally speaking, Romania has been and will remain a long-term challenging business and an attractive market for foreign*

pharma suppliers, allowing them to "juggle" costs more easily on Romania's territory compared to their home market.

Introduction

Until recently, the pharmaceutical market in Romania was considered to be a fragmented market, but lately wholesale and retail segments have brought together their forces in order to achieve important commercial consolidation. Fragmentation is recalled from the perspective of the administrative organization and not from the operational process' point of view. In the pharma industry, the operational process is complex and has to involve several business units in order to accomplish high-level standards required by the European Union (EU). In order to sell a certain medical product, an entire commercial chain (production of drugs – supplier, transportation – distributor, the point of sales perceived as proximity points – drugstores) will have to satisfy the consumer's needs. In our opinion, the fragmentation is perceived as being under the specialization tutelage, therefore the need for close collaboration between main links became mandatory for the operation of the entire mechanism.

According to Gautam (2016), the convergence of IT and healthcare is another area that would impact the big pharma model over the coming years. Big data and mobile health are starting to transform healthcare and diagnostics in a significant way, with new players such as Apple and Google acting as increasingly disruptive catalysts. According to the research of Schuhmacher, Germalann, Trill, and Gassmann (2013), in the pharmaceutical industry, the increasing complexity of the industry, new technologies, and the availability of highly qualified experts, increasing pressure and costs can lead to open innovation development. Multinational pharmaceutical companies began to realize what is the full potential of open innovation through which they began to build external sources of ideas, technologies and R&D products (Hunter & Stephen, 2010). The competitively of a pharmaceutical company is determined by its capacity to innovate and develop new drugs, which ensures its leading position on the market (Chu, Sun & Liang, 2010). Every company aims to evolve on the market or to strengthen its position. Until the '70s, the companies were struggling with their direct opponents in order to gain a greater market share, but nowadays, they adopt an opposite strategy, directly seeking the opponent's support. Companies are beginning to realize that the need to survive on the market is becoming increasingly important; they react promptly to the consumer' needs which are constantly changing.

Romanian pharmaceutical industry overview

From the point of view of economic agents, they have to specialize in different fields in order to ensure cost reduction, the efficiency of operations and market performance. Considering that the pharmaceutical sector is exposed to strict and undifferentiated regulations, companies with heterogeneous specializations are no longer reluctant to establish cooperation with other market players. Mutual support and use of each other's experience in a fixed mechanism that can balance the power of decision-making related to product pricing and other decisions regarding substances used for new drugs without the law's consent. From the outside of the industry, everything seems regulated and well set-up, but in essence, direct players are the ones that suffer from these regulations. It is not a bad thing to protect human life, but when several unnecessary taxes are imposed by the government with significant impact on the R&D area, additional costs may cause unreliability on the market. The relationship between supplier – distributor - drugstore must be sustained by cooperation. Without trust and collaboration, the relationship can generate extra costs for each partner. Thus, survival in a market with a high degree of applicable regulations remains illusive. In the pharmaceutical industry, the partners should not concentrate on short term objectives for immediate profit. The lack of product, price and distribution strategies and also the lack of specialists and management performances can lead the company to an early end.

On the pharma market, there are three main types of economic agents: suppliers, distributors, and drugstores. Under authorizations, they sell two types of pharmaceuticals products: RX – authorized drugs that are sold only by means of a medical specialist's prescription and OTC (over the counter) – drugs that are sold without issuing a medical prescription. Similar to any market within a democratic territory, local and foreign suppliers with locally rooted factories exist. In some countries, foreign agents are more numerous than local suppliers and become increasingly more interested in local sales and strategic exports where competition is not very intense compared to their home market. This is also the case of Romania, where the rules of the commercial chain are mostly "made" by foreign economic agents. Thus, the local suppliers' market share remains infallible and insignificant.

Usually, at a national level, foreign suppliers reunite in cluster organizations. As an example in this regard, in order to piece together their common objectives, the international pharmaceutical companies, present on Romania's territory, created an association that supports the interests of pharma companies in relation to the local government. It also facilitates the access of Romanian patients to the technological advances of the pharmaceutical industry related to new drugs in the R&D area. According to the official site, the common spectrum was established in 1995 under the name of the International Association of International Medicine Suppliers (ARPIM), which currently has 29 international members, including: Amgen, AstraZeneca, Bayer, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Merck Sharp & Dohme, Novartis, Pfizer, Sanofi and so on.

