

## STUDY OF LIFE QUALITY AND TREATMENT SATISFACTION OF ROMANIAN DIABETIC PATIENTS

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### Abstract:

In Romania, antidiabetic medication is free, based on a program of the Ministry of Public Health: "Treatment of patients with diabetes mellitus". Since October 1, 2006, antidiabetic drugs have been delivered through open circuit pharmacies in contractual relationship with the National Health Insurance House, after four years of centralized delivery through hospital pharmacies.

Objectives: This study aims to describe the influences of the diabetes treatment regarding patients' quality of life and their satisfaction.

Methods: A cross-sectional descriptive study was performed in pharmacies. The study includes 477 patients with diabetes mellitus from Cluj County, Romania. The interviewing method was used on a questionnaire base. The participants included in the study admitted to participate in May-June, 2016.

The questionnaire was systematically developed following comprehensive literature review and structured according to 3 main fields: 1) patient demographics; 2) diabetes patient treatment and 3) glycaemia control and patient satisfaction.

Results: The research performed in two months showed that 78% of the respondents used oral antidiabetics for treatment, more than 19% of the inquired patients reached normal glycaemia values following antidiabetic treatment, and about 82% of patients were satisfied with the current system of acquisition of antidiabetic drugs.

Conclusions: The treatment with antidiabetic drugs maintains a relatively good health status. Also, the life expectancy of diabetic patients has increased over the past period.

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### Introduction

Diabetes mellitus (DM) is a metabolic disorder produced by a defect in insulin secretion or/and insulin action which is result of an inadequate life style (Ghibu et al., 2013; Hâncu et al., 2008; Ghibu et al., 2015). The global prevalence of diabetes was 382 million people in 2013, and there it expected to rise to 592 million by 2035 (Farouhi, 2014). Cho et al. have shown that according to data presented by the International Diabetes Federation (IDF), in 2017, it was estimated that the number of people with diabetes worldwide was 451 million people (18–99 years of age), and this number is expected to rise to 693 million by 2045. The same study presented that above 5 million deaths (20-99 years age range) were caused by DM (Cho et al., 2018; IDF, 2017). Because of this, government policies have to ensure appropriate access to treatment for all diabetes patients.

Since 1998, the Ministry of Health from Romania has implemented a national health program for the diagnosis, prevention and treat of diabetes mellitus (Morgovan et al., 2010a). Although, there have been incoherent policies regarding the financing of the Romanian health system over time (Morgovan et al., 2010b), the diabetes program has provided the antidiabetic medication needed to improve the patients' pathology (Morgovan et al., 2010a).

The objectives of this program are: decreasing of glycaemia, reduction of the risk of complications, prevention of the worsening of complication, development of the patient's knowledge and skills in diabetes care etc. This program is financed by the Romanian Ministry of Public Health (MPH) and the Romanian National Health Insurance House – NHIH (Ministry of Public Health, 2006; Morgovan et al., 2011).

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The increase of the funds allocated by the authorities to treat diabetes mellitus (Cefalu, 2013; Colombo et al., 2012), should lead to optimal control of diabetes pathology, and implicitly, at the increase of life quality and satisfaction level of the patients (Lascar et al., 2018).

The diabetic patient is the most important member of the team working for the treatment of the disease. The trained patient is capable of self-observance and self-control (Hâncu et al., 2008; Ministry of Health, 2016). The satisfaction of diabetic patients results from the achievement of the above-mentioned objectives, as well as from the easy acquisition of the prescribed antidiabetic medication.

### Data and methodology

This study was carried out in the period of 1st of May 2016 – 30th of June 2016, in pharmacies from Cluj County, Romania. The selected group represents all diabetic patients who visited the pharmacies selected during the period concerned. Subsequently, the study group was divided into five age groups: A < 18 years, B = 19-30 years, C = 30-45 years, D = 46-60 years and E > 61 years; into three treatment subgroup (OAD, insulin, OAD+insulin) and five disease period subgroups (<1 years, 1-3 years, 3-5 years, 5-10 years, >10 years) in order to compare some aspects on pathology control.

