

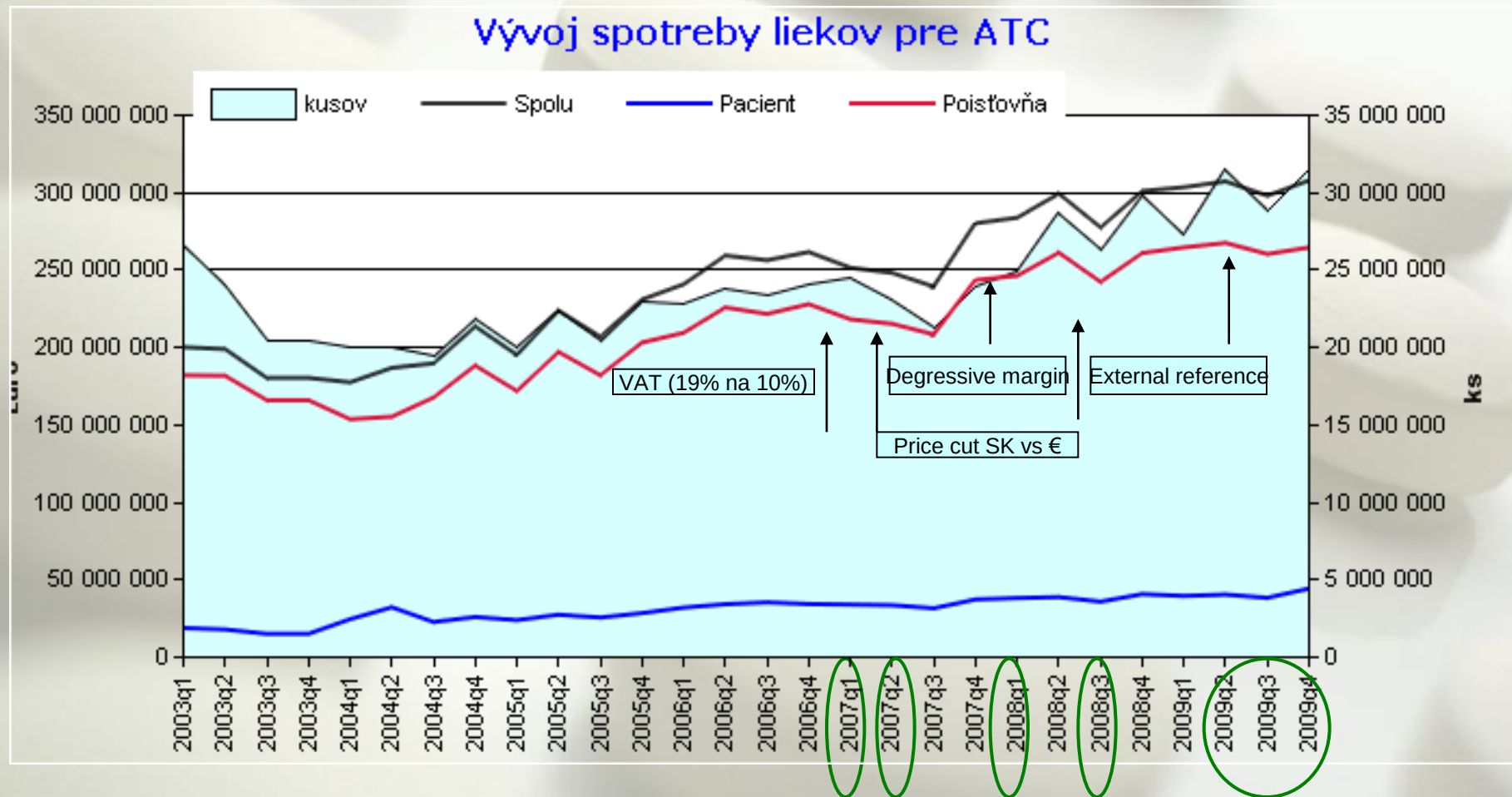
Onkologická liečba

**onkologické lieky v Slovenskej republike v
systéme úhrad z verejného zdravotného poistenia**

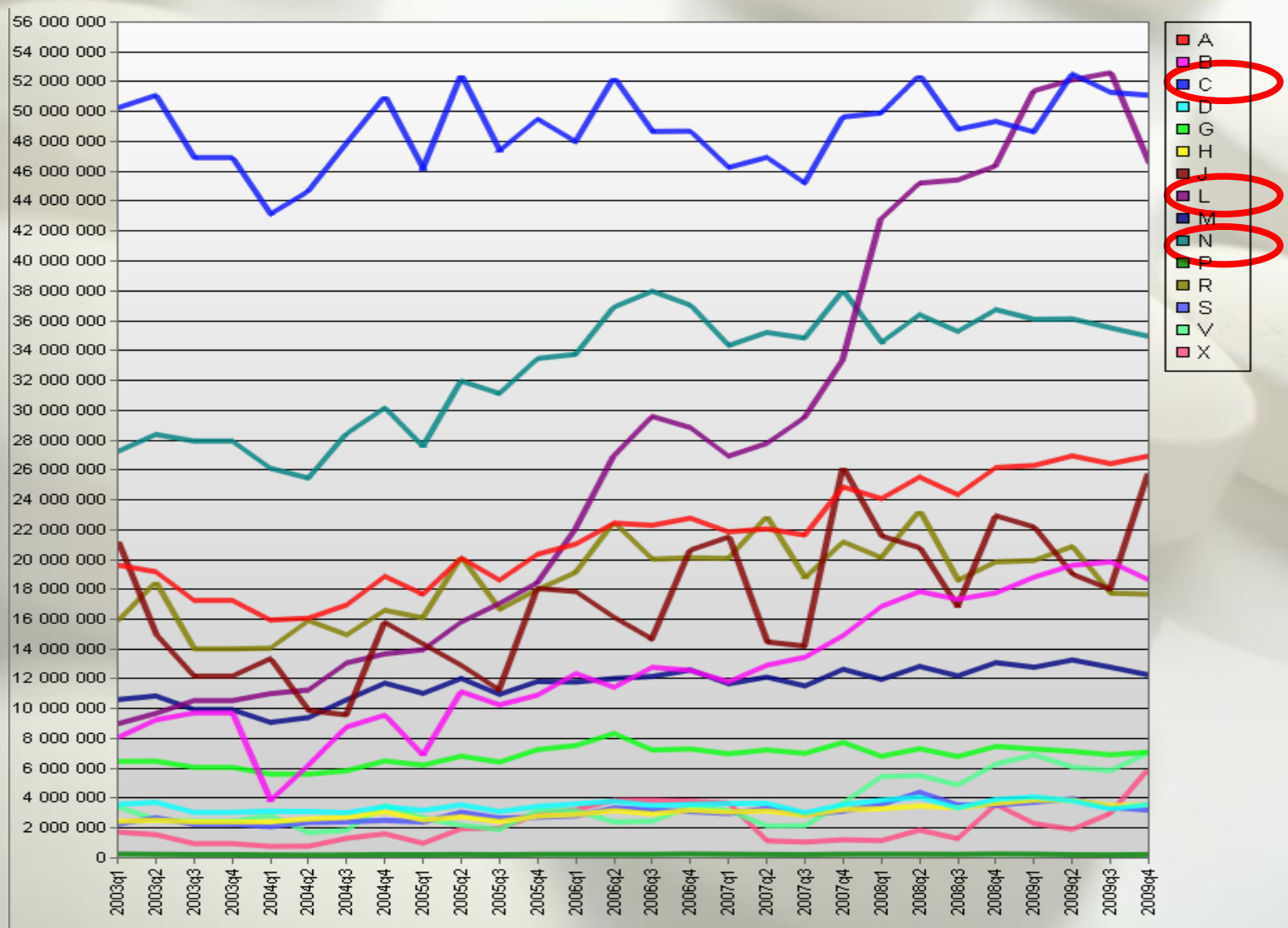
Bratislava, 27. apríl 2010

Dr. Ján Mazag

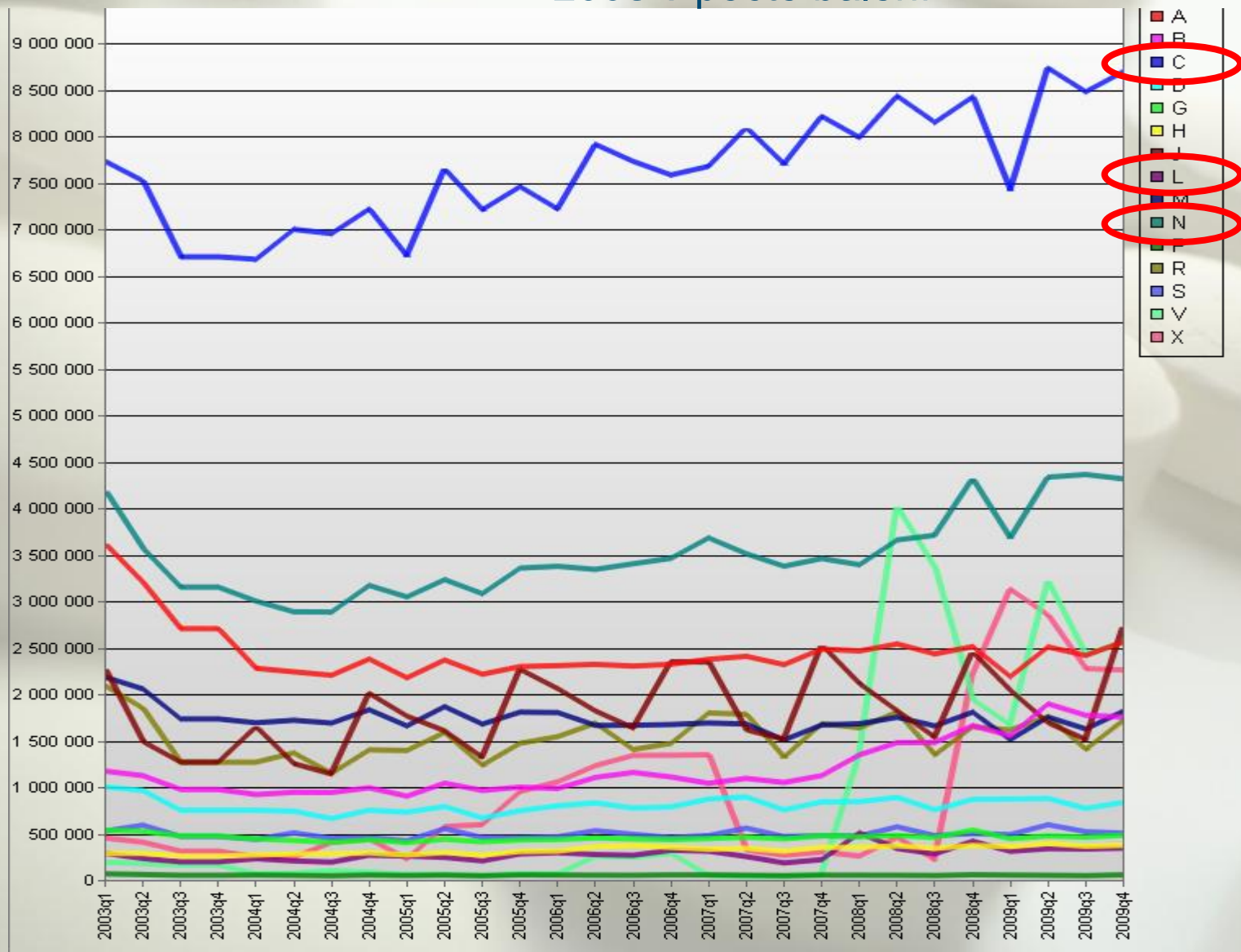
Spotreba liekov v SR podľa štvrtírokov od roku 2003 v €



Spotreba liekov v SR podľa štvrťrokov a ATC od roku 2003 v €



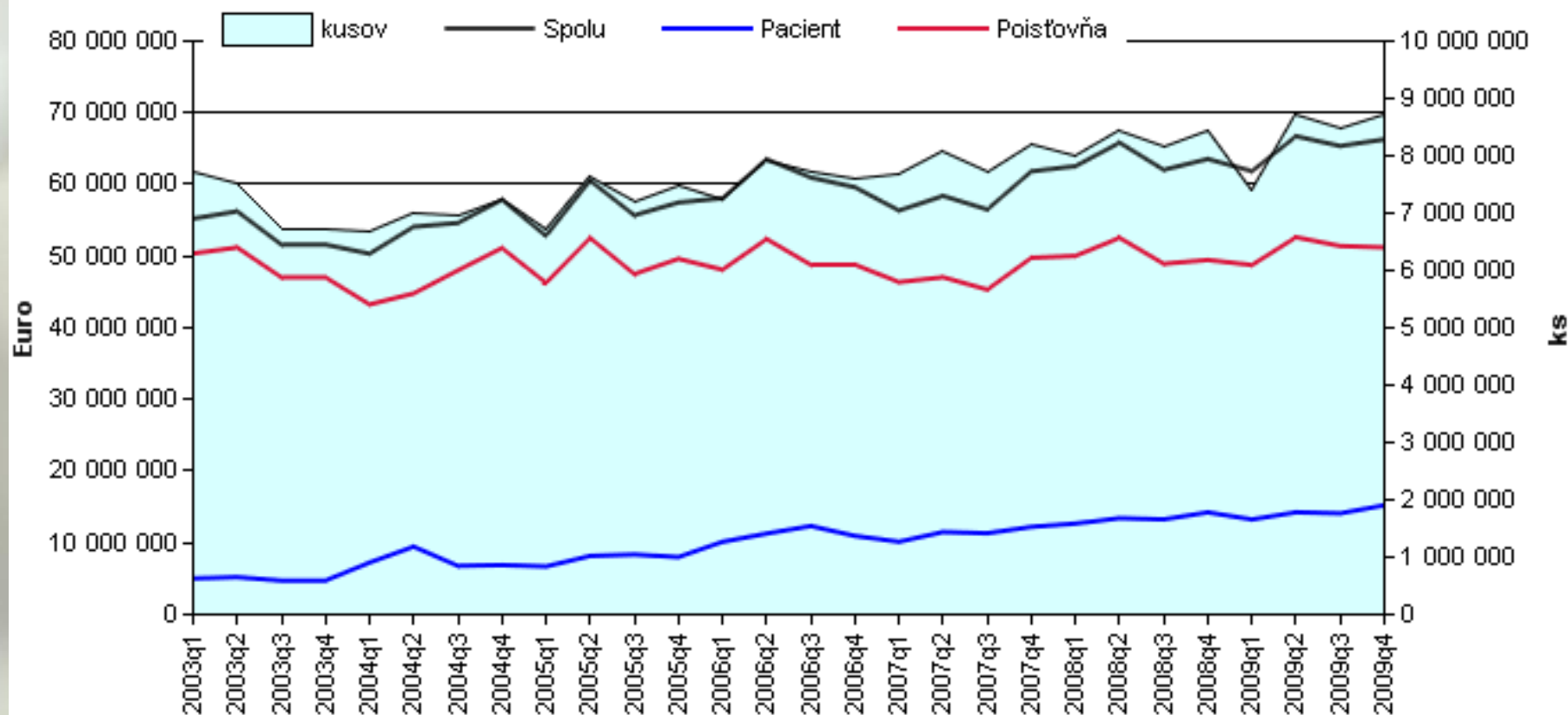
Spotreba liekov v SR podľa štvrtrokov a ATC od roku 2003 v počte balení



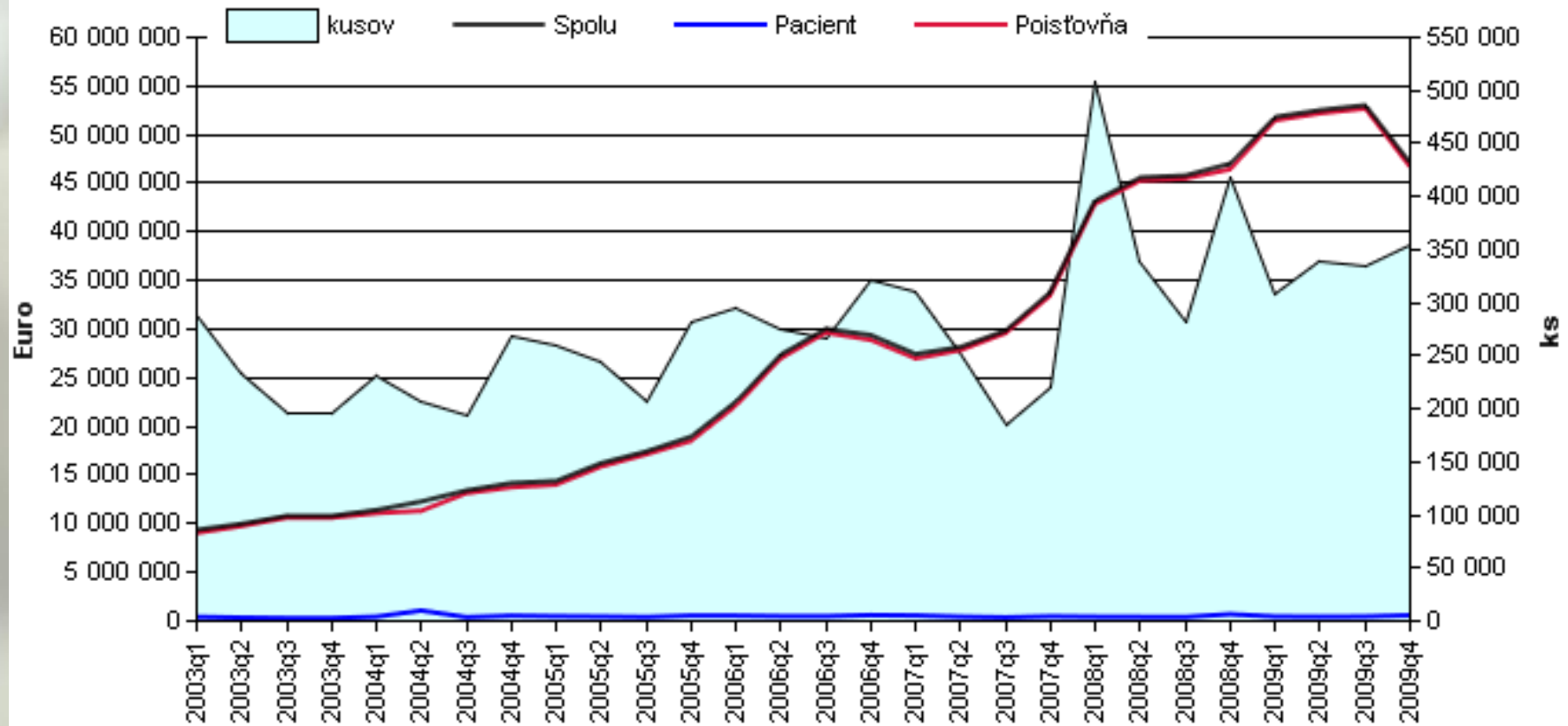
Poradie ATC v IV. štvrťroku 2009

Rank	ATC	Spolu	%	Poistovňa	Pacient	Kusov
1	C	66 123 664	21,52%	51 052 745	15 070 919	8 701 206
2	L	46 964 541	15,29%	46 512 861	468 815	354 501
3	N	40 664 625	13,24%	34 897 574	5 767 050	4 317 248
4	A	31 222 869	10,16%	26 882 421	4 340 448	2 563 338
5	J	29 915 129	9,74%	25 734 478	4 293 929	2 732 124
6	R	21 130 830	6,88%	17 628 181	3 502 648	1 720 941
7	B	19 664 793	6,40%	18 586 464	1 078 330	1 760 045
8	M	16 569 841	5,39%	12 220 619	4 349 222	1 817 510
9	G	8 622 989	2,81%	7 048 686	1 574 303	481 942
10	V	7 277 149	2,37%	7 015 288	298 122	2 657 640
11	X	6 292 626	2,05%	5 930 006	517 121	2 627 451
12	D	4 901 748	1,60%	3 535 102	1 366 647	835 767
13	S	3 873 417	1,26%	3 153 155	720 261	504 968
14	H	3 762 444	1,22%	3 521 045	258 271	375 774
15	P	220 332	0,07%	185 531	34 801	56 126

