

Cyto-smuggling

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Due to absence of cytostatic drugs in Oncology Clinic patients who suffer from cancer are forced to buy smuggled drugs. Preportr found such cytostatics in Oncology Clinic too, which used those drugs to treat patients. Responsible institutions said not to be aware that patients were being treated with such drugs in this clinic. It is easy to find illegal cytostatics - you just need to look for them in pharmacies or contact a pharmaceutical company that will put you in contact with smugglers

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Hundreds of individuals who suffer from cancer every year are necessarily subjected to therapies with cytostatic drugs. Cytostatics, as the most expensive pharmaceutical medicaments, bring astonishing profits to numerous smugglers. In this case, healthcare, which is known as the most humane profession, loses its sense and takes completely different dimension. Commerce with health and lives of desperate patients is very wild. It does not choose means to get the profit, regardless of the fact that doing business with this kind of medicaments may be fatal for many patients.

The supply by the Ministry of Health is far from meeting the needs of patients who are treated in Oncology Clinic of KCUC.

As a consequence, patients are forced to by cytostatics in private market where the circulation of smuggled medicaments is rather high too.

During its research Preportr not only found smuggled cytostatics, mainly in pharmacies close to KCUC, but also noticed high differences in prices that, according to professionals in this field, show that the said medicaments are smuggled.

Due to lack of supply with medicaments Oncology Clinic treats its patients with cytostatics bought in private markets by the very patients that, according to our research, in most of the cases are smuggled drugs.

In order to avoid responsibility in case of side effects caused by these cytostatics or in terms of the use of smuggled cytostatics in a public institution, doctors in Oncology Clinic make patients

sign a document. According to this document, which apparently remains unknown to any and all responsible institutions, patients are responsible for effects they might have from treatment with illegal medicaments.

According to available data, cytostatics that end up in private market apparently come from countries in the region where these medicaments are reimbursed by respective countries.

Moreover, there are suspicions that some of these cytostatics come or are stolen from public institutions, such as Oncology Clinic or Central Pharmacy, and end up in private market.

Kosovo Agency for Medicinal Products and Equipment and the Ministry of Health were surprised and felt no responsibility whatsoever when presented with all these facts. It seems that competent institutions are very unlikely to take responsibility and no one takes over the lead to make steps in order to prevent the smuggling of cytostatics, which, according to this research, is a business that runs quite freely.

WHEN MH DOES NOT SUPPLY, SMUGGLERS DO

Only in 2013, 730 persons were diagnosed with cancer in Oncology Clinic. This number does not include patients that are diagnosed in Albania, Macedonia, in Turkey and other countries. The average number of patients that are treated in Oncology is usually 100 but there are cases when this number reaches 300 patients.

Ministry of Health was never able to fulfill 100% of the vital

list, i.e. the list of medicaments that should by all means be found in health institutions, including cytostatics.

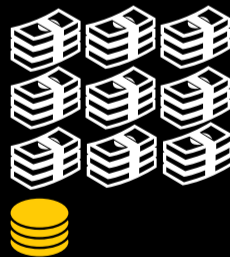

Faik Hoti, Director of Information Department at MH says that the absence of cytostatics is also linked with the lack of budget, since there is discrepancy between demand and possibilities. "The demands of Oncology Clinic for cytostatics in 2014 was around 9,3 million euros, whereas the available funds of MH for this category of medicaments was 4,4 million euros", he added.

According to an analysis of Ministry of Health related to essential list products for 2013, Kosovo is among countries with the lowest percentage of budget for health (around 2.3% of GDP), compared to countries in the region with 5-7% of GDP, or compared to European countries with 10% of GDP. This shows that health has never been a priority of any of the governments since the end of war.