The interviewing method on the questionnaire base (Cuc et al., 2015) was implemented to analyse the control of diabetes and evaluate the patients' life quality. The questionnaire was formed by structured and unstructured questions (Q) divided in 3 parts: 1) personal information (Q1-4); 2) information about disease and treatment (Q5-8); 3) Information about the patient quality of life (other diseases, control of glycaemia, the degree of patient satisfaction and patients' problems (Q9-12). For the processing of the quantitative data, the Microsoft Excel program was used (Cosma et al., 2011; Văleanu et al., 2009).

### Results and discussion

At the end of 2015, in Romania were recorded in NHIH evidences 999,192 diabetic patients, in which 36,755 were in Cluj County (~3.67%) (National Public Health Institute, 2018). The 477 diabetic patients in our sample (1.30% of all number of patients from Cluj County) were asked, to fill out a questionnaire without having to disclose their identity.

The patients' availability rate regarding the filling out of the questionnaires was 94.55%, meaning a total of 451 patients. Of all 451 questionnaires, 13 were invalid, only the 438 valid questionnaires (97.12%) were taken into consideration.

#### a) Information about the patient

The analysis of the answers given to the first question showed that 68.5% of the inquired patients were older than 46 years, 29.68% of patients were aged between 19-45 years, and only 1.83% of patients were younger than 18 years.

Table 1: Demographic data regarding the group

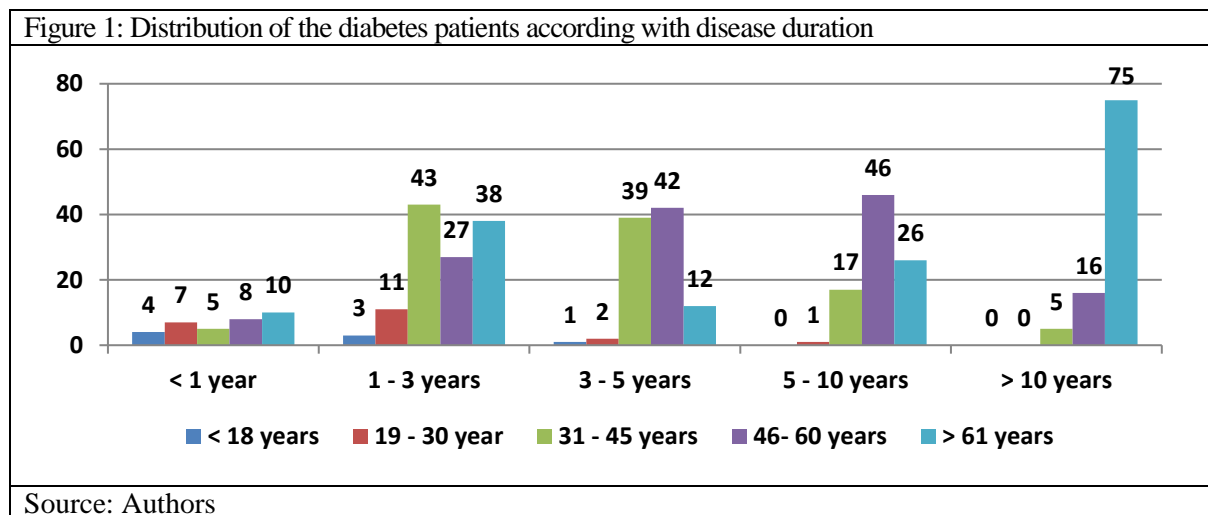
Parameter	Code	Structure	No	%
<b>Gender (n, %)</b>				
	<b>M</b>	male	191	43.61%
	<b>F</b>	female	247	56.39%
<b>Age</b>				
	<b>A</b>	< 18 years	8	1.83%
	<b>B</b>	19 - 30 year	21	4.79%
	<b>C</b>	31 - 45 years	109	24.89%
	<b>D</b>	46- 60 years	139	31.74%
	<b>E</b>	> 61 years	161	36.76%
<b>Residence area (n, %)</b>				
	<b>U</b>	Urban	276	63.01%
	<b>R</b>	Rural	162	36.99%
<b>Occupation</b>				
	<b>S</b>	Student	14	3.20%
	<b>E</b>	Employee	287	65.53%
	<b>R</b>	Retired	82	18.72%
	<b>U</b>	Unemployed	55	12.56%

