

LAW ENFORCEMENT AS AN OBLIGATION TO INFORMATION ON AMENDING REIMBURSEMENT LIST

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Abstract

Reimbursable drugs list is built on the principle of essential medicines lists. To avoid the negative effects of the pharmaceutical market and help doctors in drug treatment patients Experts Committee of WHO in 1977 has drawn Listen model of essential drugs. The concept of essential medicines is unanimously accepted by the World Health Assembly on, and the list of these medicines was adopted by 120 countries in the world beats. This list is constantly revised and improved several times over the years.

Purpose: The evidences of the violation of the law for informing pharmaceutical service as a legal right of pharmacists and as a liability for HII in the case of the approval of the reimbursement list for the coming year.

Method: In the study were required reimbursement lists for the period 2007 - 2011 and the price difference for the 10 drugs for this period. Reimbursement lists were analyzed for some of its elements: a. number of new drugs that enter the list and the number of drugs are removed for the period of mare we study, b. change of prices of 10 drugs that have the greatest consumption, c. I change the order that alternatives to these drugs that were taken in the study, d. difference in the price belonging to the patient pay for the same bar.

Result and Conclusions: In the end, the conclusion was reached that the entry into force and the beginning of implementation of the reimbursement list in different months of the year without prior notice of changes that were made has caused damage to ALL pharmacies as a result of the stock created drugs that had changed the order of the alternatives. Do not implement the law in relation to preliminary information pharmacists is put before a fait

accomplish by not leaving any opportunity to reduce stock or to obtain supplies of the drugs that enter the list for the first time or you spend the first alternative ..

Key Words: pharmaceutical legislation, information, drug price reimbursement list.

Introduction

Reimbursable drugs list is built on the principle of essential medicines lists. To avoid the negative effects of the pharmaceutical market and help doctors in drug treatment patients Ekerpeteve Committee of WHO in 1977 has drawn Listen model of essential drugs. The concept of essential medicines is unanimously accepted by the World Health Assembly on, and the list of these medicines was adopted by 120 countries in the world beats. This list is constantly revised and improved several times over the years. Tendency to draw up the list of essential nature observed today in all countries of the world, even in developed countries. Essential medicines lists are regulations between the needs of the population and the real possibility of the cost. Essential drug lists as a list of reimbursable drugs, provide drugs necessary for the treatment of patients. In these lists will include alternative medicines, in case of lack of efficacy of the drug, allergic reactions and the inability of its use.

Reimbursable drugs list changes every year by removing or introducing new drugs, changing reference prices or even change the order of the alternatives.

Reimbursable drugs list drawn up by the Commission of drafting and reviewing the list of drugs reimbursed at the Ministry of Health. Commission presents draft list for the new calendar year before the Council of Ministers, together with its financial bill.

The responsible institution for adoption and publication of this list has the legal obligation to notify interested parties of changes that will be made to the list. This is for two reasons:

1. Not to create medicine stock which will change and alternative price
2. To create the possibility of supplying pharmacy new medicines that will enter the list.

Material and methods of work

This study has been based on finding the problems associated with entry into force of list of reimbursement for the period 2007 - 2011, Base paper is a survey conducted in reimbursement lists for years taken in the study. The survey was carried out is divided into three parts. The first part of the survey related to the period when the entering into force of these lists. The second part related to the changes that were made to them in terms of new

drugs that have entered every year but also changes in prices for drugs that have a high intake. The third part relates to the difference in the price you have to pay the patients for the same bar or pharmacy loss of movement of the brain these lists year after year. Price differences are only made for packaging unit. Drugs that were obtained for the study were wider use by patients with chronic diseases who I used it for years. Change is the first payment for patients who do not benefit these drugs free seeing how varied this payment for the same bar for a one month treatment as awarded and prescriptions with a refund. This method of analysis was selected unable to have a full statistics how much is the annual consumption of these drugs on a national scale and how is the number of patients who use them.