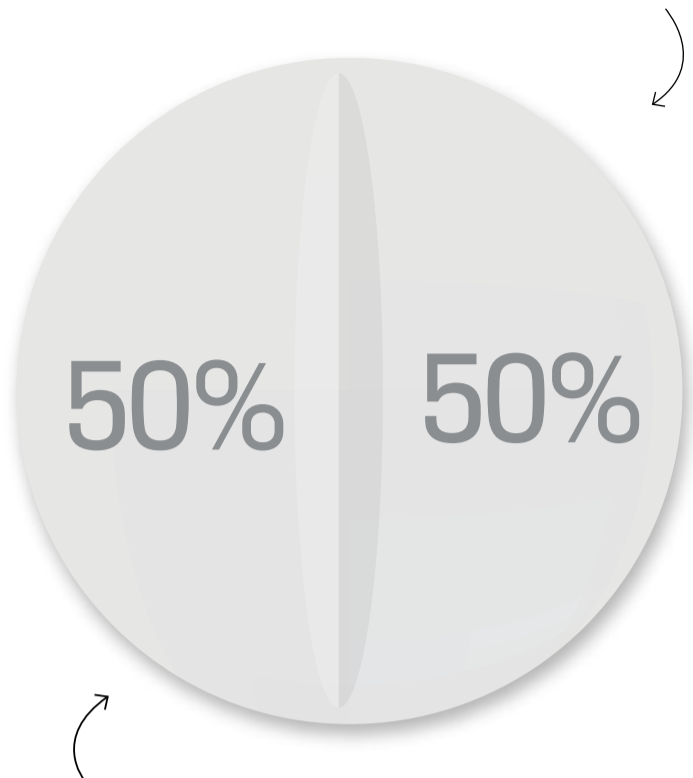
Despite partial supply with cytostatics by MH, another evident thing is wrong budget management, with supply in the first part of the year being quite higher compared to the rest of the year.

The document from Oncology, which was provided by Preportr, shows that the vital list of cytostatics is far from being fulfilled.

Although there are 59 types of cytostatics, on October 27, 2014 Oncology Clinic only had 7 types, while there was a lack of those medicaments that were mostly required for patients' treatment. This situation causes further increase of demand for

REQUIREMENTS OF CLINICAL ONCOLOGY	AVAILABLE FOR THIS CATEGORY
	
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CONTRABAND



MINISTRY OF HEALTH

“Even when this Clinic is supplied with 50% of cytostatics by the Ministry of Health, the other half comes from smuggling”

- Behxhet Osmani, The Director of Oncology Clinic

“I sell Herceptin 440 mg for 750 euros, I bring it to you, just tell me where you are. It is well preserved, don't worry, no concern. These ones, with papers, are very expensive. Herceptin is by Roche; it is best before 10/2016, I think. It does not have a banderole. For example, if I wanted I could take a banderole and stick it on, but that's not it. I should tell you the truth, that we, for instance, got those from Macedonia and Albania, and it doesn't make sense to bring them with their banderole”

- said the vendor of smuggled cytostatics.

these medicaments in private sector, and thus increasing their smuggling.

The Director of Oncology Clinic, Behxhet Osmani, says that cytostatics without banderole are brought in Oncology every day. “Even when this Clinic is supplied with 50% of cytostatics by the Ministry of Health, the other half comes from smuggling”, says Osmani.

Oncology Clinic from time to time is left with no cytostatics at all and has many complaints regarding supply, while MH blames procurement procedures for this matter.

“Economic operators that got the right for supply often use last days of legal deadline in order to deliver the supply, causing irregularities in supplies. For instance, if the deadline for the operator to deliver the medicament is 40 days, it happens that they do not do this dissemination within the first days but rather during the very last days, and in certain cases also after the deadline, for which MH has fined some companies but that did not affect them much”, stressed Faik Hoti.

But even after waiting and insisting for two weeks, he did not answer to the question regarding the companies that were fined and the amount of fines.

COMMERCE WITH HEALTH

Preportr team conducted a research on illegal cytostatics in pharmacies in Prishtina. As a sample the team used Herceptin 440 mg, product of French company Roche. This cytostatic is used to treat breast cancer and it is one of the most wanted and at the same time very expensive medicament. Only Herceptin costs 40 % of the value of total budget that Ministry of Health spends for cytostatics, and in monetary terms it is more than 1,7 million euros. Ministry of Health buys one Herceptin for 1 thousand 550 euros. Frequent demands, its absence in KCUK and its high price have made this medicament become among the most smuggled ones.

