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***IMPACT OF THE CENTRALIZED PROCUREMENT ON THE MEDICINES
PRICES – (example with oncology products in Bulgaria and Macedonia)***
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Ве известуваме дека Вашиот труд ја помина вообичаената процедура за рецензирање и според генералните оценки на рецензентите е предложен за печатење во *Македонски фармацевтски билтен*, како стручен труд.

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IMPACT OF THE CENTRALIZED PROCUREMENT ON THE MEDICINES PRICES – (example with oncology products in Bulgaria and Macedonia)

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SUMMARY

Analyzing the health economic results of the centralized procurement is important for critical assessment of the level of achievement of health goals during the tender process. **OBJECTIVE:** To compare the procurement legislation and its impact on the prices and quantities of procured medicines in the public sector. **METHODS:** Legislation analysis of both procurement laws and regulations for medicines supply issued during 1997-2003. Calculation of price and quantities indexes of procured oncology medicines via centralized tenders for the period 2000-2003. **RESULTS:** The tenders are organized in Macedonia by the Health insurance fund for all levels of health care and all medicines included in the procurement list while in Bulgaria Ministry of health is organizing a central drugs procurement for 121 INN life-saving and expensive medicines dispensed via specialized clinics. Changes in the price and quantity indexes for oncology products in Bulgaria shows increase in quantity index till 4.07, value index till 3.03 and average price index till 0.72 for the period 2000-2003. Because of the smaller number of procured oncology medicines in Macedonia the average waged price is 3.5 higher than in Bulgaria. It means than the tender in Bulgaria achieves lower prices. **CONCLUSION:** Different legislation and economic circumstances in both countries as well different organization of tenders lead to different results. Prices of oncology products in Bulgaria are lower but the quantities vary significantly among the years.

Key words: pharmaceutical procurement, drug pricing, reimbursement policy, centralized supply

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INTRODUCTION:

The goals of the pharmaceutical procurement are to achieve the minimal possible prices, assure quality and availability of drugs and increase transparency and effectiveness of the procurement process in public health settings [1-10]. Rules for good procurement practice were developed by WHO stating 12 operational principles and requirements towards the process [8]. There are also European Committee requirement for international tender development and national procurement laws in a lot of countries [2]. Organization of the drug supply system and included institutions differ among countries and procurement rules could lead to different level of achievement of the main procurement goals [11-13].

The **objective** of this study is to compare the legislation frameworks of the tenders for centralized pharmaceuticals procurement in Macedonia and Bulgaria and analyze their impact on the prices and quantities of the procured oncology medicines in the public sector.

Main study questions discussed in the study are:

1. Is the existing legislation complies with the international rules for good pharmaceuticals procurement practice?
2. Is it possible to decrease prices of centrally procured medicines and assure their availability?

METHODOLOGY:

Three main methodological approaches were used in the study.

Legislation analysis

It was analyzed the Law for public orders in Bulgaria [14]; Law for public procurement in Macedonia [15]; MoH Regulation 46 regarding rules for medicines reimbursement; MoH Regulation 12 regarding medicines for ambulatory therapy; MoH Regulation 23 regarding prescription and dispensing of life saving and expensive medicines [16-18].

Legislation analysis focused on the availability of special rules for pharmaceutical procurement, goals of the procurement process, and changes in the procured medicines.

Procurement practice study

It was collected information for all oncology medicines procured during 1997-2001 in Macedonia and 2000-2003 in Bulgaria respectively. Contracted quantities and prices are systematized according to therapeutic subgroups; INN of medicines; trade names and dosage forms.

In Bulgaria were systemized 12 therapeutic subgroups, 68 INN, 109 dosage forms of oncology products and 13 therapeutic subgroups; 42 INN, 71 dosage forms in Macedonia respectively.

Index analysis

Two types of indexes were calculated:

Indexes of the changes in values and quantities of contracted medicines in comparison with the year of reference using the following formulas:

$$I_q = \frac{Q_i}{Q_o} \quad I_v = \frac{P_i \times Q_i}{P_o \times Q_o}, \quad \text{where}$$

- I_q , I_v – indexes of changes in quantities and values respectively;
- Q_i , P_i contracted quantities or prices in year under consideration (year 2001- 2003);
- Q_o , P_o contracted quantities or values in the reference year (year 2000).