Results of treatment

The survey conducted in 30 private entities between the period January 2009 - December 2012, entities that have expressed a desire to take the path of certification and quality management standard ISO 9001: 2008, shows that 60% of them think they know that what quality management, and in connection with the question of whether they know what are the principles of quality management only 30% of them claimed, while the question of implementing quality management principles, responded positively to only 2.46% of these subjects.

None of these companies visited is certified to the standard ISO 9001: 2008, only 20% have appointed quality manager in the company and only four of these subjects stated that they use quality management principles. This shows lack and deficiency in quality management and quality management standards, mainly standard ISO 9001: 2008 and it does not Albanian firms have shown a significant competitive advantage.

Discussion

The years will have these changes reflected in the following tables:

	YEAR 2007	YEAR 2008	YEAR 2009	YEAR 2010	YEAR 2011
INCREASED drugs (new alternatives)	14	21	31	17	24
LIST enters into force	APRIL	JULY	JUNE	APRIL	JUNE

Table 1.Months of the effective date of the reimbursement list

This table was constructed based on the books for years received reimbursement in the study.

Reimbursement List YEAR 2007

YEAR ²⁰⁰⁷				
chemical Name	Trade name	Reference Price	Patient Price	Reimbursement
Isuline	ACTRAPID	779.4	39	740.4
Metformine 850 mg	METFORMINE TEVA	9.2	4.6	4.6
Metoprolol 100mg	METOPROLOL Stada	14.6	4.4	10.2
Nevibolol 5mg	NEBILET	100.8	30.3	70.5
Valsartan 80 mg	DIOVAN 80mg	95	47.5	47.5
Valsartan + HCT 80/ 12.5	CO-DIOVAN 80/ 12.5	105.8	52.9	52.9
Tamsulosin 0.4 mg	URIMAX	71.1	21.3	49.8
Letrazol 2.5 MG	FEMARA	595.7	0	595.7
Acid Valproicum 300 mg	VALPRO STADA	21	3.2	17.8
Formoterol Fumarate	FORADIL	64	32	32

Table 2. Drugs included in the study, 2007

This table was constructed based on the book of drug reimbursement in 2007

Reimbursable drugs list for 2007 are introduced 14 new drugs that were not in the previous list of 2006. These are drugs that treat mainly cardiovascular diseases, talasemine and drugs antiprostatike. Jane released constraints therefore has expanded the coverage for at least 4 important drugs cardiovascular disease, 4 other antiprostatic and neurological drugs, antidiabetic etc.. For this year were not analyzed differences and changes in option prices as we took as reference year. These changes will we take them into account in the years to come then and drugs you have selected. According to the treatment protocol for a month recommend family physicians will be calculated difference in patient ALL you need to pay for the same bar. Simultaneously in subsequent years will be calculated loss pharmacy drugs that change alternative or removed from the list. This difference will be calculated per unit packaging. We cannot give the correct value because we do not have inventory for all pharmacies in the Republic of Albania, but this calculation will be done if we have been able only one pharmacy packaging unit.

Reimbursement List YEAR 2008

YEAR ²⁰⁰⁸				
Chemical Name	Trade name	Reference Price	Patient Price	Reimbursement
Isuline	ACTRAPID	778.5	38.9	739.6
Metformine 850 mg				
	GLIFOR	5.8	2.9	2.9
	METFORMINE TEVA	8.2	5.3	2.9
Metoprolol 100mg	METOPROLOL Stada	14.1	4.2	9.9
Nevibolol 5mg	NEBILET	100.4	30.1	70.3
Valsartan 80 mg	DIOVAN 80mg	94.7	47.3	47.4
Valsartan + HCT 80/ 12.5	CO-DIOVAN 80/ 12.5	105.4	52.7	52.7
Tamsulosin 0.4 mg				
	PROLOSIN	38.4	11.5	26.9
	URIMAX (alternativ 2)	40.1	13.2	26.9
Letrazol 2.5 MG	FEMARA	593.7	0	593.7
Acid Valproicum 300 mg				
	VALPRO TAD	20.9	3.1	17.9
	VALPRO AD eshte hequr nga lista			
Formoterol Fumarate	FORADIL	63.8	12.8	51

