DECISION No. 209

Sofia August 1st, 2007

IN THE NAME OF THE PEOPLE

SOFIA COURT OF APPEAL Civil College, 4th
Panel of Judges, at a public hearing on second of July,
Two thousand seven, with members:

Chairperson : Vasilka Ilieva
Members: Veselka Mareva
Daniela Stoyanova

In the presence of Secretary Stefka Koshutova and in the presence of Public Prosecutor Kozhuharov, hearing reported by Judge Ilieva on civil case No. 161/2007. In order to pass a sentence the following was taken into account:

Proceedings are under Art. 196, paragraph 1, (2) and next of CPC. By decision No. 72, dated November 6th, 2006 on civil case No. 572/05 as scheduled in Sofia City Court, the Ministry of Health is sentenced to pay T.D.Z., under provisions of Article 1 of SMRDA the amount of BGN 960 - compensation for pecuniary damages, in terms of the value of purchased in April and May 2004 two injections Zoladex® and the amount of BGN 540 - that corresponds to compensation for pecuniary damages in terms of the cost of three blister packs of Femara® purchased in January, February and March, 2005, and the amount of BGN 80 000 - that corresponds to non-pecuniary damages compensation, as the requested full amount of 398 500 BGN, firstly claimed, had been rejected. T.Z. has been sentenced to pay state fee in the amount of BGN 12 740, under Article 10, paragraph 2 of SMRDA, including incurred costs of BGN 28, 53 that corresponds to expert witness deposit. As per additional Decision No. 92, dated December 19th, 2006, the Ministry of Health has been sentenced by the Court to pay T.Z.'s expenses amounting to BGN 1 700 – the attorney fee for one lawyer.

The decision has been appealed by both parties.

Plaintiff Z. has appealed in the part, "...., 1. claim for non-pecuniary damages has been rejected up to the full... amount; 2. she has been

sentenced to pay the amount corresponding to state fees and expenditures; 3. reduced size costs has been awarded; 4. no legal interest has been awarded. It considers the decision in the contested parts not proper and unlawful. Appeal to decision quashes and a new one, by which claims are going to be accepted in full.

The Defendant, Ministry of Health appealed the decision in the part referred to claims for non-pecuniary and pecuniary damage. It considers this decision unjustified and wrong, for breach of substantive and procedural law. It asks for revocation of the previous decision and a new one decreed, by which all the claims will be ejected or eventually reduced the amount of the compensation.

SAP (Sofia Appeal Prosecution) representative has challenged Z. appeals unfounded and sustain Ministry of Health appeal as partly founded. Appealed decision is claimed to be quashed and decreed a new one, by which compensation amounts are reduced, according to case law.

Sofia Court of Appeal, after having assessed the case evidence and each party argument, ascertains the following:

Complaints have been submitted within the statutory period against an act subject to proper instance control, realized by due parties and therefore they are procedurally admissible.

Objectively assembled claims, legally based on Article 1 of SMRDA, submitted by T. Z., against the Ministry of Health - regarding compensation payment for pecuniary damages, in the amount of BGN 960 (amount of purchased in April and May, 2004 two injections of Zoladex®) and the amount of BGN 540 (amount of purchased in January, February and March, 2005 three blister packs of Femara®), the same as non-pecuniary damages in the amount of BGN 398 500, as a result of Ministry of Health inactivity (failure in regulatory duties to provide free medicines for the period January, 2004 to March 1st, 2005), namely: no contract for supply; delayed proceedings according to law, the same as no provision of the necessary medicament quantities for this period has been referred to Sofia Court of Appeal. Non-pecuniary damages are expressed in a treatment delay of her existing disease, accelerate and increase her disease development, reducing the period of absence of serious disease symptom, pressing need of ovariectomy (oophorectomy) which aggravated her health condition -

metastases, causing the patient suffering, inadequate life, disability, inability to fulfill parenting, depression, feeling of helplessness and hopelessness that prevent normal social life and planning for the future.

The Defendant - Ministry of Health challenged the claims on the ground and size.

It was certainly found that after a mastectomy was performed on T.Z. on July 9th, 1998 (Patey method), by the National Cancer Center, "carcinoma of right breast - clinical stage III" had been diagnosed.

During the period August 12th, 1998 – September 16th, 1998, the Plaintiff had received percutaneous therapy. Between November 28th, 2002 and December 6th, 2002, the Plaintiff had undergone surgery - mastectomy of left mammal gland, clinical stage II B in the Specialized Hospital for Active Treatment in Oncology (SHATO), Clinic for Thoracic Surgery.

By LEMC (Labor Expert Medical Commission) expert decision N.0296, dated February 4th, 2003, T. Z. has been rated at 80 percent permanently reduced working capacity - with a period of disability until February 1st, 2006.

As per Protocol No. 113/March 25th, 2003, SHATO (Chemotherapy Clinic) three-member committee, has prescribed her medicaments for treatment for a period of 3 months.

Between April 13th, 2004 and April 27th, 2004 a percutaneous radiotherapy - radiation ovariectomy had been performed on the patient. On December 9th, 2004, the Ministry of Health National Specialized Hospital for Active Treatment in Oncology (NSHATO) three-member committee has issued Protocol No. 36/04 for prescribed medication - 56 pcs. (tablets).