Preportr team asked for this cytostatic in some pharmacies of the capital city, mainly in those around KCUK, to see where this smuggled cytostatic could be found in the market.

In pharmacy (A) the price for this medicament (Herceptin 440 mg), was 1595 euros. The owner of the pharmacy claimed that this medicament had a banderole. We were thus given a receipt that, according to the pharmacist, we could give to Ministry of Health and get 70 percent of the amount in return.

The same medicament in pharmacy (B) cost only 700 euros. Preportr team did not man-

age to see it since this medicament was not kept in the pharmacy, The owner, after talking over the phone with someone, went out, met a person and told us we could get the medicament for only 700 euros. To our hesitation that this medicament with that price might be without a banderole and not have the desired effect, the pharmacist stated that this is the same medicament as the one found in other pharmacies, that it is by the same producer and also has a banderole.

Three weeks later, Preportr team once again asked for this cytostatic (Herceptin 440 mg) in pharmacy (B). After three weeks, we were offered this same medicament with a price of 800 euros. This time as well, we were told that this medicament is not kept in the pharmacy but we could have it in half an hour. At this time Oncology Clinic did not have any Herceptin 440 mg at all. Pharmacies made use of the absence of this and other cytostatics for some weeks in order to increase their prices.

With a much lower price, for only 450 euros, pharmacy (C) offered us this cytostatic. This means three times cheaper than the market price, or the price paid by the Ministry of Health, which is 1550 euros. But here too, it was impossible to see the cytostatic because it was not kept in the pharmacy but we could have had it in half an hour.

During research Preportr team tried to get Herceptin 440 mg also from other companies and pharmacies. The owner of a well-known company that imports medicaments did not admit that they had cytostatics. However, this owner referred us to another pharmacy, giving us the owner's phone number. He also told us that he did not have this kind of medicament but that someone else might get it for us. The third person that we contacted turned out to be the one who could get us a Herceptin.

“I sell Herceptin 440 mg for 750 euros, I bring it to you, just tell me where you are. It is well preserved, don't worry, no concern. These ones, with papers, are very expensive. Herceptin is by Roche; it is best before 10/2016, I think. It does not have a banderole. For example, if I wanted I could take a banderole and stick it on, but that's not it. I should tell you the truth, that we, for instance, got those from Macedonia and Albania, and it doesn't make sense to bring them with their banderole”, said the vendor of smuggled cytostatics.

Representatives of pharmaceutical companies and experts of pharmaceutical market issues say that cytostatics enter Kosovo from countries in the region

in small amounts using illegal routes and transporting those in bags and similar gear.

But taking into account the price, we are talking about big amounts of money.

Mentor Latifi, representative of Roche for Kosovo, the company that produces cytostatics, says that the fact that these medicaments can be found in the market with three times lower price shows that they are illegal. According to him, the price is that low because those were obtained without any money and they usually come from countries in the region where this kind of medicament is reimbursed by state.

There are also suspicions regarding the abuse of cytostatics provided by the Ministry of Health, i.e. cytostatics that end up in private market from public health institutions.

One of the patients who was being treated in Oncology had bought Herceptin 440 mg for 1 thousand and 700 euros without a banderole. Preportr sent the photography and the barcode of this Herceptin to the representative of Roche for Kosovo in order to find out the market to which this series of production was destined. This office confirmed that this series of this cytostatic was produced in Asian countries for Kosovo market. This fact shows that the Ministry of Health bought this medicament and it was probably stolen in Oncology or in Central Pharmacy with the purpose to be sold in illegal market. The package of this cytostatics shows that this medicament was once with a banderole, which was intentionally removed.

The suspicions grow bigger when it is evident that every absence of cytostatics in Oncology Clinic and every delay in supply increase the price and the circulation of smuggled cytostatics in private market. It seems that pharmacies and smugglers are the first ones to get informed about these shortcomings.

According to patients who were contacted by Preportr, there were cases when they had not been treated with cytostatics in weeks, because they were told that KCUK did not have the supplies. However, although there was no supply coming from the Ministry of Health, other cytostatics could be found in the Clinic in the meantime. They did not know where the Clinic had obtained those cytostatics, since there were continuous complaints that there were none, according to them.