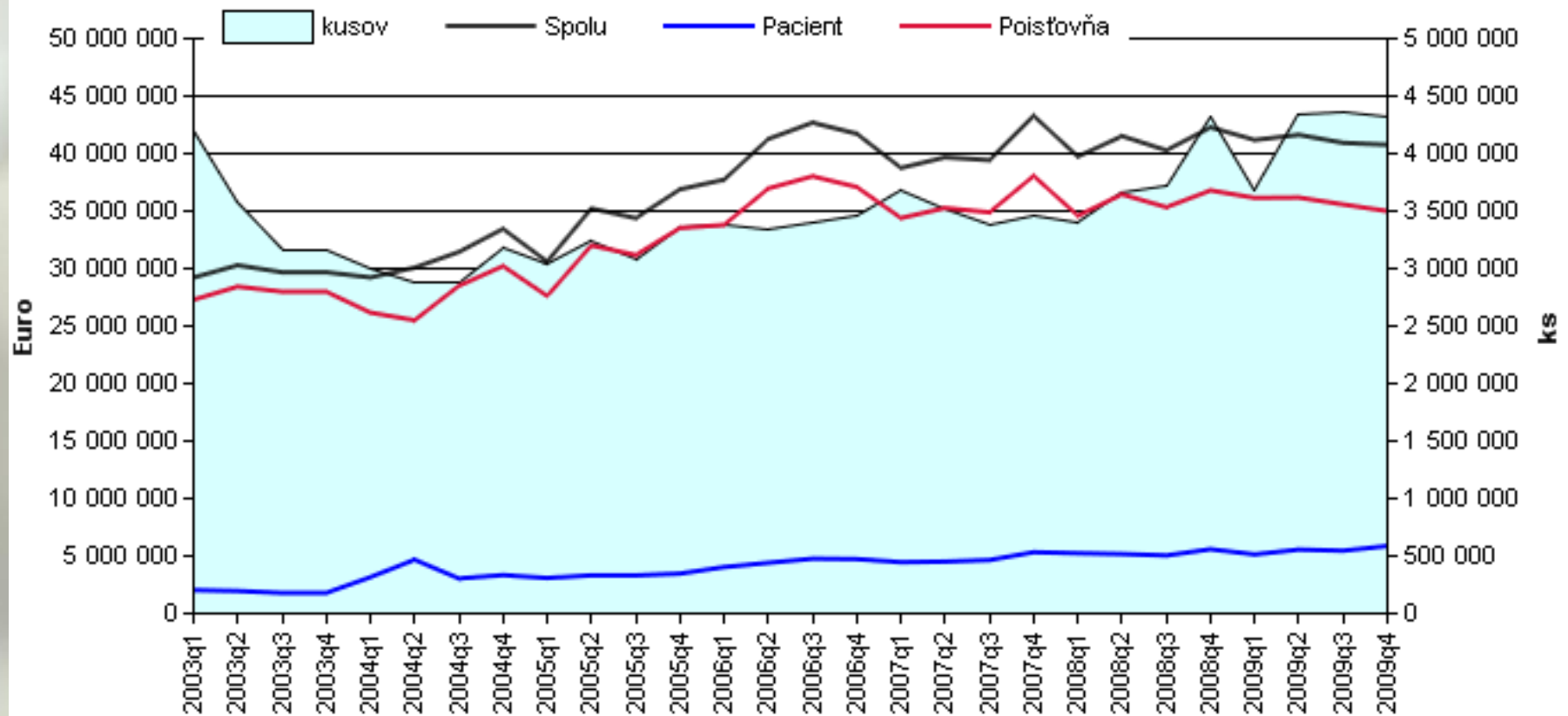
Vývoj spotreby liekov pre ATC C



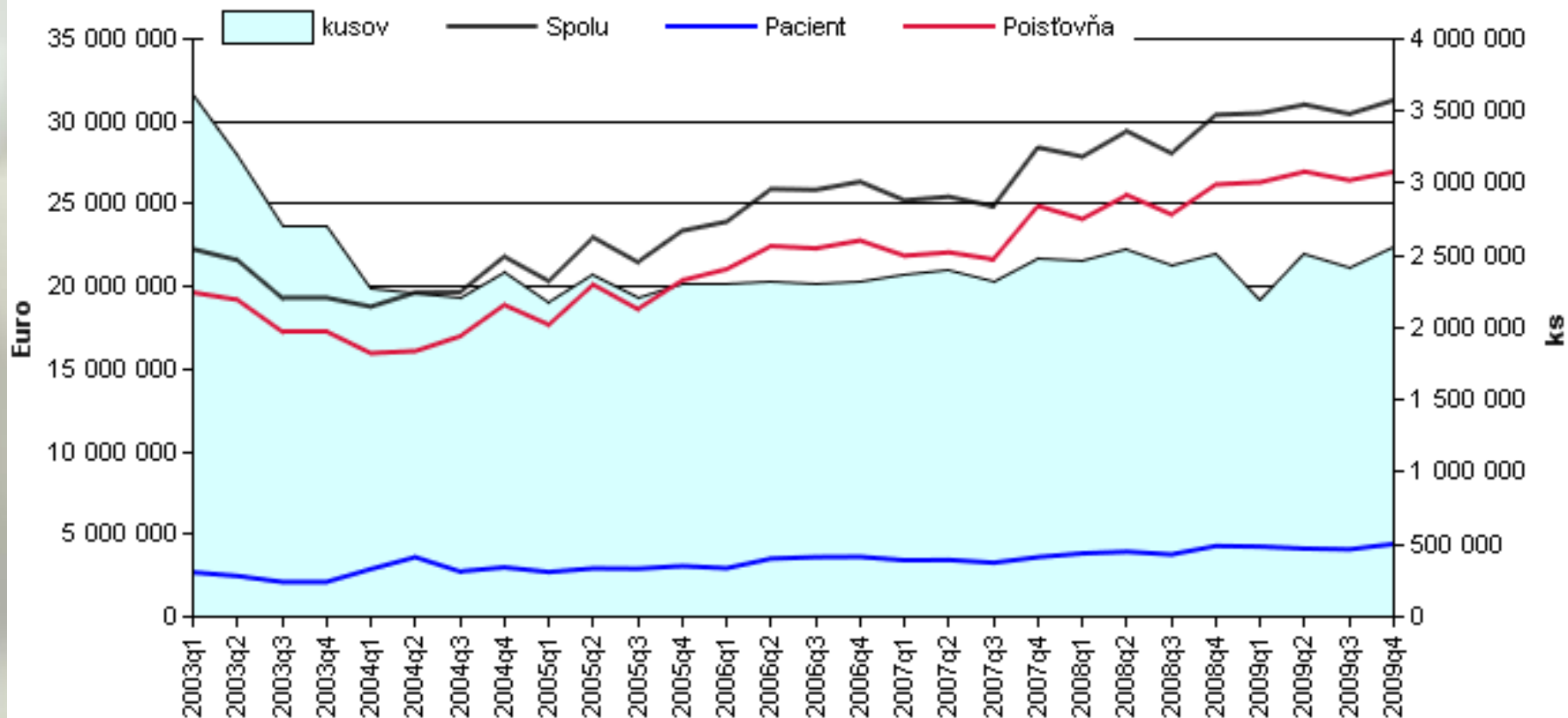
Vývoj spotreby liekov pre ATC L



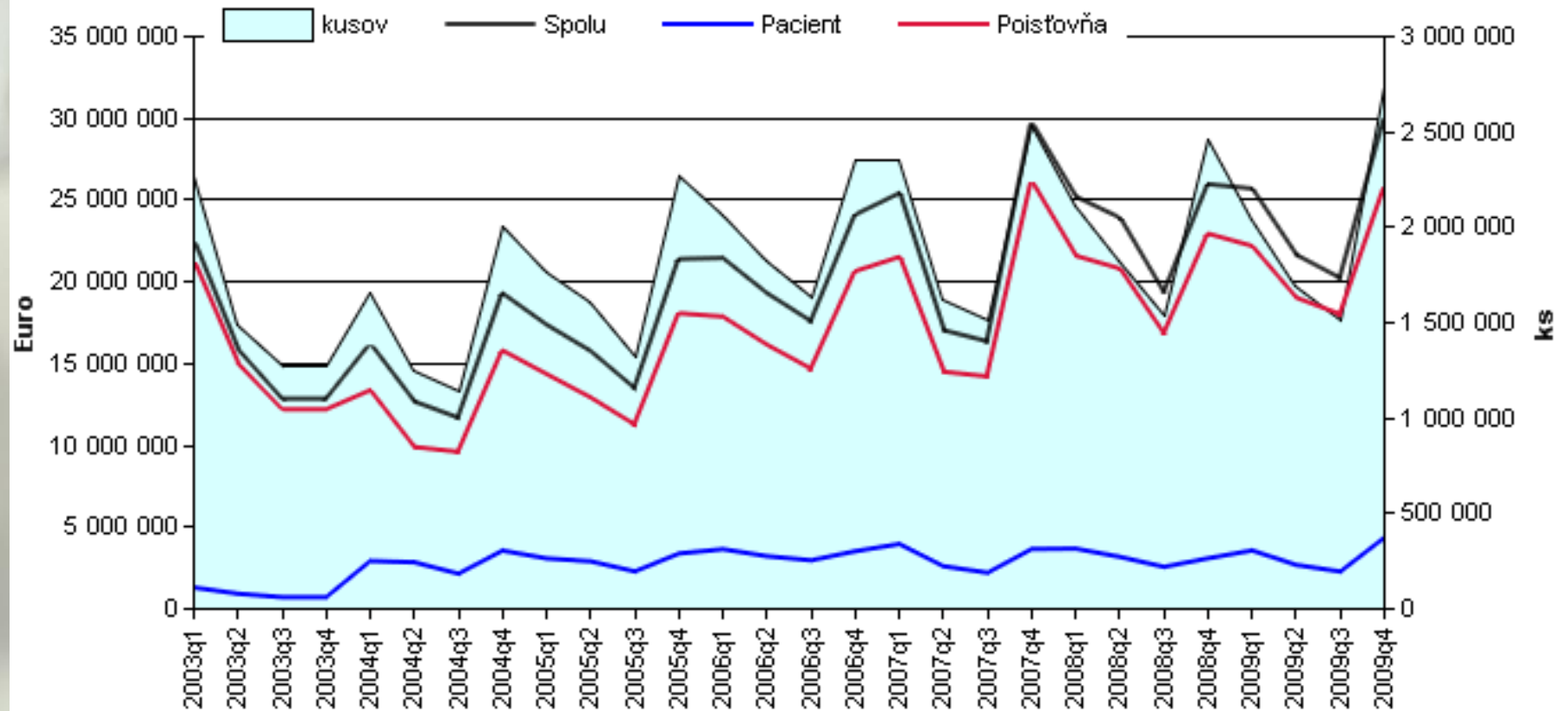
Vývoj spotreby liekov pre ATC N



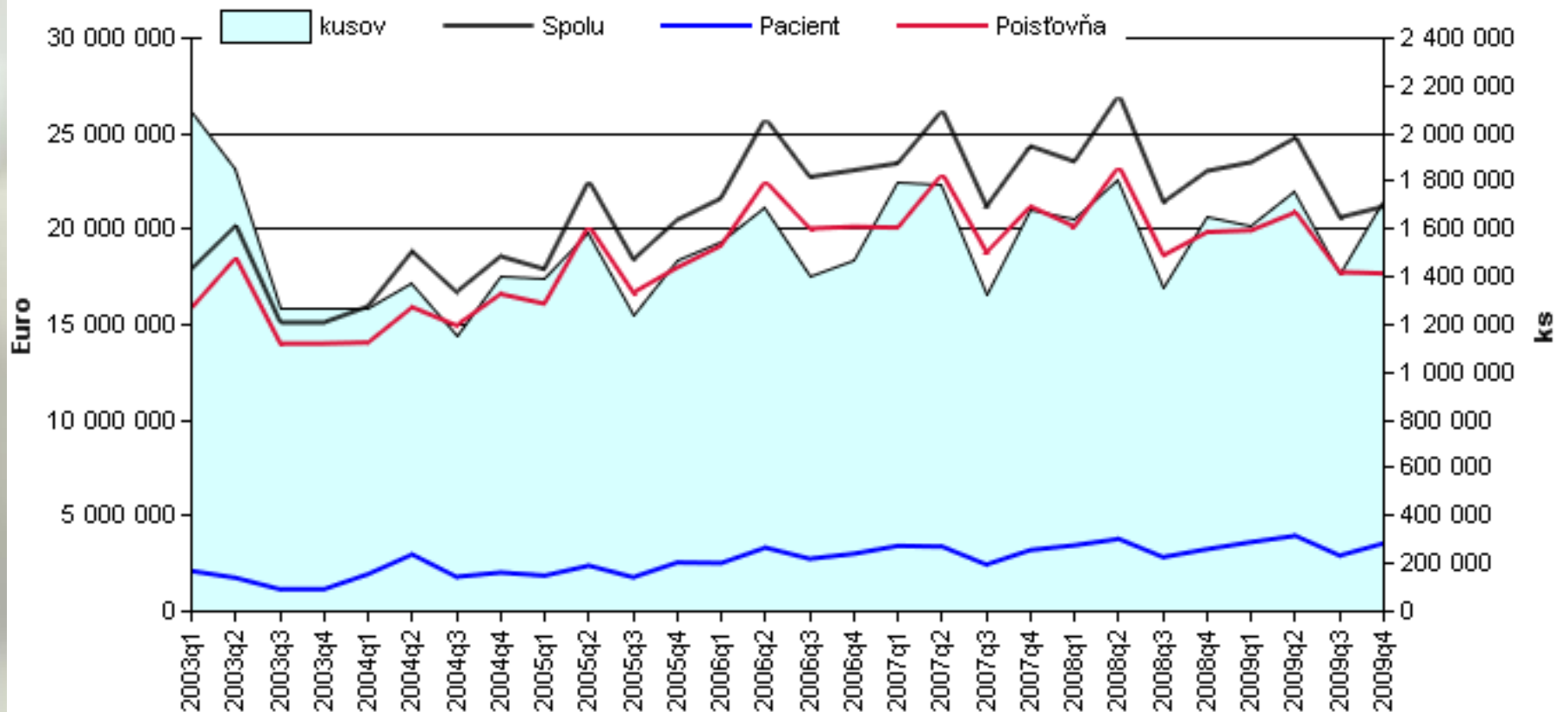