Tab.3 Drugs taken in the study year 2008

This table was constructed based on the list of reimbursed drugs in 2008

In this year the list I have added 21 new drugs alternatives, which were mainly related to heart diseases, diabetes, multiple sclerosis, etc.; and are replaced 5 drugs with new drugs. Were removed a few drugs that are produced or marketed in Albania, for which no alternative drugs in the current reimbursement list. U replaced 5 reimbursable drugs list 2007 with other dosage form of the same active principle and alternative active principles. These drugs were replaced after not being produced and marketed in our country. From the 2007 list are removed 9 drugs

Referring tab.3 note that we have alternative change to 2 drugs and a drug is removed from the list, it only selected drugs to be assessed. Difference in ALL you need to pay a patient for the same bar that was alive, in 2007 will be:

1. Metformine TEVA 60tab x 2.4 = 144
2. Urimax 0.4 mg 30tab x 1. = 51

Pharmacy for these drugs there is a loss in sales, calculated only for a packaging unit:

1. Metformine TEVA 90tab x 2.4 = 216
2. Urimax 0.4 mg 30tab x 1.7 = 51
3. Valpro AD 100tab x 21 = 2100 (removed from the list)

Reimbursement List YEAR 2009

YEAR ²⁰⁰⁹				
Chemical Name	Trade name	Reference Price	Patient Price	Reimbursement
Isuline				
	INSUMAN RAPID	775.1	38.7	736.4
	ACTRAPID(alternativ 2)	782	45.6	736.4
Metformine 850 mg				
	PROFARMA	4.3	0.2	4.1
	GLIFOR (alternativ 5)	5.8	1.7	4.1
	METFORMINE TEVA(alternative 3)	5.3	1.2	4.1
Metoprolol 100mg				
	PROFARMA	10.2	3	7.1
	METOPROLOL Stada	14.2	7.1	7.1
Nevibolol 5mg	NEBILET	100.9	30.3	70.6
Valsartan 80 mg				
	VALSACOR	48.9	24.5	24.5
	DIOVAN 80mg	95.2	70.8	24.5
Valsartan + HCT 80/ 12.5	CO-DIOVAN 80/ 12.5	105.9	52.9	53
Tamsulosin 0.4 mg				
	PROLOSIN	29.7	8.9	20.8
	URIMAX (alternativ 4)	37	16.2	20.8
Letrazol 2.5 MG	FEMARA	596.2	0	596.2
Acid Valproicum 300 mg				
	VALPRO TAD CHRONO	20.3	3.1	17.2
	VALPRO TAD	20.3	3.1	17.9
	VALPRO AD	is removed from list		
Formoterol Fumarate				
	KUROVENT	40.9	8.1	32.8
	FORADIL (alternativ 2)	64.1	31.3	32.8

Tab.4 Taken drugs in the study since 2009.

This table was constructed based on the list of reimbursed drugs in 2009

List of medications 2009 is enriched with 31 new drugs (74 drugs trade option) which not only increase the number of drugs reimbursed by the Health Insurance Institute, but above all improve significantly the quality of service to the public. The 2009 list includes 405 drugs that are 233 or 944 active principles commercial alternatives. There are introduced for the first time that drugs used for chronic diseases such as leukemia, post-transplant infections. This list has new combinations of drugs that significantly improve the quality of service for the elderly to diseases such as bronchial asthma, epilepsy, etc. In addition to covering new diagnoses drugs and new combinations of treatments, in this list are adding new dosage form of medicines which are used the most suitable for children, the chronically ill, etc.. New alternatives to drugs have had a negative impact in terms of payment of the patients and pharmacies economy. Drugs selected according to the table in 2009 will have the following changes:

Patients

1. Actrapid	4 pena	x 6.9	= 27.6
2. Metformine TEVA	60 tab	x 1	= 60
3. Glifor	60 tab	x 1.5	= 90
4. Metoprololidl STADA	30 tab	x 4.1	= 123
5. Diovan 80 mg	30 tab	x 46.3	= 1389
6. Urimax 0.4mg	30 tab	x 7.3	= 219
7. Foradil	30cap	x 23.2	= 696