As per an ultrasound test (dated March 7, 2005) and tomography examination (dated March 17th, 2005) performed upon the Plaintiff, she was found to have the existence of a hypo dense lesion on the boundary between the two liver lobes. On April 13th, 2005, T. Z. was issued a document for Taxoter® 1st line chemotherapy. By letter dated June 8th, 2005 Ministry of Health provided T. Z. with a certified muster copy of a name distribution list, which states she is eligible and included in treatment procedure with Taxoter® medicament.

By LEMC expert decision No. 0920, dated September 7th, 2005, T. Z. has been rated at 95 percent of "permanent disability without assistance" - for a period until September 1st, 2008.

According to the presented by SHATO - Sofia document, it is ascertained as fact that T. Z. has been provided with Zoladex® on: January

5th, 2004; February 26th, 2004; February 2nd, 2004; March 23th, 2004; June 10th, 2004 and July 9th, 2004 and with Femara® medicament on: September 16th, 2004; October 18th, 2004 and November 18th, 2004.

It has been unquestionably proven, that on February 21th, 2003, contract No. РД-17-203/2003 for medicament supply had been signed, between the Ministry of Health and Magined Ltd., referred to 3 types of medicaments, including the one taken by Z. - Anastrozole® /Arimidex®/; term of the contract - until December 31st, 2003.

On March 7th, 2003, Magined Ltd. had delivered to SHATO/NSII (National Social Insurance Institute), Darvenitsa 35 pieces of Zoladex® medicament, and on May 14th, 2003 - 42 pieces of the same one, according to the delivery check list. For the period May - June, 2003 SHATO - NOC (National Oncology Center) had received 42 pieces of Zoladex®, and on June 24th, 2003 SHATO/NSSI/Darvenitsa, had received 40 pieces of Zoladex®, according to state procurement tender No. 6181/2003. For the period July - August, 2003, 40 pieces of Zoladex® were received by SHATO - NOC.

On September 2nd, 2003, between Magined Ltd. and SHTAO/NSSI/Darvenitsa, a Protocol of Delivery and Acceptance had been signed regarding 10 pieces of Arimidex® delivery, the same as 40 pieces of Zoladex®. For the period September - October, 2003, SHATO-NOC had not received the medicament Zoladex®. On November 3rd, 2003, 60 pieces of this medicament had been received by SHATO-NOC.

For the period November - December, 2003, 60 pieces of Zoladex® were received from SHATO-NOC. By order No. РД-17-112/02/02/2004, the Minister of Health opened a Public tender for supply of expensive medicines for treatment of diseases that are outside the scope of mandatory health insurance, for country needs in 2004, according to Ordinance No. 23, Annex No.1, p.1 to 11.

By order No. РД-17-241/16/03/2004, the Minister of Health has ceased the procedure for Public Tender procurement on the items enumerated in detail, in Appendix No.1, an integral part of the same order opened by order No. РД-17-112/02/02/2004, and had opened a Public Procurement procedure to award a contract for the supply of expensive medicament used to treat disease that are outside the scope of mandatory health insurance, for the country needs in 2004, according to Ordinance No. 23, Appendix No. 1, p. 1 to 11; on February 10th, 2004 a contract had been signed between the Ministry of Health, as a buyer and “Alex Plus 2000” Ltd., as a seller, under which the buyer assigns to seller, and seller is

obliged to deliver to the buyer 6 types of medicaments, including the Aromazin® - up to 16470 tablets. The duration of the contract is up to February 28th, 2004.

On April 15th, 2005, between the Ministry of Health, as contractor and “Konsumfarm” Ltd., as contracted party, a contract had been signed for medicament supply (No. РД 17-480/2005), including Femara® (contract duration is up to December 31st, 2004).

On April 16th, 2004, between the Ministry of Health and “Alex Plus 2000” Ltd., a new contract (No. РД-17-383/2004) had been signed for medicament supply, including Aromazin®, as the term of the contract is up to December 31st, 2004.

On April 30th, 2004, contract No. РД-17-475/30/04/2004 was signed, between the Ministry of Health - as a buyer and “Higiya” S. A. - as seller, for delivery of the medicament Arimidex® - up to 77 000 tablets, as the term of the contract is up to December 31st, 2004.

On the same date, between the Ministry of Health and «Commercial League - National Pharmaceutic Center" SA, contract No. РД-17-477/2004 had been signed for supply of medicament, including Zoladex® - up to 3330 ampullae, the term of the contract is up to December 31st, 2004.

It is undoubted circumstance that on December 21st, 2004, Ministry of Health had decided (Decision No.РД-17-1075/2004) to declare "Meditex 2004" Ltd. as awarded at first place as per 4 positions, including the medicament taken by Z. - Letrozole® /Femara®/.

By decision, dated January 18th, 2005, decreed in regard to Civil Case No. 48/2005, SCC had canceled the decision of Sofia Regional Court (SRC), Civil Division, 28 unit, dated December 27th, 2004, in regard of Civil Case No. 000599/2004, by which the suits brought by "Commercial League-NAC" AD against Ministry of Health and "Meditex 2004" Ltd. were secured, based on Art. 120 of LPC (Law on Public Contracts), by suspension of contracting party decision implementation - Ministry of Health, namely decision No. РД-17-1075/21.12.2004, by which "Meditex 2004" Ltd. had been awarded as supply executor.