Vývoj spotreby liekov pre ATC A



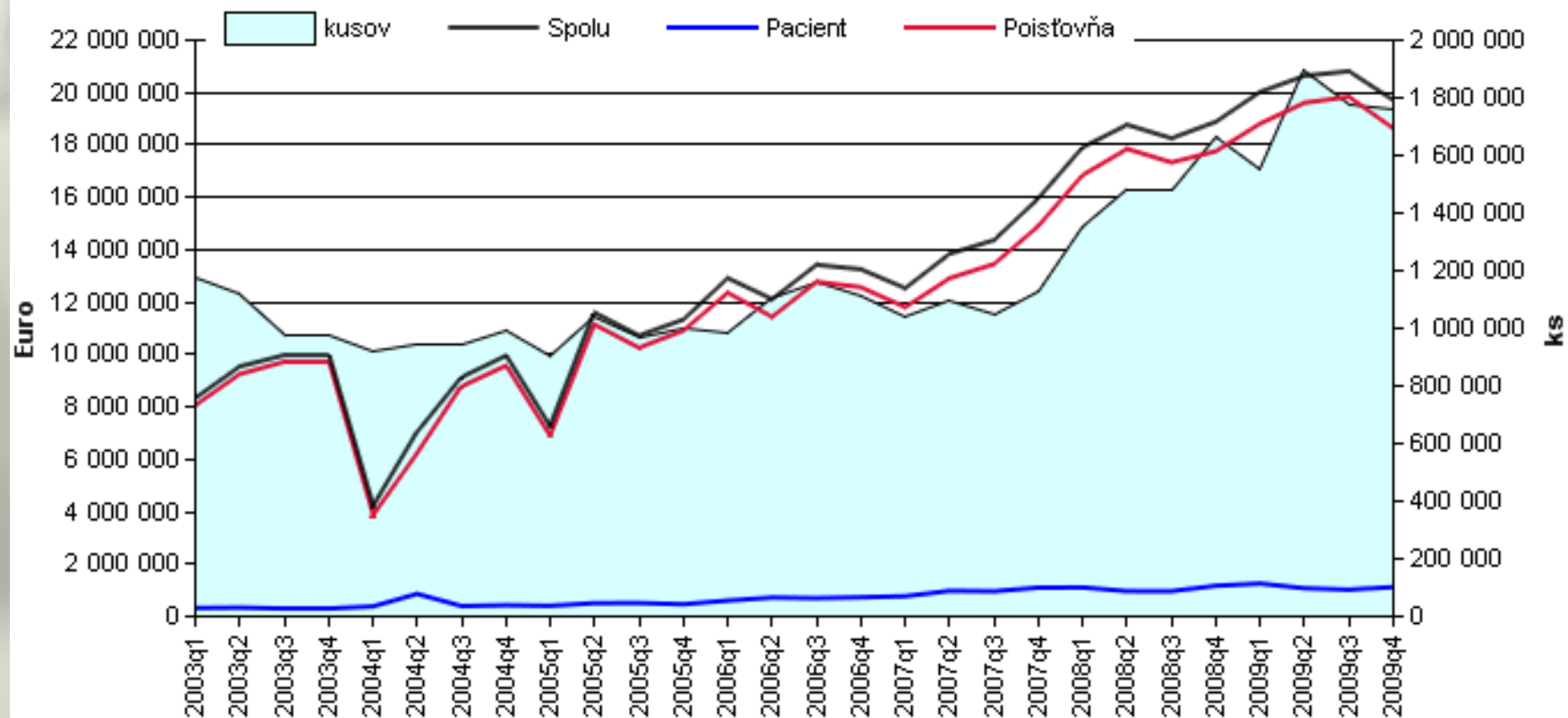
Vývoj spotreby liekov pre ATC J



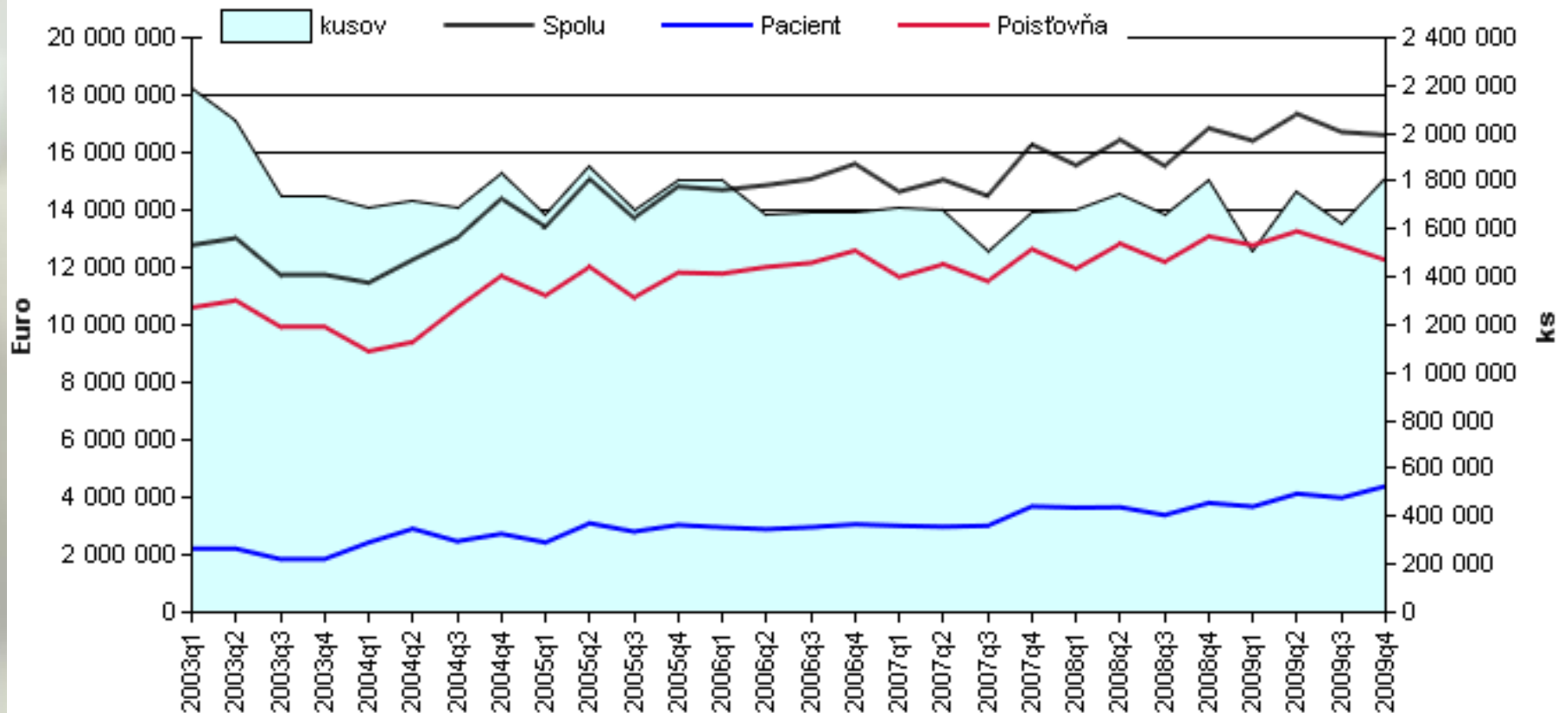
Vývoj spotreby liekov pre ATC R



Vývoj spotreby liekov pre ATC B

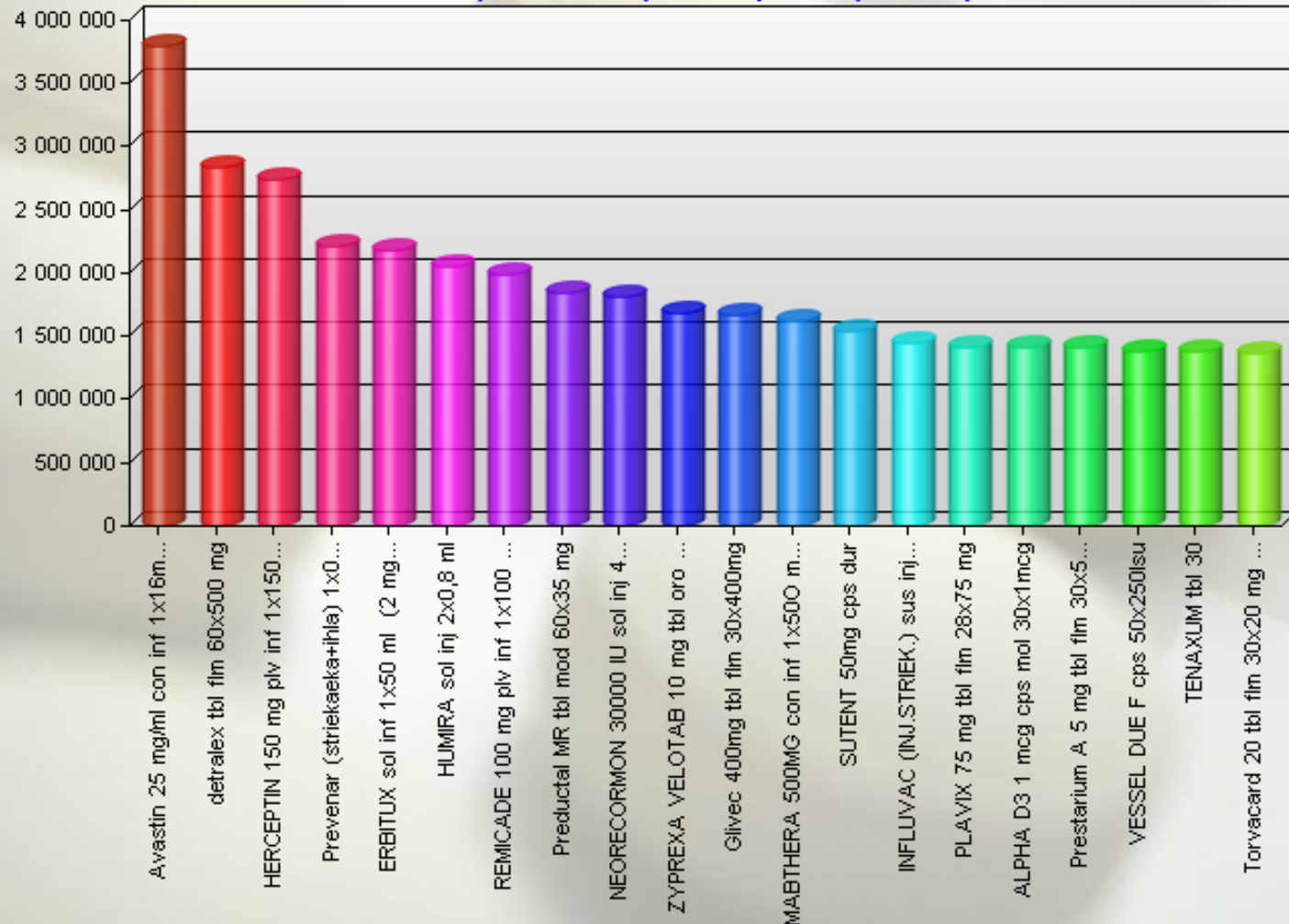