For pharmacists we will have the following differences:

1. Actrapid	5pena	x 6.9	= 34.5
2. Metformine Teva	60tab	x 1	= 60
3. Diovan 80mg	30tab	x 46.3	= 1389
4. Foradil	30cap	x 23.2	= 696

Reimbursement List YEAR 2010

		YEAR ²⁰¹⁰		
Chemical Name	Trade name	Reference Price	Patient Price	Reimbursement
Isuline	INSUMAN RAPID	889	44.5	844.8
	ACTRAPID(alternativ 2)	893	48.2	844.8
Metformine 850 mg	PROFARMA	4.3	0.2	4.1
	GLIFOR (eshte hequr nga lista)			
	METFORMINE TEVA (alternativ 4)	5.8	1.7	4.1
Metoprolol 100mg	PROFARMA	9.4	2.8	6.6
	METOPROLOL Stada	15.3	8.7	6.6
Nevibolol 5mg	NEVIBOLOL STADA	82.2	24.7	57.5
	NEBILET	109	51.7	57.5
Valsartan 80 mg	VALPRESS	39.2	19.6	19.6
	VALSACOR (alternative 2)	45	25.4	19.6
	DIOVAN 80mg (alternative 3)	103	83.9	19.6
	CO-DIOVAN 80/ 12.5	114.7	57.4	57.3
Tamsulosin 0.4 mg	TAMSUDIL	28.9	8.7	20.2
	PROLOSIN (alternative 3)	28.9	8.7	20.2
	URIMAX (alternativ 7)	53.4	33.2	20.2
Letrazol 2.5 MG	LETRAZOL FAMOZ	403.2	0	403.2
	FEMARA (alternative 4)	645.6	242.4	645.6
Acid Valproicum 300 mg	VALPRO TAD CHRONO	20.8	3.1	17.7
	VALPRO TAD	20.8	3.1	17.7
	VALPRO AD	is removed from list		
Formoterol Fumarate	IMOTEC	37.3	7.5	29.8
	KUROVENT (alternativ 2)	41.4	11.6	29.8
	FORADIL (alternativ 3)	69.4	39.6	29.8

Tab.5 Medicine taken under study since 2010

This table was constructed based on the reimbursement list 2010

List of reimbursable drugs is enriched with 17 new drugs of which some dosage drugs that treat chronic disease, creating the possibility of a better dosing and appropriate for patients. These drugs are used for treatment of anemia, chronic renal insufficiency; diabetes or pulmonary disease and CA. Drugs selected according to the table in 2010 will have the following changes:

Patients

Insuman	4 pena x 5.8	= 23.2
Actrapid	4 pena x 2.6	= 10.4
Metformine TEVA	60 tab x 0.5	= 30
Metoprolol STADA	30 tab x 1.6	= 48
Nebilet	30 tab x 21.4	= 642
Valsacor 80mg	30 tab x 0.9	= 27
Diovan 80 mg	30 tab x 13.1	= 393
Urimax 0.4mg	30 tab x 17	= 510
Femara	30 tab x 242.4	= 7272
Kurovent	30caps x 3.5	= 105
Foradil	30cap x 8.3	= 249

For pharmacists we will have the following differences:

Glifor	60 tab x 5.8	= 348 (removed from the list)
Metoprolol PROFARMA	30tab x 0.8	= 24
Valsacor 80mg	30tab x 3.0	= 117
Femara	30 tab x 193	= 579