This is the information that the representative of Roche for Kosovo, Mentor Latifi, had as well. He says that some patients told him over the phone that after weeks of absence of cytostat-

ics they had started to receive this therapy before a future supply.

“Few weeks ago, some patients called me and said there were no cytostatics in the Clinic and asked when the supply would take place. Few weeks later they saw cytostatics in Oncology again, but not in high number. In this case there was no supply coming from our side, but perhaps those were left in some refrigerators in the Ministry or in Central Pharmacy”, says Latifi.

Despite this, Oncology Clinic says that when there are cytostatics those are meant for everyone, and when they are through there is none for anyone.

PATIENTS SUFFER THE ABSENCE OF CYTOSTATICS

Patients who are treated in this clinic say that in most cases they should buy the medicaments themselves. Many of them stressed out that when they had an appointed treatment in place only in few cases did they find cytostatics.

A woman that was suffering from breast cancer, who did not want to give her name, said for Preportr that she was being treated in Oncology Clinic for six months now. She said to have bought over a half of cytostatics during this period of time, since when she had treatment appointments there were no cytostatics of that kind.

A family member of a patient that was suffering from cancer for a second time said for Preportr that, after the operation, his parent was treated with cytostatics during one year and in most cases he himself bought the therapies since those could not be obtained in Oncology.

“Since June this year, my parent continued with another therapy which was necessary since some cancer cells were found in the liver. This person received therapy in six cycles, and each one cost around 300 euros. For the second therapy, the family member bought everything including the solution. The cancer patient has now started another therapy cycle, which had to be changed because the former one did not react at all. We also need to buy this new therapy as well (Cisplatin and Irinotecan)”.

As far as medical staff is concerned, patients say that doctors and nurses behave well and take great care of them. During the monitoring of the work of this clinic Preportr team also noticed that medical staff was behaving well with the patients.

DOCTORS TREAT THEM WITH SMUGGLED CYTOSTATICS

Oncology Clinic has turned into a place where all smuggled cytostatics are accumulated.

For few days in a row Preportr

team monitored Oncology Clinic where patients are treated with these medicaments. During the monitoring of rooms where patients are treated, all cytostatics, which patients were forced to buy, were without stamps.

Behxhet Osmani, Director of Oncology Clinic, said for Preportr that doctors in Oncology are forced to treat patients with cytostatics that they bring along, which in most cases are without banderoles and not safe in terms of quality.

“Unfortunately, almost all cytostatics are smuggled and very few of those are licensed. By rule, we would not give those medicaments to patients, but we must give them”, added Osmani.

There was a notice in Oncology informing patients that when they buy cytostatics they should make sure that those have banderoles, otherwise they could produce side effects and it was patients who should take responsibility for that. Apart from this notice, patients are obliged to sign a document before they start the treatment with cytostatics that they bought, by which they take over the responsibility for possible side effects.

This document has no legal basis that would hold doctors responsible in case of a fatal epilogue of treatment of a patient with smuggled cytostatics. Osmani says that there were cases when patients, after taking this medication, accused this Clinic for not having the desired effect or for having side effects.

The spokesperson of KCUC, Shpend Fazliu, said for Preportr that Oncology Clinic during certain periods of time faces the absence of cytostatics and families of patients are forced to buy those themselves in order not to interrupt the cycle of necessary therapies.

“Families have their own worries and obtain therapies in different ways; they put pressure on staff and they just give them that therapy”, says Fazliu.

INSTITUTIONS ARE SILENT WHEN IT COMES TO SMUGGLING

Preportr made photos and recordings of smuggled cytostatics that were found in Oncology Clinic, and sent them to Kosovo Agency for Medicinal Products and Equipment and to the Ministry of Health, but did not receive answers from any of these institutions. Moreover, these institutions said not to be informed that Oncology Clinic gives smuggled medicaments.

The spokesperson of Kosovo Agency for Medicinal Products and Equipment (AKPPM), Pranvera Behrami, says: “AKPPM never received a complaint related to these claimed products in Oncology and there were no suspicions

raised by respective institutions or by certain individuals in order for Pharmaceutical Inspectorate to take measures, and thus AKPPM is not responsible for the current situation there”.