Besides locating various factories at the national level, foreign suppliers aim to reduce their consistent costs with the use of cheap local labor force. Thus, the most important costs are redirected to the research and development area. By placing their factories in Romania and benefiting from the cheap labor force and the fairly good geographic location of our country, the foreign suppliers go even further, exporting directly from Romania to the nearest countries in Europe, only to eliminate extra costs related to distance. The Romanian pharma cluster has some strategic economic connotations such as shrinking the distance between supplier and final consumer both physically and emotionally from a marketing point of view. Also, according to Sherry Ku (2015), "big pharma is also keen on in-licensing technology or projects from specialty pharma to extend product life cycles, in order to protect their blockbuster drug franchises".

We consider the pharma industry to be slightly different compared to other industries. This is not about the customers' preference for choosing a single supplier, rather it is about choosing a medication prescribed by doctors/ recommended by pharmacists for different diagnoses. People talk to each other about different health issues in order to treat them and they express their opinion regarding various drugs that benefited them. Marketing occurs differently in the pharmaceutical sector. People don't take medication because they enjoy taking it; they use drugs only to improve their health. In the pharma industry, a drug's composition is more important than the company itself, as long as the substances used in the composition help improve the condition of the patient. According to Bartfai and Lees (2013), "competition forces companies to do both: improve drugs in a class and open new markets for novel classes of drugs that treat as yet untreated diseases or treat diseases by utilizing a novel mechanism of action, i.e., being <<FIRST in class>>".

Another reason identified by us refers to the costs generated by different market regulations. In 2016, the Romanian pharmaceutical market had over 330 manufacturers, of which only 30 were local companies. The top 10 companies easily cover more than half of the total market share. A large number of local suppliers have left Romania because they have failed to combat the huge cost of good manufacturing practice and EU standards. Good manufacturing practice (GMP) describes "the minimum standard that a pharmaceutical supplier must meet in its production processes. The European Medicines Agency (EMA) coordinates inspections to verify compliance with these standards and plays a key role in harmonizing GMP activities at European Union (EU) level".

When we refer to the pharmaceutical market legislation in Romania, we recall two measures that have a major impact on this industry, namely:

a) Clawback fee - suppliers that have been authorized to sell medicines must pay a fee on a quarterly basis. Among the three categories of players on the pharma market, the suppliers are the only ones that have a disadvantage. In addition to allocating enormous amounts in the R&D field, they are bound to pay a fee that has reached up to 19.86% in Q1 2017. In 2016, The Romanian Association of International Medicine Suppliers has urged the government to increase its budget

related to pharmaceutical industry and revise its clawback tax policy as soon as possible. According to a case study from Hare, "clawback system requires pharmaceutical market players to contribute to the public health system with an amount determined on the basis of the turnover obtained on public funding (either reimbursement, hospital consumption or another type of use sponsored by State) (...). However, due to the critical situation faced by the public health system in the last year months, authorities have undertaken several steps for the implementation of this type of expenditure containment mechanism for the Romanian pharmaceutical market". However, in Romania, the clawback charge was adopted as a temporary control measure, in order to surpass 2011's crisis situation. Since its imposition, the clawback tax has been paid quarterly, which significantly impacts on suppliers' revenues. According to the Government Emergency Ordonnance no. 77/2011, the quarterly contribution is reimbursed to the National Health Insurance Fund as a genuine partnership between Government and Marketing Authorization Holders' (MAH) companies in the interest of public health. According to the National Institute of Statistics, Romania recorded an economic growth in 2016. Thus, suppliers have demanded the authorities to eliminate this tax as it no longer justifies its significance. The percentage generated by the clawback tax is calculated as follows:

$$P = (CTt\text{-}BAt) / CTt \times 100$$

where

CTt represents the total quarterly consumption of medication for which there is an obligation to pay from the National Health Insurance Fund and the budget of the Ministry of Health(...);
BAt budget is approved quarterly in relation to the quarterly approved budget.