Reimbursement List YEAR 2011

YEAR 2011				
Chemical Name	Trade name	Reference Price	Patient Price	Reimbursement
Isuline	INSUMAN RAPID	1009	50.4	958.6
	ACTRAPID(alternativ 2)	1013.2	54.6	958.4
Metformine 850 mg	PROFARMA	4.4	0.2	4.2
	GLIFOR alternativ 4	8.7	4.5	4.2
	METFORMINE TEVA	is removed from list		
Metoprolol 100mg	TARTRATE	5.5	0.2	3.8
	PROFARMA (alternativ 3)	11.4	7.6	3.8
	METOPROLOL	is removed from the list		
Nebivolol 5mg	ACTAVIS	60.5	18.1	42.4
	STADA (alternativ 4)	93.3	50.9	42.4
	NEBILET (alternativ 5)	123.9	81.5	42.4
Valsartan 80 mg	VALPRESS	30	15	15
	VALSACOR (alternative 2)	41.3	26.3	15
	DIOVAN 80mg (alternative 4)	116.9	101.9	15
Valsartan + HCT 80/ 12.5	VALSACOMBI	105.1	52.5	52.6
	CO-DIOVAN 80/ 12.5(alternativ 2)	130.1	77.5	52.6
Tamsulosin 0.4 mg	SOLESMIN	27.5	8.3	19.2
	TAMSUDIL (alternativ 4)	29.5	10.3	19.2
	PROLOSIN (alternativ 3)	28.4	9.2	19.2
	URIMAX	is removed from the list		
Letrazol 2,5 MG	LETRAZOL FAMOZ	251.7	0	251.7
	FEMARA (alternativ 4)	732	401.9	251.7
Acid Valproicum 300 mg	VALPRO TAD CHRONO	23.6	3.5	20.1
	VALPRO TAD (is removed from the list)			
	VALPRO AD (is removed from the list)			
Formoterol Fumarate	KUROVENT	34.6	6.9	27.7
	IMOTEC (alternativ 2)	38.6	10.9	27.7
	FORADIL (alternativ 3)	78.7	51	27.7

Tab.6 Drugs taken in the study since 2011

This table was constructed based on the reimbursement list 2011

Drugs selected according to the table in 2011 will have the following changes:

Patients

Insuman	4 pena x 5.9	= 23.6
Actrapid	4 pena x 6.4	= 25.6
Metoprolol PROFARMA	30 tab x 4.8	= 144
Nebivolol STADA	30 tab x 26.2	= 786
Nebilet	30 tab x 29.8	= 894
Valsacor 80mg	30 tab x 0.9	= 27
Co-Diovan 80mg	30 tab x 20.1	= 603
Tamsudil	30 tab x 1.6	= 48
Prolosin	30 tab x 0.5	= 15
Femara	30 tab x 159.5	= 4785

Valpro TAD	100tab x 0.4 = 40
Kurovent	30cap x 4.7 = 141
For pharmacies:	
Metformine TEVA	100tab x 5.8 = 580 (removed from the list)
Metoprolol 100mg	30 tab x 15.3 = 459 (removed from the list)
Tamsudil	30 tab x 0.6 = 18
Urimax	30 tab x 53.4 = 1602 (removed from the list)
Valpro TAD	100 tabx 20.8 = 2080 (removed from the list)
Foradil	30 cap x 9.3 = 279

Conclusions

First from point of view a pharmacist, but also as a lawyer not to implement EEC Directive in this case rests on the pharmacist and patient. I change the reimbursement list, not at the beginning of the calendar year but different months has led to problems in which medicines pharmacy supplies new list have passed in the first alternative, and you are required to be kept condition. With great difficulty lies on drugs that have descended from the first alternative we scale down or even in extreme cases are removed from the list without prior notice. All these changes are associated with a financial invoice where the greatest damage done pharmacy. Analysis of this bill is simple only we take into account that the state has levied its tax for the amount drugs pharmacy I remain stock, distribution warehouses are paid for the goods they have provided, while pharmacy must keep a stock destined to expire then to fail.

With regard to the damage done to the patient related to his health. Doctors who prescribe medications for chronic disease for their patients brought to a drug resort as necessary therapeutic or by economic necessity. . In Europe, the main criteria applied in the selection of therapeutic drugs, is necessary, and the freedom to choose the doctor's competence. In most cases when patients have been treated for several years with the same bar very hard to convince that new alternative that those you recommended is the same. Is also complicated even more when the doctor goes on to describe the same bar which last or alternative which must be paid or has been removed from the reimbursement list.

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