Faik Hoti said for Preportr that there was no report from the Inspectorate of the Ministry of Health that shows that such an inspection was conducted in Oncology. He says that if doctors, patients or their family members informed the Inspectorate about such cases, inspections would certainly take place.

“Health Inspectorate conducts regular and “thematic” inspections in health institutions. If during inspections they run into medicaments without banderoles, that is certainly documented and becomes part of Inspectorate reports but the Inspectorate cannot document every phenomenon in every institution if there is no cooperation coming from other parties”, says Hoti.

The spokesperson of AKPPM said for Preportr that there were complaints from distributors saying that products, for which they are licensed, can be illegally found in the market and in these cases AKPPM, “acts in accordance with the Law on Medical Products and Medical Devices and Administrative Instructions into force and the suspected products without marketing authorization are confiscated”.

AKPPM did not allow access to inspection reports that they conduct, in order to find out about the amounts and kinds of products that were confiscated. Although Preportr insisted to get information about possible analysis of any kind of cytostatics and the results drawn, AKPPM did not allow access with an excuse that these reports are not made public.

Spokesperson Behrami says that since January this year 76 fines were imposed and 7 pharmaceutical subjects were closed down due to violations of Law on Medical Products and Medical Devices.

“The products that are most frequently found by Pharmaceutical Inspectorate come from Serbia and those are with no banderole at all. So far, we have 10 inspectors, which is actually a low number in order for them to be able to cover the entire territory of Kosovo, and there should be at least 20 additional inspectors or more”, says Behrami.

According to the new law, maximum penalty for possessing medicaments without banderole or with an expired date is 1000 euros, whereas for further violations cases are processed in courts.

This penalty amount is ridiculous if we consider the amounts pharmacies gain from smuggled

Smuggled cytostatics found in Oncology Clinic



Gemcit

Produced by German company “Fresenius Kabi”, destined for Bulgarian market.



Vincristine

Produced by American company “United Biotech”, licensed to sell in many countries in Europe.



Endoxan

Produced by German company “Baxter”, destined for Turkish market.



Dakarbaz

Produced by Turkish company “Koçak Farma”, destined for Turkish market.



Flourouracil

Produced by Turkish company “Koçak Farma”, destined for Turkish market.



Herceptin

Produced by Swiss company “Roche”. It is destined for the Ministry of Health and it was probably stolen at KCUC. It can be noticed that it also had a banderole, which was removed. It was bought for 1700 euros.

medicaments. Just by selling two cytostatics that cost more than that, pharmacies that smuggle medicaments can pay this fine.

Taking into consideration the way in which cytostatics are smuggled, there is little amount of confiscated cytostatics in Customs reports related to confiscation of smuggled medicaments.

According to Customs report, during 2002-2014 three Doxel 250 ml and one Doxel 80 ml cytostatics as well as 5 Ampulla Vincristine were caught. In 2012 five packages of Gemcitabine 2000 mg and 40 pieces of Etoposide were caught. In 2009 a package of 30 Tamoxifen tablets was caught. In 2007 15 pieces of Doxorubicin and 13 pieces of Cisplatin were caught.

SMUGGLED CYTOSTATICS, FATAL SIDE EFFECTS

The main problem of smuggled cytostatics is their quality. It is imperative that cytostatics are transported in a temperature between 2 and 8 degrees Celsius and in proper transport conditions. The stocking and transport of these medicaments in high summer temperatures not only harms their quality but they also lose their effects in therapy and might cause side effects too.

“It may happen that a patient takes that medicament in three cycles and no effect is done to the disease”, says the Director of Oncology Clinic.

On the other hand, pharmacist Adnan Mustafa says that every smuggled medicament is dangerous for patients who use it because apart from not having the desired effect the medicament can also cause side effects.

“Every smuggled medicament is at risk of being falsified and may contain active substances, it may contain reduced amount – insufficient pharmacological effect, or higher amount of active substance – toxic effect. Even if the product is original it is at risk of degradation of its content if it is kept and distributed in inadequate conditions – more notable toxic effects (for instance, Herceptin can be degraded if it is shaken during transportation).