On January 26th, 2005, contract No. РД-17-040/2005 had been signed between the Ministry of Health and "Meditex 2004" Ltd. for medicament supply as per 4 items (cited in the contract); It has entered into force on the date of signature and action period of one calendar year.

On February 2nd, 2005, protocol of acceptance No. 3/2005 had been signed, between "Meditex 2004" Ltd. and SHATO – Sofia, referred to medicament Femara® delivery

As per Contract N. РД-17-040/2005 distribution list for January and February, 2005 of medicament Femara® - Sofia Region has received 40 tablets.

On March 11th, 2005, between the aforementioned parties, acceptance protocol No. 70/2005 had been signed that refers to medicament Femara® delivery.

According to distribution list for March and April, 2005 (contract No. РД-17-040/2005), it has been determined that SHATO had received 45 tablets of Femara® medicament.

According to letter, dated January 3th, 2006, the Director of "MDL" (Medical Diagnostic Laboratories) Department, at the Ministry of Health, had informed hospital directors that since the Commission for distribution of expensive medicament for oncology treatment session was programmed to start in late February, 2006 - requests based on contracts for expensive treatment medicament supply concluded on December 31st, 2005, should be sent to Ministry of Health after this Commission Session.

Based on the accepted and uncontested in the first instance ruling conclusion of the expert witness, Dr. R. I., it was determined that Plaintiff Z. oncology disease dated July, 1998, with diagnosis: carcinoma of right mammal gland, clinical stage III; on November 29th, 2002 a surgery had been performed – removed carcinoma of the left mammal gland, clinical stage II B. Practiced treatments: 1. Preoperative radiotherapy on July 1st, 1998; 2. surgery intervention - in July, 1998; 3. postoperative radiotherapy - from August 12th, 1998 to September 16th, 1998; 4. adjuvant chemotherapy - 6 courses following FEC scheme - from September, 1998 to January, 1999; 5. anti-estrogen hormone therapy for a period of 5 years (1998-2003) with Tamoxifen®, subsequently with Nolvadex®; 6. surgery practiced in November, 2002; 7. postoperative chemotherapy - 6 course TMZ system - from January 3rd, 2003 to June 11th, 2003; 8. administration of Zoladex® on September 3rd, 2003, October 3rd, 2003, October 31st, 2003, November 28th, 2003, January 5th, 2004, February 2nd, 2004, February 26th, 2004, March 23th, 2004, June 10th, 2004, July 8th, 2004; 9. radiation ovariectomy for the period July 13th, 2004 to July 27, 2004; 10. hormone therapy on October 18th, 2004 with Femara® and on December 9th, 2005 - Arimidex®; 11. curative chemotherapy - 4 mono-courses chemotherapy with Taxoter® - March 22nd, 2005, April 13th, 2005, May 30th, 2005, June 20th, 2005 and then began chemotherapy treatment with Taxoter® and Cisplatin® - 4 courses - on July 18th, 2005, August 15th, 2005, September 8th, 2005 and September 28th, 2005; on October 27th,

2005 III line curative chemotherapy with Xeloda® had been initiated - it actually continues in a day stationary hospital conditions.

According to the expert, treatment of oncologic diseases is comprehensive, involving surgery, radiation therapy and medication; i. e. the three main curative methods support and complement each other; an individual treatment plan /a fundamental principle in oncology/ is designed for each oncology patient. Combined (comprehensive) therapy improves life duration of patients. The aim of radiation and medicament therapy after removal of the tumor in II B and II stage is to extend disease-free interval, i. e. a period without recurrence and metastasis, in which case life duration vary between 50% - 60%.

The Plaintiff had been prescribed expensive medicament pursuant to Ordinance No. 23/2000 of Ministry of Health. After conducting a comprehensive treatment for carcinoma of the left mammal gland, adjuvant chemotherapy for carcinoma of the right mammal gland and five years hormone therapy with antiestrogen, the Plaintiff has been prescribed hormone therapy with Zoladex® - medicament that causes temporary ovarian suppression, i. e. leads to cessation of ovarian function. The application of Zoladex® is part of the comprehensive treatment, since the patient was evaluated as high-risk patient who may be expected the appearance of recurrence or metastasis; administration of this medicament has begun in September, 2003 as the last application had been in July, 2004. On June 10th, 2004, the opinion of the doctor in charge of Plaintiff treatment has been recorded in her personal ambulatory file - namely that actually Zoladex® supply was irregular and thus he proposed to practice radiation ovariectomy. After radiation ovarian suppression practiced (ended July 27th, 2004), in Plaintiff personal ambulatory file had been recorded initiation of hormone therapy with a peripheral aromatase inhibitor Femara® and Arimidex®.