Average waged price for every therapeutic subgroup were calculated dividing the sum of the contracted quantities multiplied by their prices on the sum of the quantities for the year under consideration using the following formula:

$$P_t = \frac{\sum P_i Q_i}{\sum Q_i}, \quad (i = 1, 2 \dots n),$$

- Q_i contracted quantity of the concrete product;
- P_i average price for a product.

RESULTS:

Legislation analysis

The National health insurance fund in Macedonia is organizing tender for medicines procurement for all health facilities [4,15]. The tender is separated according to the level of health services (primary, secondary etc.) and according to the therapeutic group, e.g. oncology products, insulin etc. The tender is organized to guarantee availability of necessary quantities at reasonable prices. Contracted quantities are dispensed to the health settings at the agreed prices within the framework of the reimbursement system. Medicines could also be sold at market price without reimbursement but this quantity is not an object of tendering. Till the middle of 2002 were developed four tenders in year 1995, 1997, 1999 and 2001. They are organized

according to the Law for public procurement in Macedonia that regulates procurement for all types of goods and services in all publicly funded institutions [15]. The open tender procedure is stated as default in the law and used for organizing the tenders with pharmaceutical manufacturers.

In 2001, are created internal rules for pharmaceuticals procurement by the Health insurance fund. A list of medicines under INN is developed; necessary quantities are calculated on the basis of previous consumption, health statistics information for morbidity frequency as well market analyses were taken in consideration [14]. Quantities of oncology products are calculated for 6 months period and for the rest of products for one year. Manufacturers are selected on the basis of quality of products, certification of manufacturer, financial guaranties, prices and volumes agreed [19-22]. In the offers manufacturers should stated also suppliers and financial conditions. Only registered in the country products could be offered. Variety of difficulties refer to the lots of sources for information, some of them evaluated as suspicious, frequent changes in the drug list, lack of therapeutic guidelines, lack of technical support, availability of a lots of unnecessary medicines and lack of important ones, higher prices of orphan and patented products [21].

In Bulgaria is organized central tender drug supply financed by the Governmental budget since 1995 according to 3 regulations of the MoH – Regulation 46/1995, Regulation 12/1997 and Regulating 23/2001 [16-18] in the framework of health and procurement laws [14-22]. Separated regulation exists for the low value procurements and whole process is supervised by the transparency committee [23-4]. The regulations define the list of diseases, list of life saving or expensive medicines supplied via tender as well the rules for prescribing and dispensing those medicines through specialized hospitals. After the creation of the health insurance fund (HIF) in the country in 2001 part of the medicines started to be paid via the general reimbursement system but new rare diseases were included in the centralized system (Table 1).

Table 1. Medicines included in the centralized drug supply regulations in Bulgaria

Regulation N	N of diagnoses	N of medicines
46/1995	12	20 INN, 3 therapeutic groups and 2 medical devises
12/1997	12	65 INN, 3 therapeutic groups and 2 medical devises
23/2001	12, out of them 3 replaced	98 INN, 5 ATC groups (B02BD, J05AF, J05AG, J05AE, R07AA) consisting of 23 INN.

Some differences and similarities could be pointed out concerning the legislation:

- the goal of the procurement process in Bulgaria is to procure small number of expensive medicines for all patients at national level. In Macedonia the main goal is to reach price-volume agreement with the industry for the reimbursed medicines on the market or within the health facilities;
- in both countries procurement is organized through general health or health insurance laws as well procurement laws;
- there is no regulation stating special conditions for the organization of the pharmaceuticals procurement complying with good pharmaceutical procurement practice [8]. Existing regulations especially in Bulgaria are focusing more on the rules for prescribing and dispensing rather than procuring.

It is obvious that the goals and organization of the tenders differ and there should be expected differences in the contracted prices and quantities, as well indexes of their changes.