This percentage applies to total sales made by the pharma suppliers. The total consumption value is calculated with the help of monthly reports submitted by drug stores and hospital units with beds or dialysis centers.

b) The second regulation is the imposition of prices for RX drugs. The drugs with a special regime are those in the category of "toxins and drugs". These drugs can be sold only to authorized hospitals and pharmacies. The drugs have standard prices, which are mentioned in the CaNaMed reports. This official list is published every quarter by the Ministry of Health. The company is informed about these official modifications of medication prices, through ANM (National Medication's Agency). The list is usually issued quarterly, but there are cases when the price list is released over a long period of time and there are also other situations where prices for certain drugs change in less than three months. The last CaNaMed list was issued on April 2017. According to the Business Monitor Information (BMI) report from 2016, in line with Romania's economic outperformance in Europe, the country's pharmaceutical and healthcare markets will face a strong growth given the increased consumer spending power and higher healthcare contributions. The Romanian local drug manufacturing industry gets taken over by the private sector and foreign companies. The strengthening of wholesale and retail trade signals a high degree of maturity on the market. BMI expects sales of RX drugs to increase to RON 11.42bn (USD3.01bn) by 2019, and to RON 16.86bn (USD4.39bn) by 2024.

Regarding worldwide prescription drug sales, according to Evaluate Pharma consensus forecasts, the pharmaceutical industry is set to grow at 6.3% per year (CAGR) reaching $1.12tr by 2022.

By nature, drugs are divided into two categories: generic and innovative. According to the US Food and Drug Administration, "a generic drug is identical or bioequivalent to a brand name drug in dosage form, safety, strength, and route of administration, quality, performance characteristics and intended use (…) generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price". We expect the growing take-up of generic drugs and patented drug substitutions to impact sales in the future; we think that the demand for innovative medicines will drive growth. Nonetheless, declining spending on generics will free up expenditure for newer, innovative medicines. Generic drugs will not be the key to drive overall market growth, given the severe constraints stemming.

A specific feature of the pharmaceutical products market is the existence of a classification system through which the drugs are grouped by functional substitution, i.e. according to the therapeutic indications. The Anatomical-Therapeutic-Chemical (ATC) system is hierarchically organized and contains 16 categories (A, B, C, D, etc.), each category contains up to four levels. The first level (ATC1) is the most general and the fourth level (ATC4) is the most detailed. This classification system has been designed by the European Pharmacist Marketing Research Association (EPhMRA) and it is widely recognized as Intercontinental Medical Statistics (IMS).

The best-selling OTC drug in 2015 and 2016 is Nurofen. In 2016, it was followed by ParaSinus and No Spa. The ATC* codes for these medications are as follows (Table 1)**:

Table 1. Top 3 OTC sales- pharma products
(according to Anatomical Therapeutic Chemical Classification System)

Nurofen – MO1AE01	Parasinus – N02BE51	No Spa – A03D02
M Musculo-skeletal system	N Nervous system	A Alimentary tract and metabolism
M 01 Anti-inflammatory and antirheumatic products	N02 Analgesics	A03 drugs for functional gastrointestinal disorders
M 01 A Anti-inflammatory and antirheumatic products, non-steroids	N02B other analgesics and antipyretics	A03A Drugs for functional gastrointestinal disorders
M 01 AE Propionic acid derivatives	N02BE Anilides	A03AD Ppaverine and derivates
M 01 AE 01 Ibuprofenum	N02BE51 Paracetamol, combinations excl. psycholeptics	A03D02 droverine

*National Health House's site: http://www.cnas.ro/page/consum-medicamente.html
**WHO Collaborating Centre for Drug Statistics Methodology -
https://www.whocc.no/atc_ddd_index/