Ultrasound examination practiced to the Plaintiff on March 3rd, 2005 showed the existence of liver metastasis; this finding was confirmed on March 17th, 2005 by the means of computer tomography examination; that is why Z. began chemotherapy treatment, as in her history of disease was the recorded "initiation of 4 cycles of chemotherapy with Taksoter®, 4 cycles of chemotherapy with Taksoter® and Cisplatin®, 4 cycles of chemotherapy with Xeloda®". Prescribed medicaments had been recorded in the personal ambulatory file or in Plaintiff medical history; prescribed medicaments had been received and the treatment - conducted. Z.'s medical documentation contained protocols issued to prescribe medicaments for expensive treatment based on Article 3 of Ministry of

Health Ordinance N.27/2000. These expensive medicaments (same Ordinance Article 3) are granted by the Commission (Article 3 of the Ordinance) and at the discretion of the treating physician. Plaintiff's stage of the disease was not an early one. Five-year survival according to statistical data varies between 50-60%; there is a relatively high likelihood of appearance of distant metastases in cases of patients that are at this stage. Comprehensive systemic treatment implementation significantly improves life duration. There is a 2-month interruption of prescribed hormone therapy in the Plaintiff's particular anti-tumor treatment. No scientific evidence is available that suggests how this fact would affect the outcome of the disease. If prescribed medicines are not taken for a prolonged period of time, advance of the disease should be expected in II B and III stages cases. Medium life duration in these stages is about 3 - 4 years.

Evidenced by the additional finding of the same expert, accepted and uncontested in the first instance proceedings is the fact that in September, 2002 Plaintiff had undergone surgery because of second cancer complaint - carcinoma of the left mammal gland, II B clinical stage, with a histological result "moderately differentiated, invasive ductal carcinoma". Any cancer disease poses a risk of recurrence or metastasis and only early stage develops in a favorable manner, when it is curable. In this particular case, in stage II B - only about 50% of cases develop recurrence or metastasis, and 10-year life duration is 51%. Liver metastases are cancer consequence - this connection may be considered regularity. During the period November, 2002 - March, 2005 Z. had been given chemotherapy and hormone therapy. Following medicaments were applied during hormone therapy: Nolvadex® (antiestrogen), Zoladex® (ovariectomy), Femara® (aromatase inhibitor), and Arimidex® (aromatase inhibitor). Zoladex® therapy can be replaced with another type of treatment - operative ovarian suppression or radiation ovarian suppression. Hormone therapy has been practiced with one of three medicaments: Arimidex®, Aromazin®, and Femara®. Zoladex® is administered every 28 days and the effect is reversible after discontinuation of treatment, i. e. there is no adequate therapeutic effect if it is administered every 56 days. Alternative to Zoladex® treatment is radiation or surgical ovariectomy. Ovariectomy has curative effect and in this case it is part of the comprehensive treatment, practiced to Plaintiff complaint. There is no Zoladex® alternative and medicaments: Arimidex®, Femara® and Aromazin® are IInd line hormone therapy, part of the group of aromatase inhibitors and as medicaments of II line hormone therapy have no alternative ones. Medicament hormone therapy with aromatase inhibitor is applied to postmenopausal women, i. e. after ovarian function

cessation - hormone therapy should initiate about 1 month after ovarian suppression. IInd line hormone therapy with peripheral aromatase inhibitor is being administered, once in a day, in an appropriate dose, without interruption until disease progression is obtained. Hormone therapy medicaments (Femara®, Aromazin®, Aridimex®) are prescribed monthly.

At the hearing, the expert stated that T. Z. had been provided with the treatment prescribed in her personal ambulatory file. The recommended treatment had been applied with temporary interruptions or delays, as reflected in expert conclusions. In this case the interruption period lasted 2 months, so it is impossible to assess whether this suspension has affected patient's health state. Forced menopause is achieved with Zoladex® application; it is reversible when medicament is suspended. Second line therapy could not be applied when woman still menstruates. Metastases in the liver have a direct connection with the underlying disease of the Plaintiff.

As per Plaintiff's doctor - Dr. H. - interrogated (as a witness) it is established that Z. has been a strict patient, always attending examinations and treatments. There were problems with hormone therapy because the hospital supplies required for the treatment hormones were irregular. There were also cases of irregular supply of Zoladex®, Armidex®, Femara® and Aromazin®; treatment with these agents should be performed rhythmically, otherwise the disease may progress. The lack of medicaments has affected Plaintiff's emotional state; stress and negative emotional state led to deterioration of patient health condition.

As per the testimony of interrogated witnesses, Y. K. — Plaintiff's sibling, who shared the same household with her in the previous 6 years, determined repeatedly that they should purchase medicaments on their own, as every time, 2-3 days before the day of these medicines intake (marked off with a cross on the calendar by T.), she got worried whether it would be possible to obtain required medicaments or not.

This situation had been repeated over and over again. Sometimes the Plaintiff called him by lunch time, crying, walking aimlessly on the streets, unknowing what to do in order to solve the lack of medicaments. She did not dare to go home in order to avoid her daughter's alarm.

On other days, bitter and ambitious she called to inform him that she was waiting in front of the actual Minister or deputy Minister's door expecting to find solution of her problem.

In early 2005, the situation became particularly tragic. Plaintiff ceased work activity because her whole time had been committed to medicines procurement.

One of the most difficult moments for this patient was associated with the ovaries suppression surgery, because after it, the boyfriend of long standing parted from her. During this period, all kind of thoughts had spun round in her head, including ones of suicide. The next particularly difficult moment she experienced had been the detection that cancer spread to the liver. For a long period of time, Plaintiff was totally confused, as the fight against cancer had to be initiated again, after four years lasting treatment. In May, 2005 feeling herself at a total impasse and hopeless, the Plaintiff started a hunger strike. She has been a strict patient who allows no omission of any designated treatment procedure and examinations. She repeatedly has been left without required medicaments for her treatment; there were many delays in their delivery.