Vývoj spotreby liekov pre ATC M



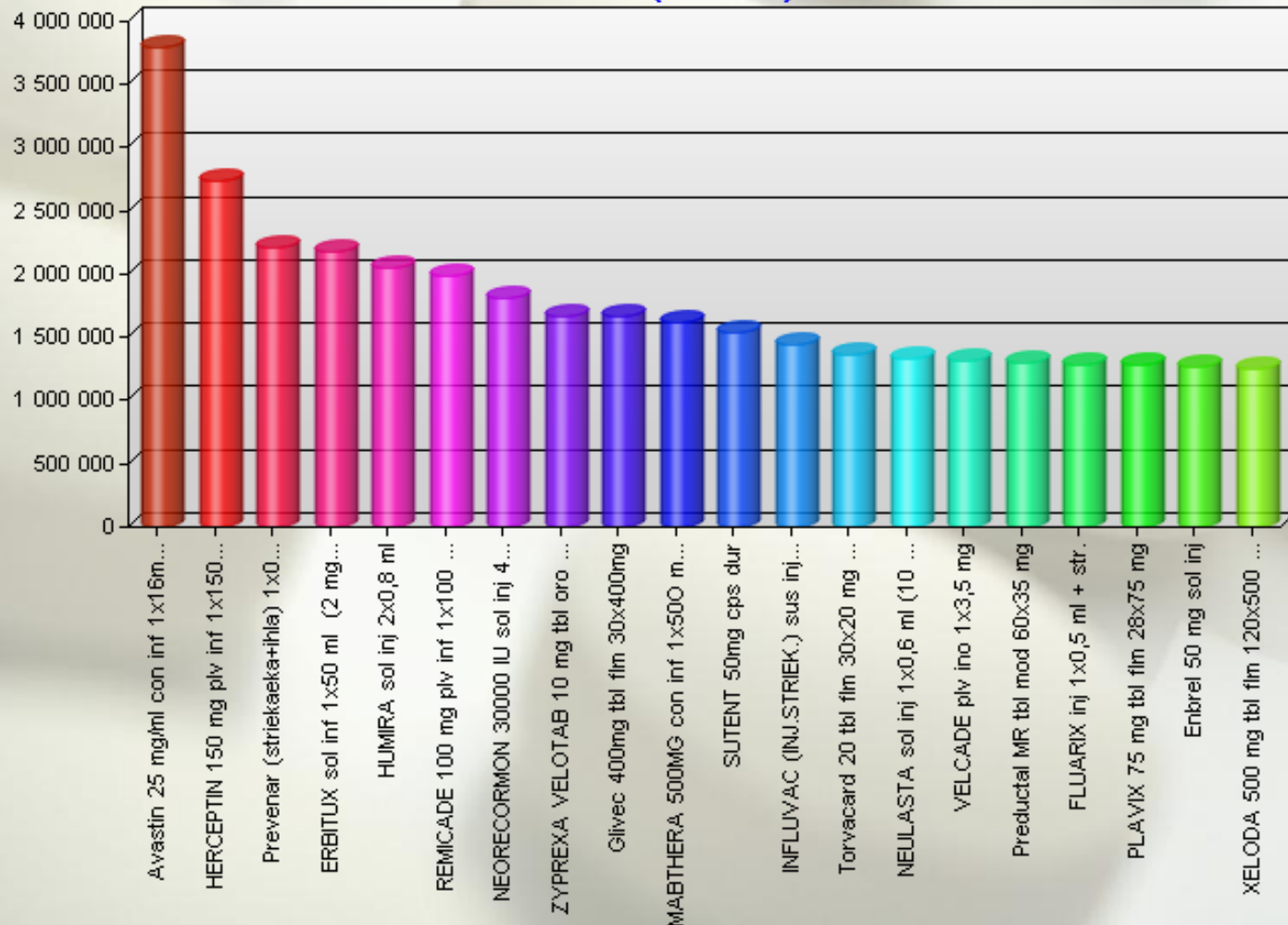
Obdobie IV. štvrťrok 2009

Top lieky podľa hodnoty konečnej spotreby za použité množstvo lieku.
ATC: (v Euro - použitý fixný kurz)



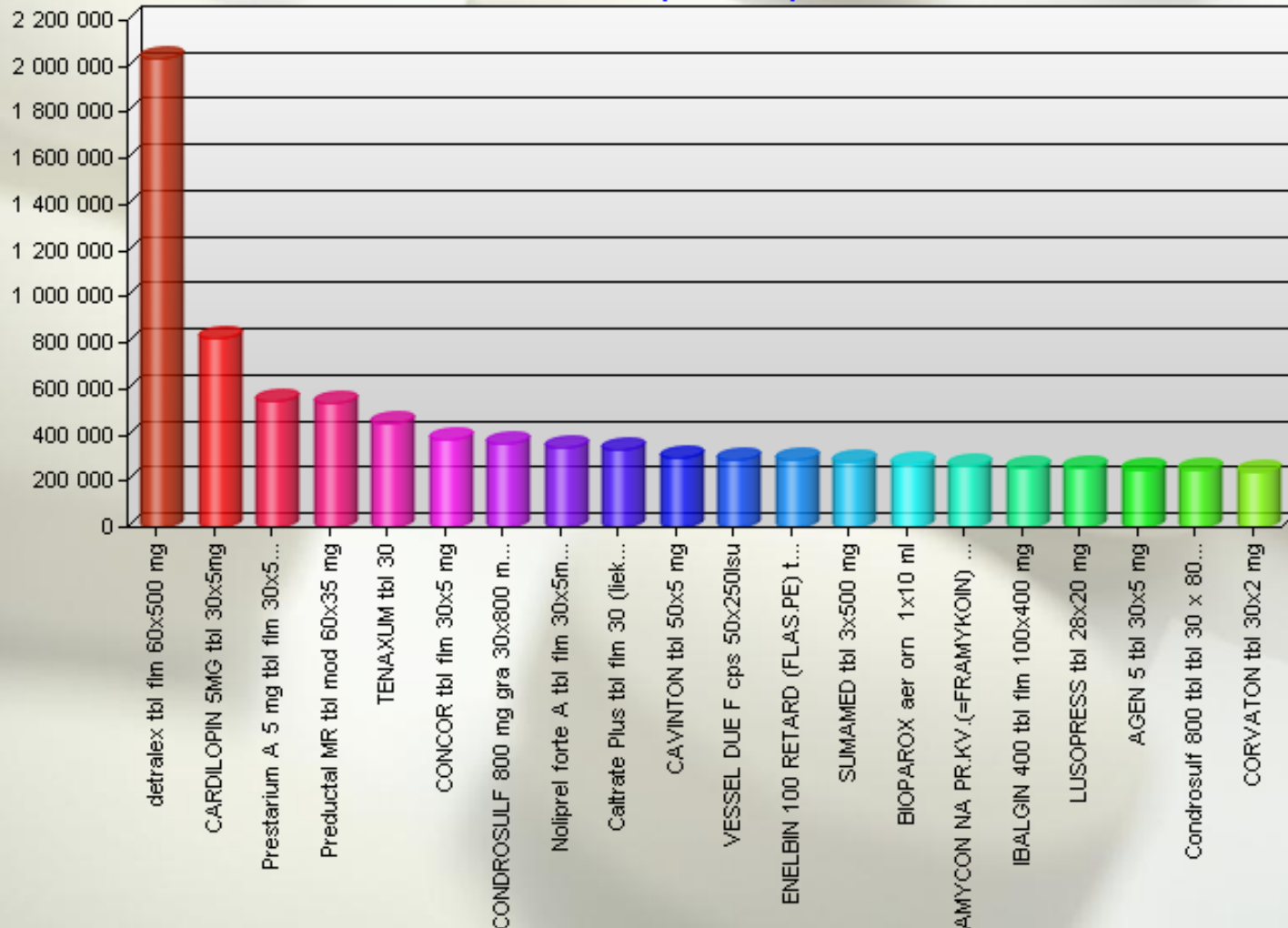