We further analyzed the total value of prescription drugs used in 2016 based on ATC levels. The databases are downloaded from the National Health House's site and contain the consumption of drugs borne by the FNUASS and the Ministry of Health including VAT (without the value of consumption for drugs issued in 2016 for Q1, Q2, Q3 and Q4 which are subject to volume/cost resulting volume contracts). Following the analysis that we made on these databases, we reached the following conclusions:
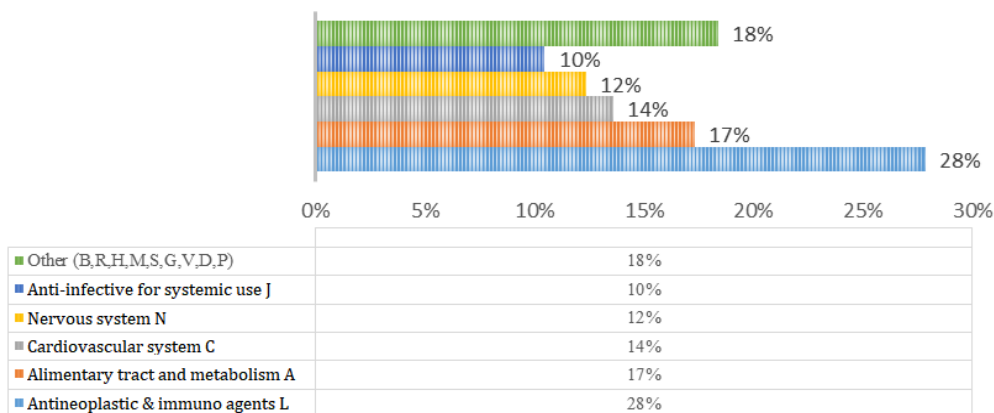
All four quarters of 2016 have the following dominant classes: L Class - Antineoplastic and immunomodulation agents RON mil. 2,016, A Class - Alimentary Tract and Metabolism with RON mil. 1,251, C Class - Cardiovascular System with RON mil. 984, N Class - Nervous System with RON mil. 894, J Class - Anti-infective for systemic use with RON mil. 757, B Class - Blood and blood forming organs with RON mil. 501 and R Class - Respiratory system with RON mil. 280. As seen below, the first quarter of 2016 registered almost the same value (RON mil. 1,794) as the second quarter, the third quarter decreased slightly with RON mil. 15 to RON mil. 1,779 and the fourth quarter recorded the highest value of all quarters for the year 2016 RON mil. 1,865. For further details, please see Table 2. We have excluded the databases formed by ATC4 classes that were not found in CaNaMed lists.

Table 2. Q1-Q4 2016 total RX consumption
(data downloaded from National Health House's site, processed by the authors)

ATCCS	Class	Q1*	Q2 *	Q3*	Q4*	Total 2016*
Antineoplastic and immunomodulation agents	L	490,445,789	502,405,330	508,412,927	514,996,101	2,016,260,147
Alimentary tract and metabolism	A	306,923,193	307,830,661	312,054,817	324,956,284	1,251,764,954
Cardiovascular system	C	241,628,385	244,909,523	244,059,862	253,925,404	984,523,174
Nervous system	N	223,016,853	223,813,394	219,312,055	228,660,321	894,802,624
Anti-infective for systemic use	J	195,156,119	187,588,596	178,598,294	196,004,018	757,347,028
Blood and blood forming organs	B	120,453,587	124,859,459	124,587,734	131,656,339	501,557,119
Respiratory system	R	77,336,679	66,005,495	59,023,917	77,789,936	280,156,028
Other (H, M, S, G,V, D, P)		39,773,266	37,467,394	133,189,945	137,999,523	139,773,266
	Total	1,794,733,872	1,794,879,853	1,779,239,550	1,865,987,927	7,234,841,202

* without VAT (9%), the values are stated in RON

In order to see how each class's percentages related to total consumption in 2016, we represented graphically the main classes of the Anatomical Therapeutic Chemical Classification System. L Class covers 28% of total drug use in 2016 (Figure 1).

■ Other (B,R,H,M,S,G,V,D,P)	18%
■ Anti-infective for systemic use J	10%
■ Nervous system N	12%
■ Cardiovascular system C	14%
■ Alimentary tract and metabolism A	17%
■ Antineoplastic & immuno agents L	28%

Figure 1. 2016 RX Consumption (%) (made by the authors)

Through data processing, we have obtained the results from Table 3. Hence, the classes that had increased are the following: Respiratory System (R) - variation that reached 32% in Q4 compared to Q3; Class of Anti-Infectious Systemic Use (J) - variation that reached the 10% threshold over Q3. The classes that decreased the most are the following: Respiratory system class in Q2 compared to Q1, and the same class decreased by 11% in Q3 compared to Q2.