It is admitted in the First instance Court contested decision that there has been Defendant omission, resulting in: lack of supply contracting; Public Procurement Act /PPA/ delayed procedures; PPA impracticable procedures and provision want of medicaments in quantity required for treatment, during the claimed period - that resulted in treatment delay of Plaintiff's existing disease, the same as her disease development acceleration and enhancement, leading to reduction of the period of absence of severe signs of disease manifestation and the unnecessary ovariectomy, which have caused pecuniary and non-pecuniary damages.

Based on an audit report on the implementation of procedures for administering and receiving of expensive medicaments used for malignant disease treatment presented to this court, funded by the Ministry of Health state budget for the period January 1st, 2001 – December 31st, 2005 the following situation had been established: there was no constructed and validated medicament policy, with clearly defined objectives and priorities as part of state policy in health care, according to Article 5, Para 1 of MH Organization Rules.

As per Article 3 of Public Health Act (PHA), in force until December 31st, 2004, certain health care activities were defined to be financed by the state budget and municipal budgets and citizens were entitled to them, for free, as in item 13 of the same provision regulated the payment of expensive treatment, not covered by compulsory health insurance, in the manner determined by the Minister of Health.

In compliance with the legal requirement, Minister of Health had issued Ordinance No.23/October 30th, 2000, referred to the procedures for administering and receiving of expensive treatment medicaments, funded by the state budget, which establishes a legal regulation frame on Ministry and health care institutions functions, in order to assure expensive

treatment medicaments that are not covered by the compulsory health insurance. This Ordinance is in force since January 1st, 2001. When performing its duties, implementing the state policy in health care, including the provision of expensive medicines for malignant disease treatment, the Ministry interacts with other institutions, such as: Council of Ministers (CM), Bulgarian Drug Agency, National Health Insurance Fund (NHIF), District health care centers, hospitals and others. During this audited period, two main laws that rule social relations in health care sphere and connected to public health protection - Public Health Act (repealed) and Health Law (enacted January 1st, 2005). As regards the procedures for the medicaments purchase for expensive treatment, Public Procurement Act (PPA) is being applied. According to medicaments nature (product of a specific kind), the special Law on drugs and pharmacies in human medicine provisions and regulations are applied. The audit has found that Ordinance No.23/October 30th, 2000 (that refers to procedures on administering and receiving medicaments for expensive treatment, funded by the state budget) does not provide policy for such activity financing (expensive treatment assurance, by means of municipal budgets). Substantial change, as regards to medicaments for expensive treatment is carried out by amending the Ordinance of October 5th, 2004. It has expanded the drug list, and some medicaments are excluded from Ordinance Annex 1. The selection of newly included medicaments has been made subjectively, without any specific statutory criteria for their therapeutic effectiveness assessment and pharmacy-economical expedience. As per analysis of 2001 - 2005 period data, the average annual increase in the number of patients needing expensive treatment amounted to 3,4% and patients with cancer - 10,1%. Therefore, a need for annually raising the state budget funds destined to purchase of medicaments for expensive treatment is identified. There is no documentary database constructed, regarding medicaments needs for expensive treatment, in Ministry of Health. Working activity is based on operational information gathered from hospitals two-month requests. The lack of a document that summarize annual medicaments requirements of medical institutions, under the Ordinance, is a prerequisite for poor planning of the necessary budgetary resources, formation of shortages and medicines costs for expensive treatment inefficiency, including for cancer patients. The audit has found that Ministry of Health does not summarize the information submitted by hospitals, under Article 8 of the Ordinance, on the number of cancer patients, the expected number of cancer patients, or the number of deceased and newly diagnosed patients, the same as on medicaments that the country requires

year by year, and also does not analyze and forecast oncology diseases trends.

Opened procedures for medicines supply in 2001 and supply of newly included ones in 2004 and 2005 had been conducted without the adequate information provision for required medicaments quantities for the next year. In addition, all acts emitted by the Minister of Health for public procurement procedures opening on medicines for expensive treatment did not describe the factual basis for initiating the procedures, related to the requirement of Article 22, paragraph 1, p. 2 of PPA. Data analysis of contracted and supplied medicaments for expensive treatment, including malignant disease in 2003 showed that hospitals are being provided, in a greater degree with the necessary medicaments, but not sufficiently for patients with malignant diseases, who are prescribed treatment under Article 8 of Annex No. 1 of the Ordinance.

In 2004, deterioration in the work of MH has been observed in defining the necessary medicaments quantities for expensive treatment and the contracting on time of types and quantity. During this year, structural reform has been realized, which had a negative rather than positive influence on MH performance with respect to optimizing the process of necessary medicines provision. Conducted procurement procedures in 2004 for determined annual quantities are two such reforms, but they were opened with a considerable delay - on February 2nd, 2004 and on March 16th, 2004. Another contracting procedure had been opened first, on December 29th, 2003 but only for partial deliveries instead of for all required types and quantities. The audit is categorical that in 2005 the practice of delayed procurement procedures opening continued with two procedures openings in a month and for partial quantities. 2005 contracting procedure for 31 types of new medicaments for expensive treatment, including primarily those used by people with cancer and their re-distribution among hospitals, without being previously requested, had resulted in significant decreases of the quantities of some drugs due to included new ones.