“Medicrime” – Council of Europe Convention for falsified medicaments – considers every smuggled product a crime. According to Mustafa, Kosovo had to sign this Convention that was approved in 2010 in Basel, Switzerland.

Agron Sadiku, director of “Meditech”, the company that

Apart from this notice, patients are obliged to sign a document before they start the treatment with cytostatics that they bought, by which they take over the responsibility for possible side effects.

is licensed to import cytostatics from “Roche”, says that the way in which these medicaments are preserved and transported is of great importance.

“In order to preserve the effectiveness of this medicament it is highly important to keep and preserve those in optimal conditions, since the change of temperature can destroy the structure of that medicament, and then, not only does it lose its effect but it can also have negative effects. Medicaments are transported with refrigerated trucks. These trucks measure the temperature every 15 minutes, they print and keep the record and when we receive this record we can see the temperature in which the medicament was transported. In warehouses likewise, if the temperature changes slightly the alarms are activated”, says Sadiku.

PHARMACEUTICAL COMPANIES INTERVENE IN THE LIST OF CYTOSTATICS

One of the problems that continuously showed up was the drafting of the list of cytostatics at the time when the tender was prepared. Some oncologists who wanted to remain anonymous said for Preportr that companies that import cytostatics contacted them and offered them different favors if they included cytostatics that these companies are licensed to import. Preportr sources confirm that these favors are also done to other doctors who are part of the committee that drafts the list of medicaments that have to be purchased by MH.

In order to do favors to certain companies, products Ondansetron and Granisetron, which were initially included by oncologists in the list of essential medicaments, were removed from this list while their value in the market was 1.32 euros. Later on, the list was changed and these products were replaced by much more expensive ones, i.e. Palonosetron, which cost 77.79 euro.

Besides adding it, this medicament was also included in the list of cytostatics although Palonosetron is not a cytostatic but an anti-emetic that is used in the prevention and treatment of chemotherapy-induced nausea and vomiting.

Even in the protocols of British “BC Cancer Agency”, in instructions of use of therapy to prevent vomiting among adult patients when using chemotherapy, it is said that Ondansetron and Granisetron are products that have the same effect as Palonosetron.

In relation to suspicions raised regarding the removal of abovementioned products from the essential list, Enkelejda Gjonbalaj, director of KCUC pharmacy and former Head of Pharmaceuticals in the Ministry of Health was arrested in April this year.

The economic crimes police has also interrogated secretary general of the Ministry of Health, Gani Shabani, as part of investigation related to changes made in the essential list, making way for purchase of a much more expensive medicament.

State Prosecution has confirmed for Preportr that charges were raised in September this year and they are waiting for an invitation from the court for the session to start.

Behxhet Osmani, director of Oncology Clinic, says that this happened before he was appointed director, not giving any other details since this is an issue to be addressed by the prosecution.

“It was an issue related to a medicament used to prevent vomiting, at the time when I was not running the Clinic. When I was appointed director the investigation came to deal with this issue. I did not order it, and it was somebody else who included it in the list. That medicament is good and we have discussed to have 10-20 of that kind (Polestetron), but someone removed all the cheap ones and left only this one, the most expensive one”, says Osmani.

DURING A DAY 70 PATIENTS WHO SUFFER FROM CANCER ARE TREATED WITH RADIATION THERAPY, BUT IT HAS BEEN OVER A MONTH (THE INTERVIEW WAS MADE ON OCTOBER 17) SINCE RADIATION EQUIPMENT IS OUT OF ORDER.

Director of Oncology Clinic, Behxhet Osmani, says that during a day 70 patients who suffer from cancer are treated with radiation therapy, but it has been over a month (the interview was made on October 17) since radiation equipment is out of order.

“The breakdown of this equipment causes a problem because the continuity of treatment is lost; there was a high number of patients that were receiving treatment and now they have stopped it. We give instructions with three signatures for the treatment abroad, which is covered by the ministry, but all this requires time and procedures, which are not in favor of patients. So, it is a procedure which requires that the family also pays by participation and some families do not have this possibility to participate with financial means and patients are left without radiation therapy” stressed Osmani