Source: Authors

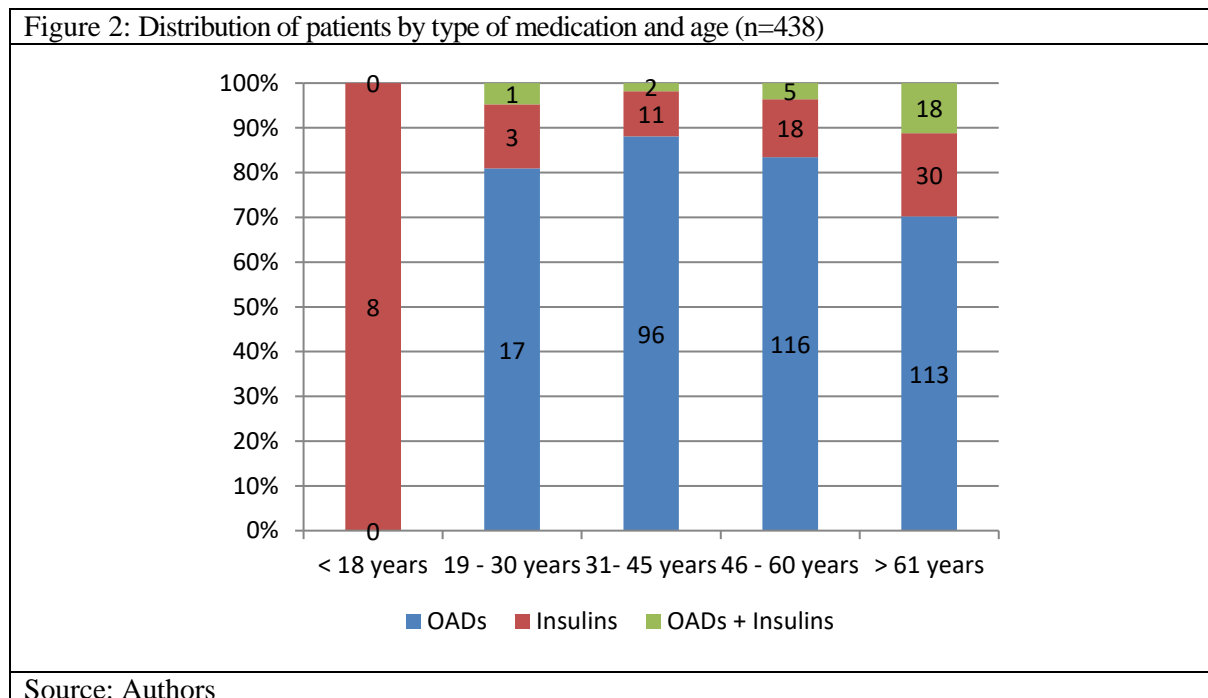
**b) Information about treatment**

34 patients (7.76%) were diagnosed with diabetes mellitus over the past year, 27.85% were diagnosed in the past 1-3 years, 21.92% 3-5 years ago, 20.55% were diagnosed between 5-10 years ago, and the others (21.92%) were diagnosed more than 10 years ago. In the last year, 11 young patients, aged less than 30 years (2.5%) and 5 patients from the C group (31-45 years old) (4.59%) were diagnosed with diabetes mellitus (Figure 1). According to the results of other studies (Dabelea et al., 2014; Mayer-Davis et al., 2017; Lascar et al., 2018) there is an increased diabetes risk for young people.

Of the 438 respondents, 342 used OADs (78.08%) and 70 used insulin injections (15.98%). A number of 26 patients (5.94%) have to use both OADs and insulin to control their glycaemia.



The ratio of the patients requiring insulin alone or combined with OADs in the studied group (21.92%, n=96) can be compared to the estimations of the Minister of Public Health (28.16%) (National Health Insurance House, 2015) (Figure 2).



Oral antidiabetic drugs (OAD, n=342) were taken alone by: 4.97% from group B, 28.07% from group C, 33.92% from group D and 33.04% from group E.

Insulin therapy (IT, n=70) was used by all patients from group A (11.43% ), 4.29% from group B, 15.71% from group C, 25.71% from group D and 42.86% from group E.