Growth in the number of cancer patients needing drugs is 46,8% compared with 2001. But this growth was not foreseen in the planning of necessary financial funds and thus a shortage was generated that has affected the treatment of cancer patients, who require these drugs under the provisions of Ordinance Annex 1, Article 8. It was found that the number of ongoing procurement procedures in any given year increased as increasing the number of contracts, rather than conducting one basic procurement procedure at the end of the previous calendar year for the next

one, based on the approved specification for annual needs. Based on the presented information on expensive drugs group for treating cancer patients, the audit found that they are destined for relatively less than 1% of them.

2004 allocated funds destined for supplies of these products represent 34% of the total medicaments supply for cancer patients. In 2005 this amount was reduced, although the number of patients treated with these agents has increased, leading to significant shortage. According to this data it is found that drug quantities assured for cancer patients were 30% less than requested by the hospitals (personal requests, including diagnosis and indicated treatment regimen for each cancer patient), under the statutory provision. Furthermore, the audit found that the Ministry of Health (principal contractor for supply of medicaments for expensive treatment) has not claimed in court to suppliers for any failure or delay in performance which is equivalent to complete non-feasance, as consideration after the expiry appears unnecessary, due to disruption of patient's therapeutic regimens.

The assumed present proceeding's conclusion of the Triple judicial-medical expertise has found that Zoladex® application is an alternative to radiation ovariectomy in premenopause (perimenopause) patients with breast cancer, with positive hormone receptors. One of these two methods of application excludes the other one usage. Ovariectomy application (by surgery or radiation) is the oldest method for systemic treatment of mammal gland cancer; medicated ovariectomy with Zoladex® was introduced during XX century (80s), aiming ovarian function reversible block, i. e. after completion of therapy with Zoladex® most of the patients recover their ovarian functions. This is particularly important for young women with early breast cancer stage, in which cases practicing a comprehensive treatment (surgical intervention, chemotherapy and hormone therapy) make healing process effective. Permanent blocking of ovarian function by surgery or radiation oophorectomy leads to an increased risk of osteoporosis, which develops much faster than in women with natural menopause; to increase cholesterol and triglyceride levels in the blood causes atherosclerosis and increased myocardial infarction incidence.

Therefore, ovariectomy is an independent method of treatment, but due to the severe consequences that it may provoke, currently in clinical practice it is being applied only in situations when it is impossible to provide Zoladex®.

In European Union, radiation ovariectomy is not applied generally, but to a relatively small number of patients. There are no specific criteria to follow when radiation ovariectomy is applied except for common indications for ovarian function suppression - premenopause (perimenopause) and hormone-dependent breast cancer. Plaintiff's disease meets both criteria.

The performance of radiation ovariectomy in 1998 would increase Plaintiff's chance to have avoided the appearance of carcinoma on the left mammal gland in 2002, the same as Zoladex® application at least two years after 1998, would have increased this chance. The addition of Tamoxifen® to ovarian function suppression increases the chance, by 23%, compared only to suppression of ovarian function.

In Plaintiff's case, there was no need of radiation ovariectomy in 1998, because there was Zoladex® then and she has been undergoing a 6-month course, which causes menopause within 3 years from its commencement. Radiation ovariectomy applications in June, 2004, performed by her doctor in charge was the right therapeutic approach because of the risk of disease progression caused by the irregular supply of Zoladex®.

The breast cancer (MGC) operated on in 2003 had contained a high level of hormone receptors, which determines the leading role of hormone therapy in the process of prophylactic treatment. SHATO had the technical capability to provide radiation or surgical ovariectomy during March - May, 2004 but such procedure was not been required in Plaintiff's case because she had received application of Zoladex® in late March and the following one had to be done at the end of April. After finishing chemotherapy's sixth cycle, as per scheme CMF (cyclophosphamide + methotrexate + fluorouracil), according to Plaintiff's medical history - hormone therapy with Zoladex® had been properly prescribed and when she had achieved "lasting menopause - II line hormone therapy" applied.

Hormone therapy cannot be replaced with another type of treatment because there is no other effective form of cancer treatment. If, however, it is known that there will be no available drugs to practice hormone therapy, only ablative hormone therapy (Oophorectomy, ovariectomy) should be prescribed. The presence of metastasis in the liver, found in March, 2005 is the worst development of the disease, because at this stage no cure could be achieved. Median life duration of patients is about 24 months. Patients do not die because of the breast cancer, but because of its metastasis in internal organs. When there is no metastasis, operable MGC does not cause death. In March, 2007 new metastasis in liver had been found which represented a stage of the same disease. Breast carcinoma removed in November, 2002 could spread to the liver despite practiced prophylactic