Table 3. Q1-Q4 Variations - absolute and percentage values (made by the authors)

ATCCS	Class	Variation Q1 – Q2	Variation Q2-Q3	Variation Q3-Q4	Var Q1-Q2 %	Var Q2-Q3 %	Var Q3-Q4 %
Antineoplastic and immunomodulation agents	L	11,959,541	6,007,596	6,583,174	2%	1%	1%
Alimentary tract and metabolism	A	907,468	4,224,156	12,901,468	0%	1%	4%
Cardiovascular system	C	3,281,138	(849,661)	9,865,541	1%	0%	4%
Nervous system	N	796,541	(4,501,339)	9,348,266	0%	-2%	4%
Anti-infective for systemic use	J	(7,567,523)	(8,990,303)	17,405,725	-4%	-5%	10%
Blood and blood forming organs	B	4,405,872	(271,725)	7,068,606	4%	0%	6%
Respiratory system	R	(11,331,183)	(6,981,578)	18,766,018	-15%	-11%	32%
Other (H, M, S, G,V, D, P)		(2,305,872)	(4,277,450)	4,809,578	-8%	-12%	15%
	Total	145,982	(15,640,303)	86,748,376			

Although Q2 balance did not vary greatly from Q1, it can be noticed that things were different at the class level. L class variation closed with R class variation, also B and C classes closed with J class; a closing balance of only RON mil. 0,145 remained.

Onward, the average price/unit for RX was calculated according to the CaNaMed prices list for each class published by the Ministry of Health between September 2015 and October 2016 in correlation with data downloaded from the National Health House's website. For Q1, we correlated the price list published in September 2015; for Q2 we used the CaNaMed list published in April 2016, for Q3 we used the

CaNaMed list published in July 2016 and last but not least for Q4 we used the price list published on October 2016.

As a summary, the average prices varied from one class to another (Figure 2), exerting an impact on the medicine market value. It can be seen that Class L is on top of the list and Class P - Antiparasitic products fall to the queue of the ranking with an average price of RON/unit 8. As it can be seen in the chart below there is an increase in drug prices from one quarter to the next. The highest prices` increase was recorded in the following classes:
- Blood and blood forming organs (B): 602 units from Q3 to Q4;
- Varia (Various) (V): 321 units from Q3 to Q4;
- Systemic hormonal preparations, excluding sex hormones and insulins (H): 247 units from Q1 to Q3;
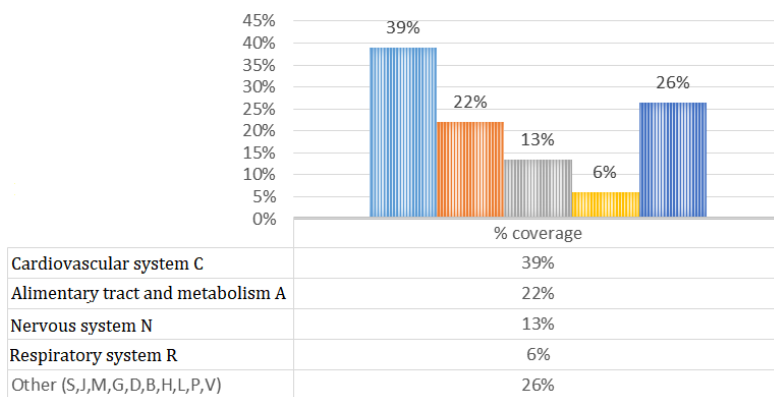- Sensory Organs Class (S): 289 units from Q2 to Q3.
The biggest drops in unit prices were registered in the following classes:
- Sensory Organs (S): - 289 units from Q1 to Q2;
- Respiratory system (R): - 203 units from Q3 to Q4.
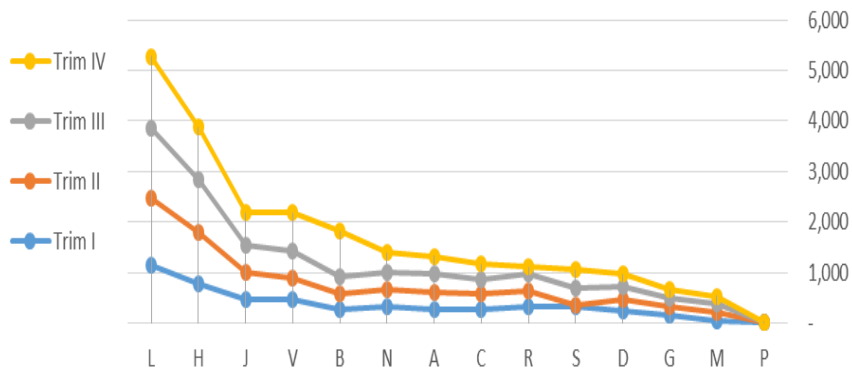
*Figure 2. Q1-Q4 2016 RX average price (made by the authors)*

Following Figure 3, the highest RX drugs consumption was registered in class C with 39% of total ATC classes, class A ranked second with 22%, followed by class N with 13% and class R with 5% of total ATC year value.