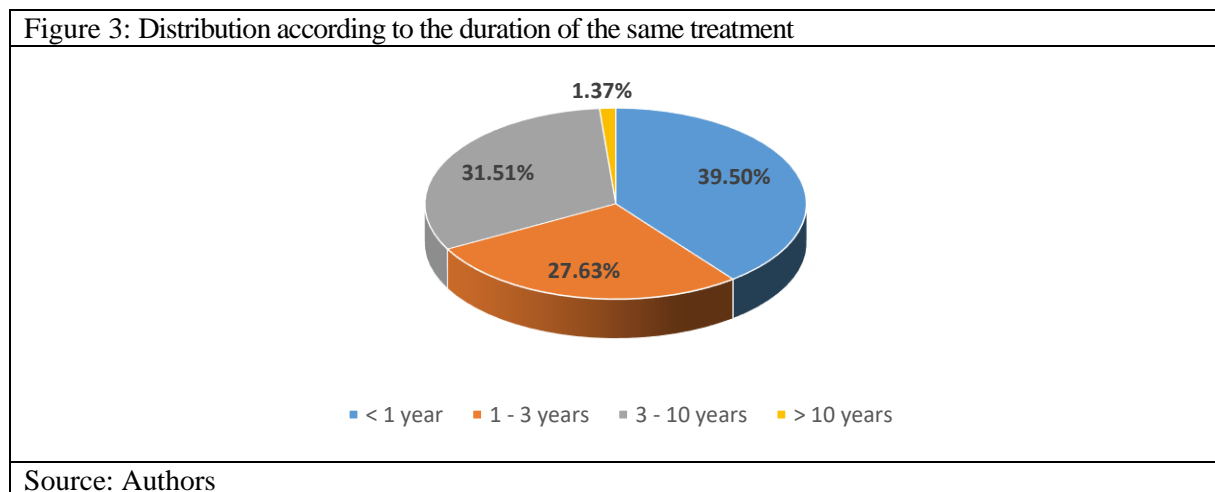
Oral therapy taken in addition to insulin therapy (OAD+IT, n=26) was found in 3.85% patients from group B, 7.69% from group C, 19.23% from group D and 69.24% from group E.

OADs (n=368) consisted in a proportion of 26.35% of *sulfonylurea* drugs (n=97). The *biguanides* were prescribed for 178 patients (48.37%). The combination of *metformin-sulfonylureas* represented 13.05% from the prescriptions (48 patients). Expensive oral antidiabetic drugs: *pioglitazone* (n=6), *acarbose* (n=12) (Morgovan et al., 2011), *sitagliptine* were prescribed (n=8, 12.22%) for a smaller number of patients. At the time of the study, no respondent was treated with *saxagliptine*, *exenatide* or *dapagliflozin*.

Of the 96 patients treated with insulin, 17 used prandial insulin (17.71%), 55 used basal insulin (57.30%) and 24 used both types of insulin (25%). As prandial therapy (Yonliang et al., 2015) were used: 1) human insulin [rDNA origin] and 2) insulin analogues (*insulin aspartat*, *insulin lyspro*, *insulin glulysine*). Basal insulins used were *recombinant human insulin* and *insulin glargine* (a long acting analogue). The combined IT can be assured by a combination of two insulins (one prandial and one basal) or by premixed preparations (biphasic insulins) (Yki-Jarvinen, 2001).

Other results refer to the use of insulin analogues. A number of 44 patients (45.83%) used insulin analogues or premixed combinations with analogues: a) fast acting analogues – 10 patients; b) long acting analogues - 16 patients; c) 18 patients with combined IT. Insulin glargine, the most expensive insulin currently available on the Romanian market (Morgovan et al., 2011), was prescribed to 28 patients (29.17%).

Another point of our study was to identify the efficacy of the treatment (Q8): a) 173 patients (39.5%) had used the same treatment for less than one year; 121 patients (27.63%) had used the treatment for 1-3 years; c) 138 patients had used the same treatment between 3-10 years (31.51%); d) 6 patients diagnosed with diabetes mellitus more than 10 years had been under the same treatment for more than 10 years (1.37%) (Figure 3).