radiotherapy and hormone therapy. During the period November, 2003 - March, 2005 the Plaintiff underwent drug ovariectomy with Zoladex®, followed by a radiation course, and by October, 2004 - maximum estrogen blockade with aromatase inhibitor /Femara®/. Replacement of Femara® with Aromazin® for 1 month is not desirable, but it does not alter substantially the effect of the treatment. It could be assumed that the initiation of maximum estrogen blockade early in 2003 would reduce the risk of spread due to the greater efficiency of the combination of ovarian function suppression plus aromatase inhibitor compared with only ovarian suppression. Once encountered, metastasis in liver may temporarily be affected, favorably, by hormone therapy and chemotherapy, but cannot be cured; that is Plaintiff's health condition at the moment. During the period 1998 - April, 2004, examinations have been performed regularly on Plaintiff - presence of metastases has not been found. Experts are adamant, given the stage of Plaintiff's disease - II B, her young age and large number of metastatic axillaries lymph nodes (10), that there are reasons to expect development of distant metastases, since the Plaintiff was found to have metastases in the liver in 2005 and in 2007 - new lesions in the same organ. Zoladex® and Femara® medicaments have proven antitumor effect in hormone-dependent BC (breast cancer) patients and their application in patients with early BC stage significantly increases the patient chance to be cured.

At the hearing, experts affirmed that when preparing their conclusion they used all the medical documentation that provided Plaintiff's entire history of the disease, of her treatment in SHATO-Sofia and her personal ambulatory file, which contained all treatments carried out during her hospitalization.

All medical records for the period 1998 - April, 2007, on the treatment of the patient have been kept in the hospital. Radiotherapy-induced tumors have been caused by the relatively low doses of radiation, used during the radiation ovariectomy. First, such radiation doses have cancer-inducing action and the second reason is that during irradiation not only the ovaries are exposed, but other tissues, which can cause malignant tumors. Plaintiff's irradiation was practiced in 2004, so no one can categorically declare whether a radiotherapy-induced tumor will appear or not. When Zoladex® application is stopped, resulting deviations from the norm cease too and normal levels are re-established, while with surgery and chemotherapy treatments, ovarian function is irreversibly damaged and also other symptoms appear.

In 2004 the Plaintiff had been curable. Bulgarian radiotherapy specialists have found (after completing their respective specializations in

major European centers) that radiation oophorectomy (ovariectomy) has been practiced nowhere, except separated Oncology Institutes in some countries (where radiation ovariectomy has been accepted as a standard treatment method) and they are not leading in this area. A year and a half after having been treated by chemotherapy and not by hormone therapy with Zoladex® and Femara® preparation, Plaintiff obtained a relapse - metastases in the liver. Radiation ovariectomy patients should not been treated with Zoladex®. It is not possible to replace the hormone therapy with some of the following therapy types - surgical intervention, chemotherapy or immunotherapy.

To replace one kind of hormone therapy by another one is admissible, but it is distinctive that if the patient has undergone one hormone treatment type, this same one cannot be repeated, but in principle, interchangeable medicaments could be chosen. The expert, PhD T. said that in tracing Plaintiff's treatment process, treatment cessation had not been detected, although there were no Zoladex® and Femara® preparations supply, in view of the fact that she purchase them on her own.

In the actual proceedings it has been established that no changes are required to be done in the initial findings, after reviewing the available medical documentation in SHATO and Plaintiff Private Ambulatory File (PAF), and according to the admitted additional conclusion of the medical experts. About 70% of patients with breast cancer are hormone dependent. As per statistical data, all patients with tamoxifen intolerance (15%) and all patients with disease advance, after taking tamoxifen (about 40%), are subject to treatment with aromatase inhibitors.

During hearing, experts declared they saw in Plaintiff's personal ambulatory files, all original records that correspond to previously presented copies; these documents, by their nature represent a request to the Ministry of Health for medicament supply.

As per established facts, this second instance has found the following:

Under Article 1 of SMRDA, the State is liable for damages caused to citizens by illegal acts, actions or omission of its organs and officials when executed administrative activity or because of this execution. The purpose of this Act is to establish procedures for realization of damages that are state responsibility according to exhaustively numbered hypothesis that meet the interests of the individual injured citizen and functions specificity performed by various authorities whose officials may cause damage. Structurally, in Art. 1 of SMRDA's wording, concrete cases are given that cause liability and also conditions under which it could be fulfilled. It should

be noted that the law is in full compliance with the constitutional principle of strict liability (absolute liability) of State for illegally caused, by its organs and officials, public damages. In this case, the court ruled on the illegality of the act or omission when the damages are caused by unlawful act or omission. The right to compensation for damages arises out of substantiation implementation that includes the following elements: damage; unlawful act, action and/or omission of state authority or official during/or in execution (process) of administrative work; causation relation between the damage and the act, action and/or omission. By its nature, State Responsibility under Article 1 of SMRDA is objective; i. e. presence of guilt is not required.

From collected ample evidence in this case, the Court accepts that there was Ministry of Health omission, resulting in improper conduct of contracting and delivery of expensive drugs, namely: lack of a basic procurement procedure implemented at the end of the year, covering the next one, based on the approved specification for annual needs, delayed and unrealized procedures under the PPA, contracting for partial quantities of drugs and irregular and chaotic supply of medicament quantities that do not cover the number of cancer patients, for the period January 1st, 2004 - March 1st, 2005.