Obdobie IV. štvrťrok 2009

Top lieky podľa hodnoty úhrady poisťovne za spotrebované množstvo lieku ATC: (v Euro)

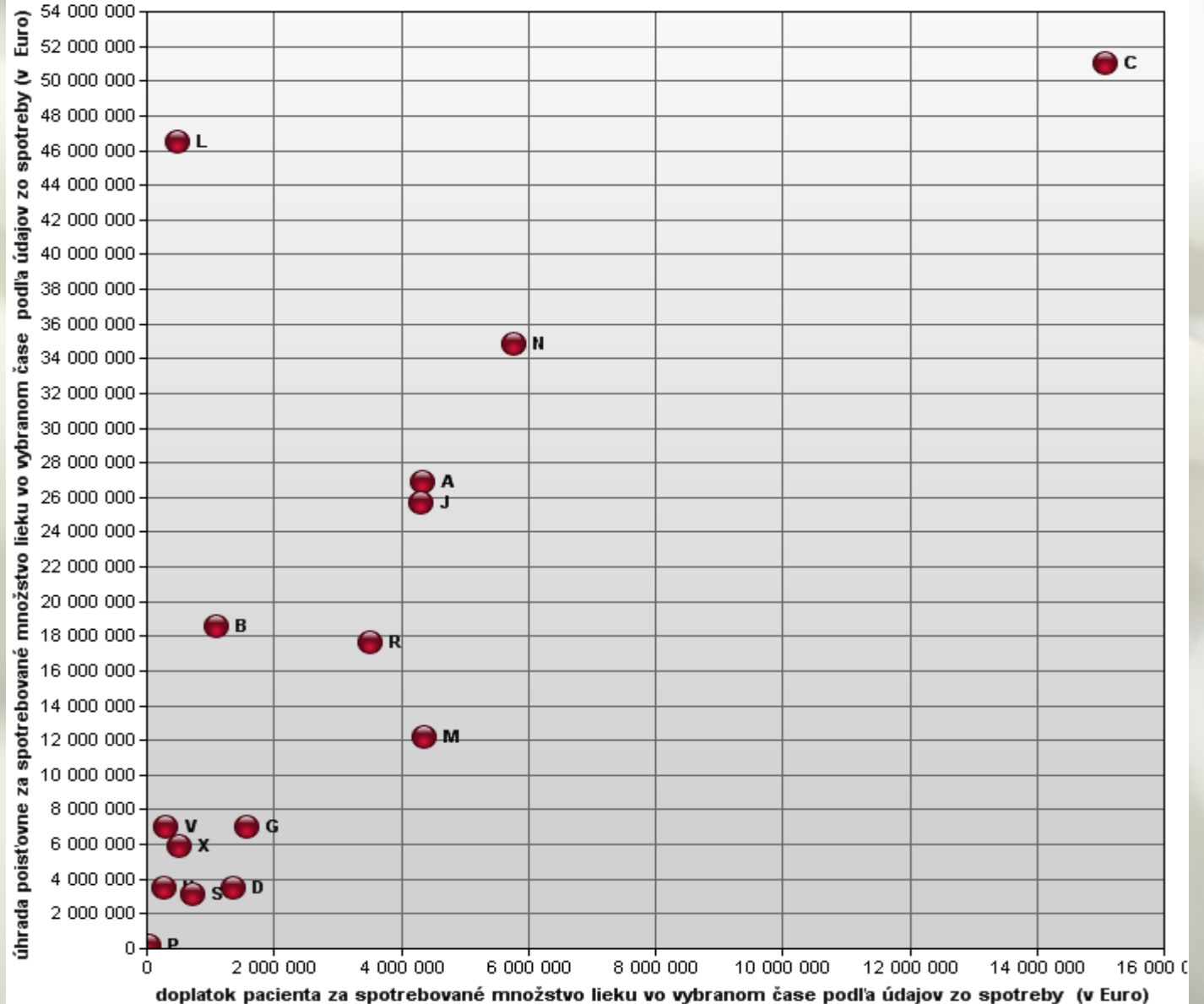


Obdobie IV. štvrťrok 2009

Top lieky podľa hodnoty doplatku pacienta za spotrebované množstvo lieku
ATC: (v Euro)