Analysis of the contracted quantities, prices and their indexes

Oncology medicines procurement in Bulgaria

During the observed four years period the contracted quantities of oncology medicines in Bulgaria perform five times increase in comparison with 2000 while the value of procured medicines increase three times (Table 2) that could be explained through the increase in the budget resources after starting separated reimbursement via HIF and achievement of lower prices during the tender process.

Table 2. Contracted quantities, values of oncology medicines, waged prices and indexes in Bulgaria during 2000-2003

Indicator	2000	2001	2002	2003
Quantity	2500794	7075907	9976802	10666058
Quantity index	1	2,83	3,99	4,27
Value	12239244	30109336	28570710	37543880
Value index	1	2,46	2,33	3,07
Waged price	4,894	4,255	2,864	3,52
Average waged price index	1	0,87	0,59	0,72

The quantity index also increase mainly because of the introduction of new INN in the corresponding regulations. The average waged price index performs decrease from 1 to 0.72 that is due to the increase in contracted quantities and lower increase in contracted prices. There is also influence of some therapeutic groups with low price indexes and high relative share among the contracted medicines. Significant changes of value and quantity indexes are observed for therapeutic group's antimetabolites, hormones and antihormonal active drugs, opiod analgesics, antiemetics and biphosphonates (Table 3).

Table 3. Therapeutic groups with significant changes

Therapeutic group	2000	2001	2002	2003
Antimetabolites				
Index quantity	1	2,45	2,41	5,18
Index value	1	14,19	7,13	9,92
Antihormonal active drugs				
Index quantity	1	1,65	2,76	3,52
Index value	1	1,53	1,16	1,49
Hormones				
Index quantity	1	1,4	1,4	1,66
Index value	1	1,07	1	1,41
Opiod analgesics				
Index quantity	0	1	1,31	1,56
Index value	0	1	2,09	2,51
Antiemetics				
Index quantity	0	1	2,19	1,43
Biphosphonates				
Index quantity	0	1	1,41	0,01

The value index for antimetabolitics increased 14 times in 2001 and decreased to 9.9 in 2003 in comparison with 2000 mainly because of the high quantities calculated in

2001 that cover part of the following years and because of inclusion of 6 new expensive INN. In contrast value index for antihormonal active drugs increase only with 0.49 while quantity index increased with 2.52 in 2003 because of the introduction of cheaper medicines and significant reduction in the prices. Value index of opioid analgesics increases to 2.51 for two years and quantity index to 1.56 due to the inclusion of expensive new analgesics. Both quantity indexes of biphosphonates and antiemetics decreased sharply because of the wrong calculations. For the rest part of the therapeutic groups was observed smaller increase of the quantity and price indexes corresponding to the changes in the morbidity patters (Table 3).

Table 4. Average waged prices achieved during the procurement process in Bulgaria

Therapeutic groups	Indicator	Years			
		2000	2001	2002	2003
Alkilators	Average waged price	13,111	4,835	12,212	11,224
	Changes in comparison with 2000	1	0,37	0,93	0,86
Anti metabolites	Average waged price	5,997	34,764	17,751	11,243
	Changes in comparison with 2000	1	5,8	2,96	1,87
Herbal products	Average waged price	94,936	129,155	190,982	216,964
	Changes in comparison with 2000	1	1,36	2,01	2,29
Cytotoxic antibiotics	Average waged price	26,932	59,779	69,6	69,752
	Changes in comparison with 2000	1	2,22	2,58	2,59
Hormones	Average waged price	9,35	7,165	6,688	7,917
	Changes in comparison with 2000	1	0,77	0,72	0,85
Antihormonal activity	Average waged price	1,425	1,056	0,598	0,602
	Changes in comparison with 2000	1	0,74	0,42	0,42
Imunomodulators	Average waged price	95,317	84,6	115,588	145,915
	Changes in comparison with 2000	1	0,89	1,21	1,53
Antiemetics	Average waged price	20,891	19,175	34,381	0
	Changes in comparison with 2000	1	0,92	1,65	0
Biphosphonates	Average waged price	0	1,281	0,394	134,319
	Changes in comparison with 2000	0	1	0,31	104,9
Anti poisoning	Average waged price	7,298	8,325	7,367	6,621
	Changes in comparison with 2000	1	1,14	1,01	0,91
Opiod analgesics	Average waged price	0	0,771	1,223	1,235
	Changes in comparison with 2000	0	1	1,59	1,6
Other	Average waged price	2,75	2,82	2,18	2,07
	Changes in comparison with 2000	1	1,03	0,79	0,75
Total for all therapeutic groups	Average waged price	1,894	4,255	2,864	3,32
	Changes in comparison with 2000	1	0,87	0,59	0,72