	% coverage
Cardiovascular system C	39%
Alimentary tract and metabolism A	22%
Nervous system N	13%
Respiratory system R	6%
Other (S,J,M,G,D,B,H,L,P,V)	26%

Figure 3. 2016 RX Total Consumption value (percentage)
(made by the authors)

The quantity expressed in units for each class was calculated as the ratio between total value without VAT per ATC – level 3 (i.e. A02A) and the average unit price calculated for each ATC3 based on the CaNaMed lists.

As a review of the quarterly evolution (Figure 4), we can see that the highest absolute consumption increase was recorded in Q4 with approximately 759K units compared to Q3 in Respiratory System (R) and the highest decrease can be found in Q2 vs. Q1 in N- Nervous System class with approximately 1644K units. The percentage of the largest decrease per class was recorded in Q2 by -35% compared to Q1 in R class and the highest increase was registered in class R by 45% in Q4 compared to Q3.
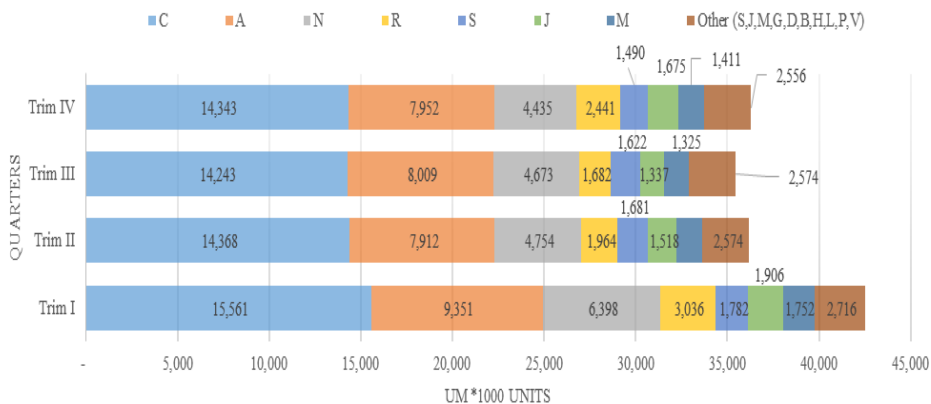
Figure 4. Q1-Q4 2016 RX Total Consumption values based on ATC classes
(made by the authors)

Conclusions and implications

As a conclusion related to the drug consumption value, the total value decreased from one quarter to another. The increases in RON were generated by the price increases and not by the quantities of units bought by the final consumer. Between September 2015 and October 2016, there were 6033 RX drugs settled in CaNaMed lists. The most regulated drugs remain in class N, followed by class C and class J. The number of the regulated drugs increased from 5223 to 5547 including new/removed drugs (Table 4).

Table 4. Number of RX drugs based on CaNaMed lists (made by the authors)

CaNaMed list	Sep-15	Apr-16	Jul-16	Oct-16
Total	5223	5392	5418	5547
N	1047	1123	1137	1158
C	1009	988	993	992
J	653	683	682	699
L	590	620	627	647
B	397	416	416	431
A	412	422	420	427
M	279	285	283	281
G	220	242	245	248
R	200	202	203	202
V	93	97	97	139
S	103	102	103	111
D	115	106	106	105
H	84	86	87	87
P	21	20	19	20

According to Table 5, we can see that generic drugs are more numerous than innovative ones. Innovative drugs are more expensive compared to generic drugs.