### c) Control of glycaemia and degree of patient satisfaction

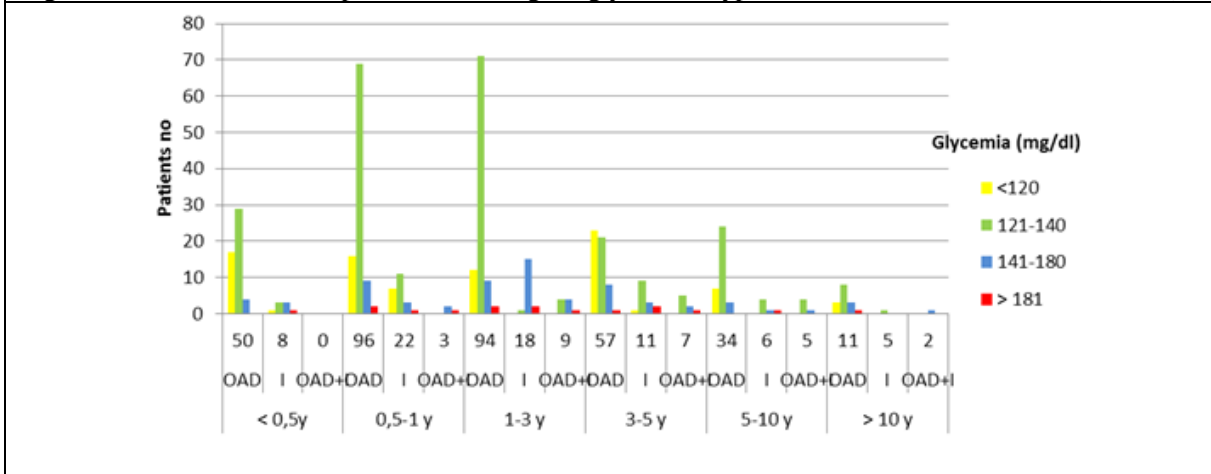
Regarding diseases associated with diabetes, only 252 patients (57.53%) had reported complications: a) one complication for 156 patients (35.6%); b) two complication at 54 patients (12.3%); and c) three complications for 42 patients (9.6%). Of all the inquired patients, 32.9% had heart diseases (n=144), 19.2% presented with neuropathies (n=84), 17.9% had ophthalmologic disorders (n=78), 0.7% renal disorders (n=3), and 18.5% (n=81) had other disorders.

The patients with other disorders can be classified as follows: a) patients treated with *biguanides* alone or in combinations (156); b) patients treated with *acarbose* (4); c) patients treated with *other OADs* (33); d) patients with IT (53). *Metformin* can improve the glucose and lipid metabolism and it can offer protection against cardiovascular diseases (lowering the risk of myocardial infarction and atherosclerosis by promoting endothelial integrity and preventing the formation of plaques) (Pryor, 2015). Also, *biguanides* or *thiazolidinediones* treatment are associated with 70% hepatocellular carcinoma risk-reduction among diabetics (Hassan et al., 2010). Because the majority of these patients were under treatment with *biguanides* or its combinations, obesity and dyslipidaemia can be considered another category of disorders.

Another question referred to the glycaemia values obtained following the administered treatment. As shown in Figure 4, values lower than 120 mg/dl were found in 87 patients (19.87%). For 264 patients, the glycaemia

was 121-140mg/dl (60.28%) and for other 87 patients the values were greater than 141 mg/dl (19.87%). These results show that, for the majority of the diabetic patients, the glycaemic control is optimal.

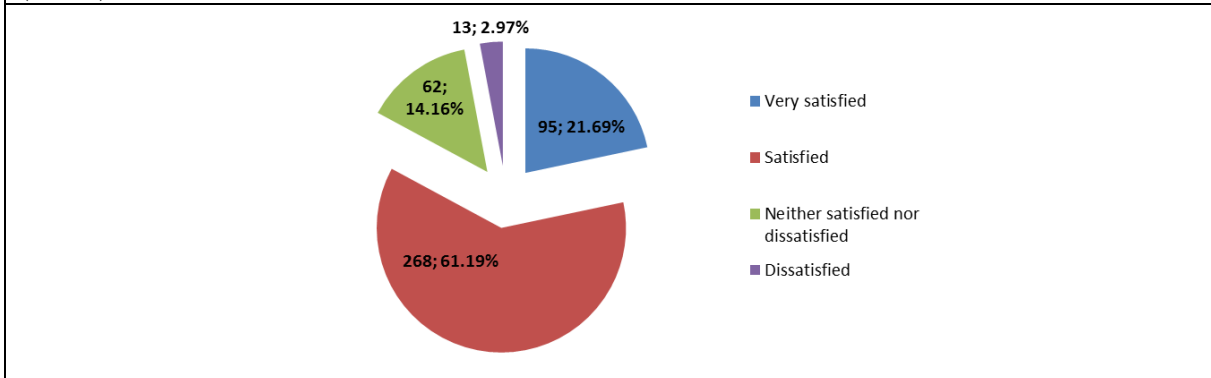
Figure 4: Distribution of the patients according the glycaemia, type and duration of the treatment (n=438)