According to Art. 4 of SMRDA, the State owes compensation for the damages that are direct and immediate consequence of the injury. In this particular case, it was clearly established that as a result of Defendant omission, Plaintiff’s treatment of existing disease had been postponed which accelerated and increased her disease development, augmented the periods of severe disease symptoms and led to unnecessary ovariectomy - all the above causing her pecuniary and non-pecuniary damages. It was found unquestionably that during the claimed periods, medicament treatment has been practically missing, as the want of Zoladex® has led to forced ovariectomy and ovariectomy without II line treatment had little effect; so that in March, 2005 patient had been found to have metastasis in her liver. Irregular delivery of Zoladex® is the only reason for amending Plaintiff’s individual treatment plan through the application of radiation ovariectomy treatment. Inevitably, surgical ovariectomy leads to serious negative psychological alterations and to changes in the physical health condition of the woman.

Non-pecuniary damages compensation is aimed to repair in a relatively full way pain and malady suffered by Plaintiff. The content of the concept "non-pecuniary damage" is defined by case law and the unwritten rules of morality. This particular case has to do with non-pecuniary

damages of a peculiar character and nature, much different from the concept of non-pecuniary damages with the already adopted content - suffered pain and malady. Indeed, the Plaintiff - Applicant has suffered and is suffering now pain and malady, but among them are superimposed also all the negative experiences, stress and discomfort that go along with the daily worry for her physical survival. Also all the inconveniences of contacts with relevant officials in the system of Ministry of Health, concerning the search for the necessary medicaments in order to fulfill an adequate treatment should be added.

Everything mentioned above has obstructed a peaceful environment for treatment. Furthermore, the Plaintiff has been awarded of the unfavorable prognosis of her disease and the stressful situation, which has experienced because of uncertainty whether there will be drugs delivery for her treatment, and also the impossibility to obtain such medicaments are disproportionate to the inconvenience of searching for necessary drugs in the case of any other disease (without such a forecast).

In the light of the foregoing and in accordance with criteria of justice referred to in the provision of Article 52 of Law on Obligations and Contracts (LOC) this instance considers that the amount of BGN 100 000 is fair compensation for non-pecuniary damages endured by the Plaintiff. Compensation thus determined is due to legal interest from the date of application submitting - February 2nd, 2005.Request for award of statutory interest was made by the Plaintiff attorney in the essential pleading in the first instance proceedings.

As regard to the amount of the compensation for pecuniary damages, this court considered undisputed that Plaintiff purchased, on her own, in April and May, 2004 Zoladex® medicament, and in January, February and March, 2005 - Femara®. This also has been established by the enclosed to the case information by SHATO - Hospital pharmacy, which demonstrated that Plaintiff had not been assigned these two medicaments during the mentioned in the case period of time. According to the wholesale unit price of these medicament preparations under the provisions of Article 130 of CPC, the present instance, given the rise in prices of medicines, considers that the cost of a blister pack of Femara®, for 2005 is BGN 180, and an injection of Zoladex® - BGN 480; consequently the claim is legitimate and proven in the amount of BGN 540 - for preparation Femara® and BGN 960 for the preparation Zoladex®.

Given the outcome of the dispute and on the grounds of Article 64 of CPC, Defendant - Ministry of Health - should pay these costs in accordance with the upheld part of the claims. The Plaintiff has incurred expenses for

attorney fee amounting to BGN 1 700 and as per claims honored part a total of BGN 101 500 is entitled to expenses of BGN 431, 38. First instance Court had awarded expenses in the amount of BGN 1 700, but the amount due should be adjusted to the above mentioned amounts.

According to the provisions of Article 10, paragraph 2 of SMRDA, Plaintiff owes state fee payment according to the rejected claim size and this amount is BGN 11 940.

Subject to the above conclusions there is a partial discrepancy with the adopted ones by the first instance court. The contested decision must be annulled in the part referred to non-pecuniary damages claim, it has been dismissed for the sum of BGN 80 000 to BGN 100 000 (i. e. BGN 20 000) and instead of this a new decision has been emitted, based on Art.208 of CPC, where the claim has been accepted in that amount. A legal interest should be added to the full compensation amount, calculated according to the date of claim submitting - February 2nd, 2005.In the rest of the appealed part the decision should remain in force.

Conducted by the above, the Court has

DECIDED:

To ANNUL the decision of November 6th, 2006 decreed for civil case No. 572/05 of SCC, 1st Civil Division, 12th Panel of Judges, insofar as non-pecuniary damages claim, brought by T.D.Z. against the Ministry of Health has been rejected in the amount over BGN 80000 to BGN 100 000 (i. e. BGN 20 000) as in the part that ordered T.D.Z. to pay state taxes over BGN 11 940 and instead of this STATES:

CONDEMNS the Ministry of Health to pay additionally to T. D.Z., pursuant to Art. 1 of SMRDA, the sum of BGN 20 000, that represent non-pecuniary damages compensation, including statutory interest from February 2nd, 2005, due on the full amount of compensation - BGN 100 000.

REMAIN in force the decision in the rest of the claimed part.

REVOKE the additional decision of December 19th, 2006 decreed for civil case No. 572/05 of Sofia Civil Court, 1st Civil Division, 12th Panel of

Judges, in the part which benefits T.D.Z. with awarded expenses over BGN 431, 38.

This Decision is subject to appeal to SCC within 30 days of the notification of the Parties for its enactment.

CHAIRPERSON: (signature)

MEMBERS: 1. (signature)
2. (signature)

(There is a rectangular stamp that certifies issued writ on June 5th, 2008)