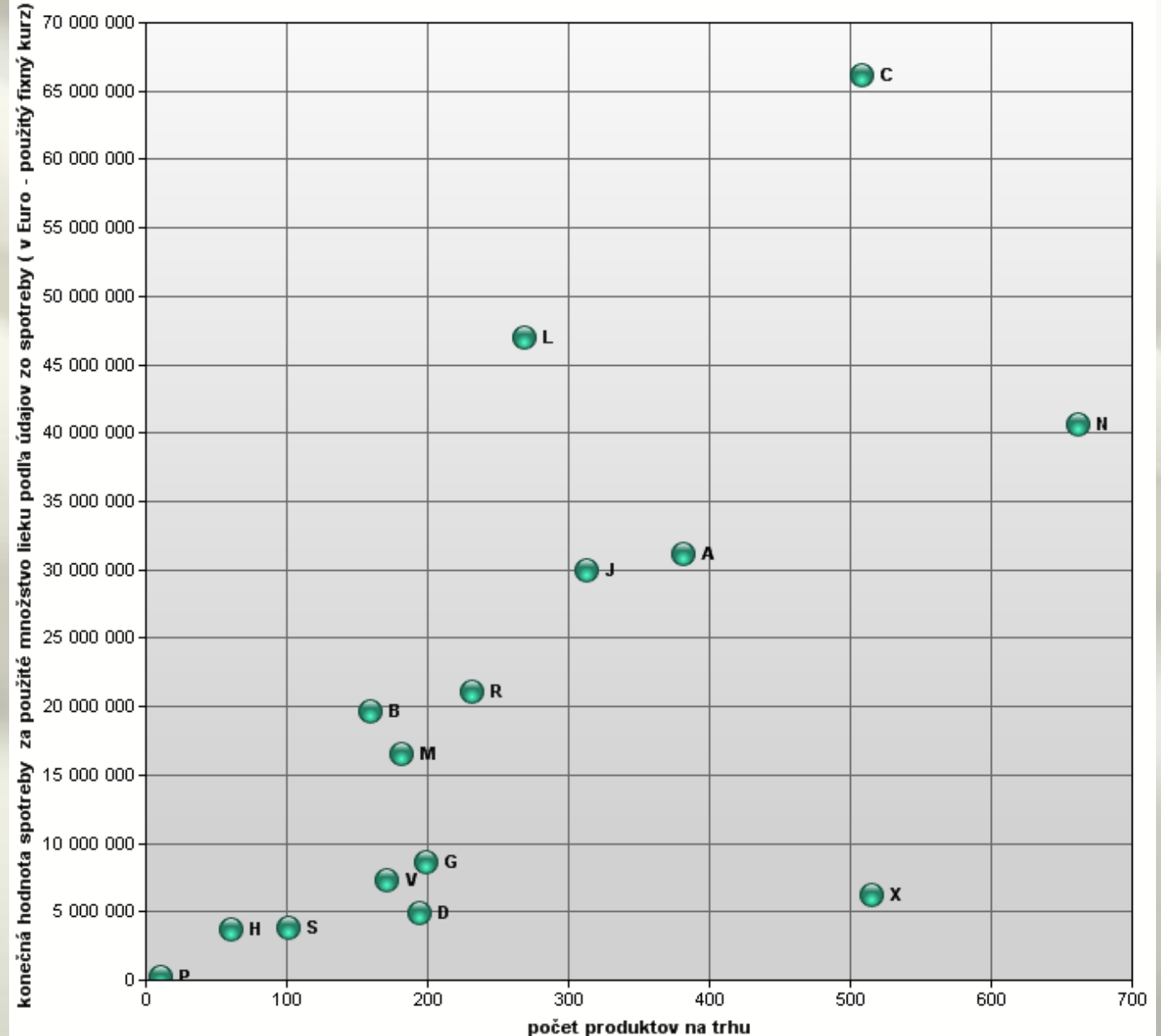


ROZDELENIE ATC za obdobie 2009q4 podľa
doplatku pacienta za spotrebované množstvo lieku podľa údajov zo spotreby
a úhrady poisťovne za spotrebované množstvo lieku podľa údajov zo spotreby