Source: Authors

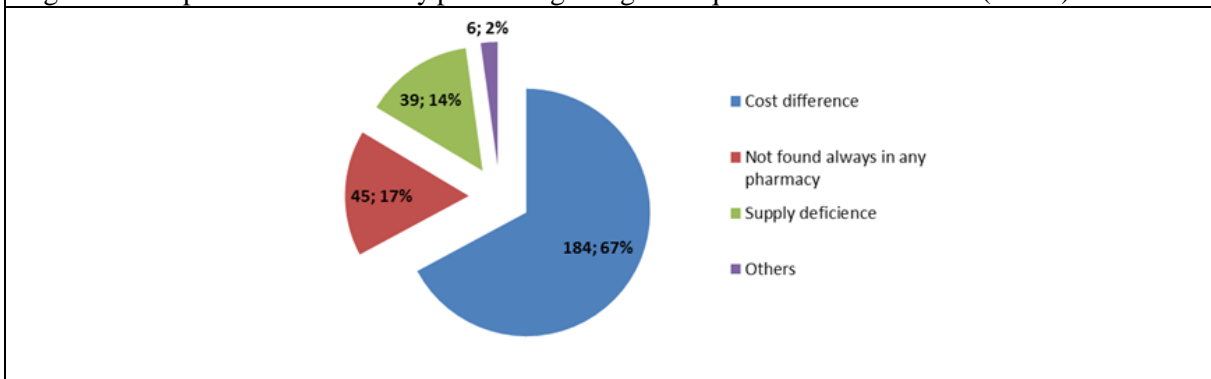
Only 6 patients with OADs had very increased values for glycaemia (>181 mg/dl) and 36 of them (10.35%) had increase values (141-180 mg/dl). It can be observed that a high value of glycaemia (141-180 mg/dl) is presented only for 5 patients with the same medicines in the 5-10 years and for 4 patients with the same treatment more than 10 years. Referring to drug acquisition, more than 82% of the inquired patients reported that they were satisfied or very satisfied with the current system of drug acquisition (363 patients). Only 13 patients (2.97%) expressed their total dissatisfaction with the system of drug acquisition. The remainder of the patients refused to answer (Figure 5).

Figure 5: Distribution of patients according to their satisfaction regarding the acquisition of antidiabetics (n=438)



Source: Authors

Figure 6: The problems identified by patients regarding the acquisition of antidiabetics (n=274)



Source: Authors

Further, it was aimed at finding out if there were difficulties in drug acquisition. No patient should interrupt treatment in order to keep the disease under control. 274 answers were given, some patients also providing two answer variants.

The main problem posed by patients was that they could not find the drugs in any pharmacy (45 patients). The deficiencies in the supply of pharmacies was a problem indicated by 39 respondents. A number of 184 patients reported to be dissatisfied because they had to pay additionally for antidiabetic medication. The six patients who indicated other problems did not mention their nature (Figure 6).

## Conclusions

A study based on questionnaires was performed in a group of 438 patients with diabetes mellitus in Romania, in order to find out more about diabetic patients, the disease characteristics, the treatment used and the difficulties related to drug acquisition. The study showed that people younger than 45 years have an increased risk for diabetes. Also, in the past period, adequate treatment can lead to a good health status and increase life expectancy. Only 252 patients presented complications (heart diseases, neuropathies, ophthalmologic or renal diseases). More than 80% of the patients have glycaemia values lower than 140 mg/dl, which shows the efficacy of the administered treatments. It can be noted that the degree of satisfaction of Romanian diabetic patients is high. The main concern for patients is their ability to purchase antidiabetic medicines from any pharmacy.

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