Table 5. Total RX drugs categories (made by the authors)

CaNaMed list	Sep-15	Apr-16	Jul-16	Oct-16
Generic	3381	3456	3475	3578
Innovative	1714	1835	1834	1856
Others	128	101	109	113
Total	5223	5392	5418	5547

The pharmaceutical market remains a booming industry in Romania, being full of opportunities and attractiveness for foreign suppliers. Furthermore, the dismissal of the clawback tax could greatly stimulate research and development in Romania, taking into consideration that this tax affects the suppliers' budgets.

As a repertory of this phenomenon, if we look at the macroeconomic level, it would also have an impact on the life expectancy indicator. According to the National

Institute of Statistics' publication in 2016, "medical factors (prevention, important advances in the diagnosis and treatment of diseases as well as in the development of surgical interventions, new generation drugs), economic factors (costs associated with chronic healing and reforming health systems) and social factors (...) have been the basis for increasing life expectancy in recent years, but developed countries have made a stronger advance from this point of view". This topic will be approached in another scientific paper that we aim to develop.

References

Bartfai, T., & Lees, G.V. (2013). The Future of Drug Discovery, Who decides which diseases to treat? Retrieved from http://www.sciencedirect.com/science/article/pii/B9780124071803000076.

Chu, S., Sun, C., & Liang C. (2010). Pharmaceutical Enterprises' R&D Strategic Alliance - the Road for Small and Medium Sized Pharmaceutical Enterprises' R&D in China, *International Business Research*, 3(1), 131-135.

Evaluate Pharma Worldwide Preview (2016). Outlook to 2022, 9th Edition September. Retrieved from http://info.evaluategroup.com/rs/607-YGS-364/images/wp16.pdf.

Hare, Clawback - Either RO or HU is the lesser of the two "evils"? (case study). Retrieved from http://www.hare.linkresource.ro/public/articles/case_study_details/59.

Hunter, J., & Stephens, S. (2010). Is open innovation the way forward for big pharma? *Nature Reviews Drug Discovery.* 9(2), 87–88.

Gautam, A., & Pan X. (2016). The changing model of big pharma: impact of key trends *Drug Discovery Today*, 21(3), 379-384.

Good manufacturing practice (GMP) – European Medicines Agency. Retrieved from http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001205.jsp&mid=WC0b01ac0580027088.

National Health Insurance Fund and the Ministry of Health budget (2017). Q1 2017 Drugs consumption. Retrieved from http://www.cnas.ro/media/pageFiles/ATC3%20consum%20Clawback%20T1%202017.pdf

National Institute of Statistics (2017). Gross Domestic Product grew by 4.8% in 2016 compared to 2015, Press release, 42/14 February. Retrieved from http://www.insse.ro/cms/sites/default/files/com_presa/com_pdf/pib_trim4r2016_0.pdf.

National Institute of Statistics (2016). Healthy life expectancy. Retrieved from http://www.insse.ro/cms/sites/default/files/field/publicatii/speranta_de_viata_sanatoasa.pdf.

Schuhmacher, A., Germann, P.G., Trill, H., & Gassmann O. (2013). Models for open innovation in the pharmaceutical industry, *Drug Discovery Today*, 18(23-24), 1133-1137.

Sherry, Ku, M. (2015). Recent trends in specialty pharma business model, *Journal of Food and Drug Analysis*, 23(4), 595-608.

553/05.08.2010 Official Gazette of Romania

77/2011 General Emergency Ordonnance. Retrieved from
http://lege5.ro/Gratuit/gi3dcnrvgi/ordonan-a-de-urgen-nr-77-2011-
privind-stabilirea-unor-contribu-ii-pentru-finan-area-unor-cheltuieli-n-
domeniul-s-n-t-ii.

Websites

International Association of International Medicine Suppliers – official site:
http://arpim.ro/.
National Drug Agency's official site,
http://193.169.156.200/app/nom1/anm_list.asp?s_den_com=&s_dci=&s_fir
m_tar_d=&anmOrder=Sorter_firm_tar_d&s_forma_farm=&s_cod_atc=&s_cim=
&anmDir=DESC&anmPage=375.
National Health House's official site, http://www.cnas.ro/page/consum-
medicamente.html.
US Food and Drug Administration (2015). Retrieved from
https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedic
inesafely/understandinggenericdrugs/ucm144456.htm.
WHO Collaborating Centre for Drug Statistics Methodology. Retrieved from
https://www.whocc.no/atc_ddd_index/.