The increasing average waged prices were observed for herbal products, cytotoxic antibiotics, imunomodulators. Those of the medicines with anti hormonal activity and opioid analgesics are constantly decreasing and for the rest six therapeutic groups are varying among one average rate. For all therapeutic groups the average waged price is

decreasing constantly which means that the tender achieve the basic goal for price reduction (Table 4).

Oncology medicines procurement in Macedonia

The lack of computerized information for all procured quantities during the same period like in Bulgaria makes full comparison impossible. Information for all quantities was available for 2000-2001. In 2001 were procured oncology medicines for 3,814 060 Euro (Table 5).

Table 5. Procured oncology medicines in Macedonia in 2001

Indicator	Value
Contracted quantities	500 959 unit dosage forms
Contracted financial value	3 814 060 Euro
Average waged price	14, 892 Euro

Because of the smaller number of contracted oncology products in Macedonia the contracted value is less than in Bulgaria but average waged price is 3.5 times higher. It could be considered that procurement is better organized in Bulgaria and achieves lower prices. The other possible influencing factors are price control in Bulgaria and stable economic situation during the observed period.

Among the three leading therapeutic groups only herbal products (alkaloids) increase contracted quantities and values while the other two groups (cytotoxic antibiotics and alkilators) decreased contracted quantities in 2001 (Table 6).

Table 6. Procured quantities and values by the leading oncology therapeutic groups in Macedonia

Therapeutic groups	Indicators	2000	2001
Herbal alkaloids	Quantity	12100	14350
	Quantity index	1	1,186
	Value	1378620	2222080
	Value index	1	1,612
	Waged price	113,935	154,848
	Index	1	1,359
Cytotoxic antibiotics	Quantity	15400	8160
	Quantity index	1	0,53
	Value	441325	3382240
	Value index	1	0,766
	Waged price	28,657	41,451
	Index	1	1,446
Other alkilators	Quantity	15800	10540
	Quantity index	1	0,667
	Value	246465	158105
	Value index	1	0,641
	Waged price	15,599	15
	Index	1	0,962

The waged price index for the herbal products and antibiotics increased significantly but this is mainly because of the increasing prices and not because of assured quantities. The bigger quantities were contracted for cyclophosphamid, bisulfan, mercaptopurin, vincristin, etoposid, erythropoietin and cyclosporine but their relative share is lower than the share of the same medicines in Bulgaria.

It ones more confirm that the tender in Macedonia aims more at the quantities assuring and less at the price decreasing.

DISCUSSION AND CONCLUSION

Analysis of the legislation shows that number of oncology products procured via centralized tender in Bulgaria is bigger than in Macedonia. In spite of the fact that almost all contemporary oncology products are included price indexes in Bulgaria are lower than in Macedonia.

The different aims and separation of tenders in Macedonia let to higher price indexes and stable quantities of procured medicines while in Bulgaria let to decreasing price indexes but quantities vary significantly among the years. One of the reasons might be lack of officially approved and published methodology for necessary quantities calculation especially in the earlier years in Bulgaria. The other reason is the restrictions in the financial policy and decrease of the centralized procurement financing after the creation of National health insurance fund. It is also partly due to the increase of the number of INN and decrease in procured quantities.

Both countries suffer of a lack of specific regulation focusing on the rules for pharmaceuticals procurement and endorsing good procurement practice principles for pharmaceuticals. It is a crucial point for transition countries because of the lack of procurement practice not only on central level but also at hospital level. Strong rules at the EC level for public finances allocation require contemporary procurement culture that is still lacking and might lead to future difficulties.

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