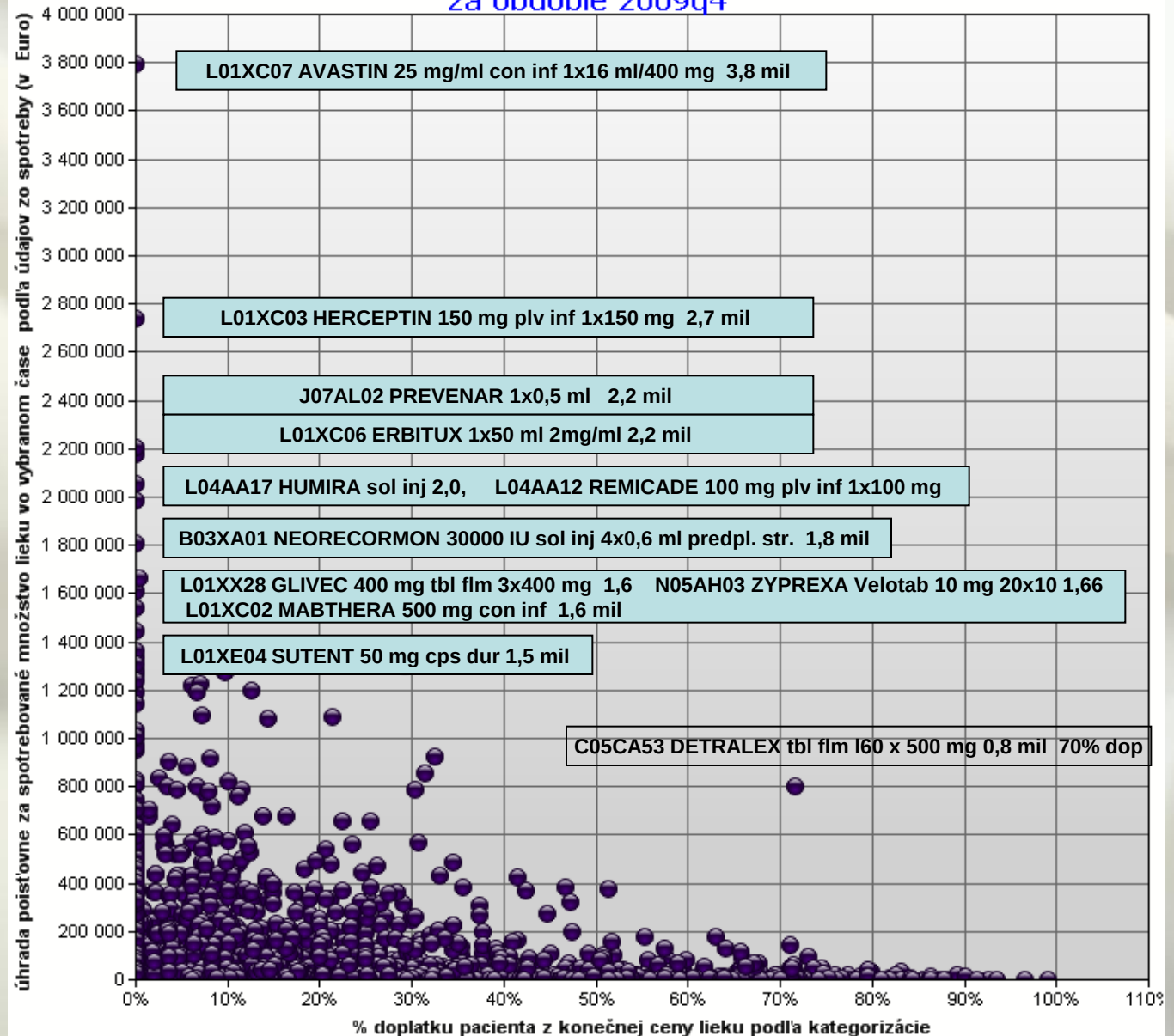


ROZDELENIE ATC za obdobie 2009q4 podľa
počtu liekov na trhu

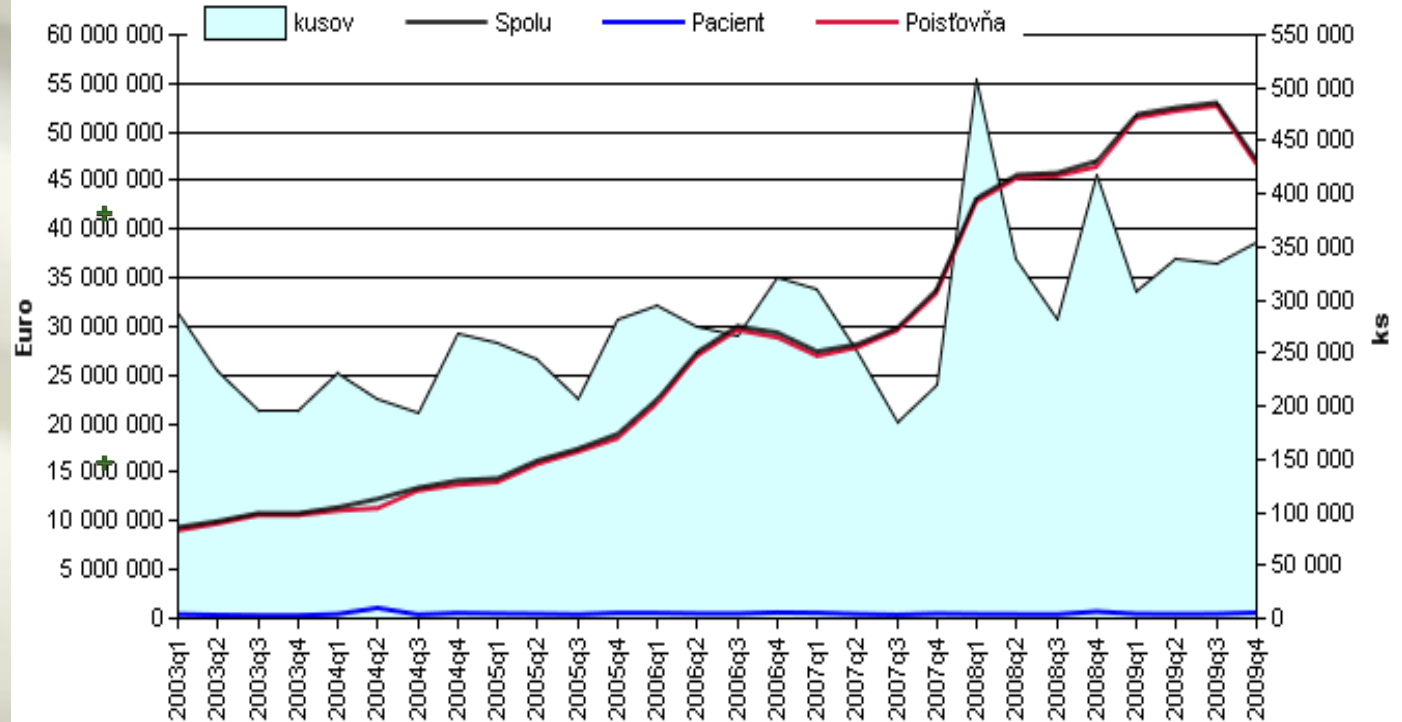
konečná hodnota spotreby za použité množstvo lieku podľa údajov zo spotreby



ROZDELENIE Liekov v ATC skupine: podľa
úhrady poisťovne za spotrebované množstvo lieku podľa údajov zo spotreby
a % doplatku pacienta z konečnej ceny lieku podľa kategorizácie
za obdobie 2009q4



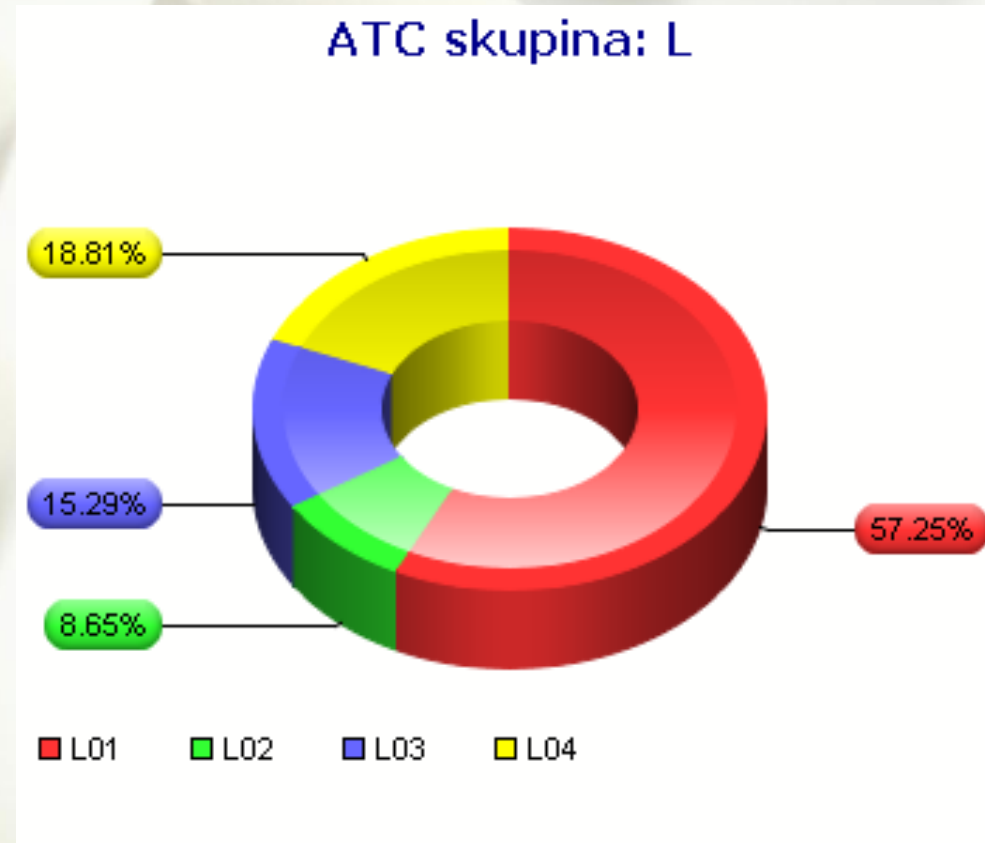
Vývoj spotreby liekov pre ATC L



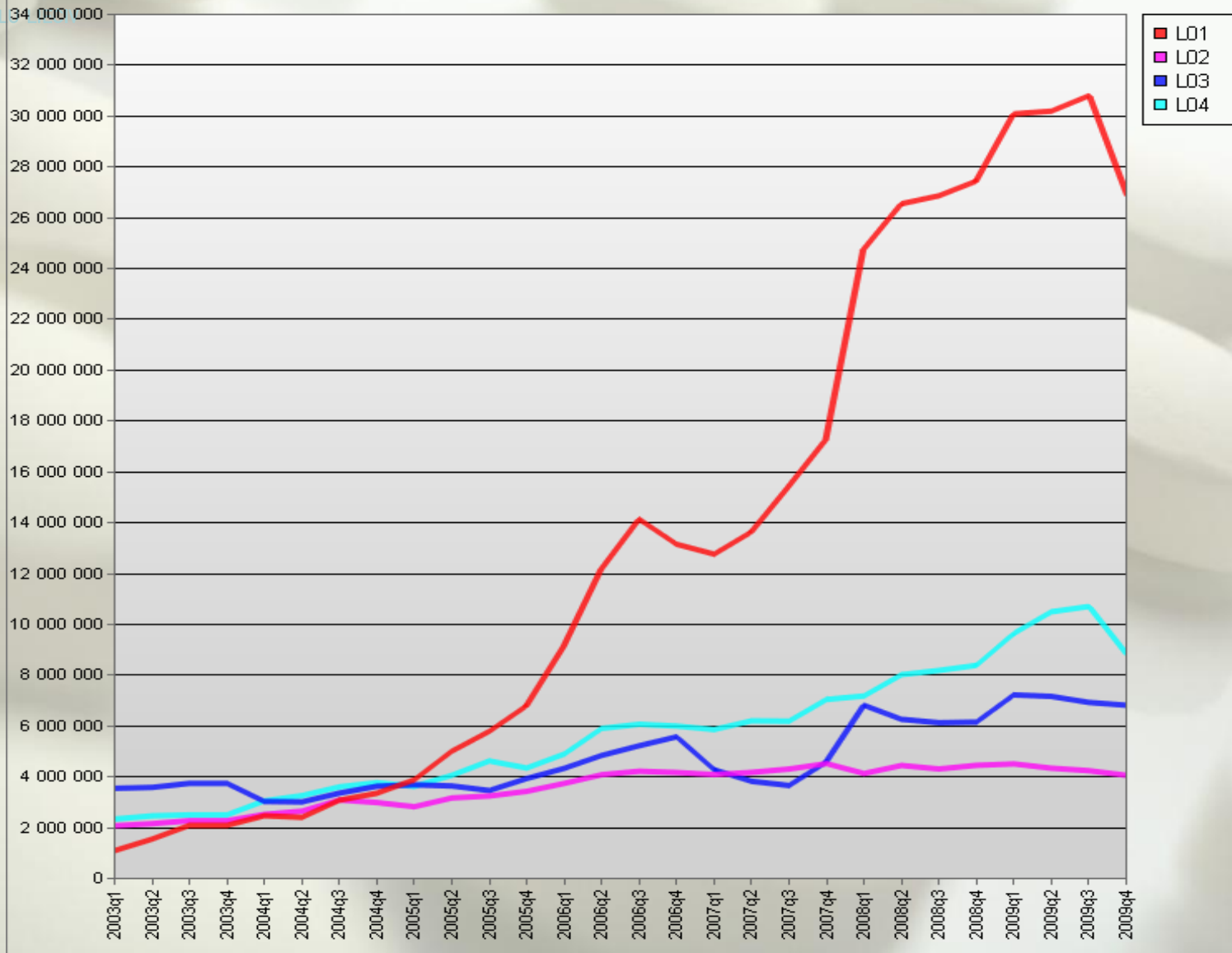
Rank	ATC	Spolu	%	Poistovňa	Pacient	Kusov
1	L01	26 885 197	57,25%	26 884 910	287	126 069
2	L04	8 836 308	18,81%	8 805 133	31 175	35 636
3	L03	7 180 936	15,29%	6 790 337	407 734	161 324
4	L02	4 062 100	8,65%	4 032 481	29 619	31 472

Obdobie 4 štvrťrok 2009 - štruktúra ATC L

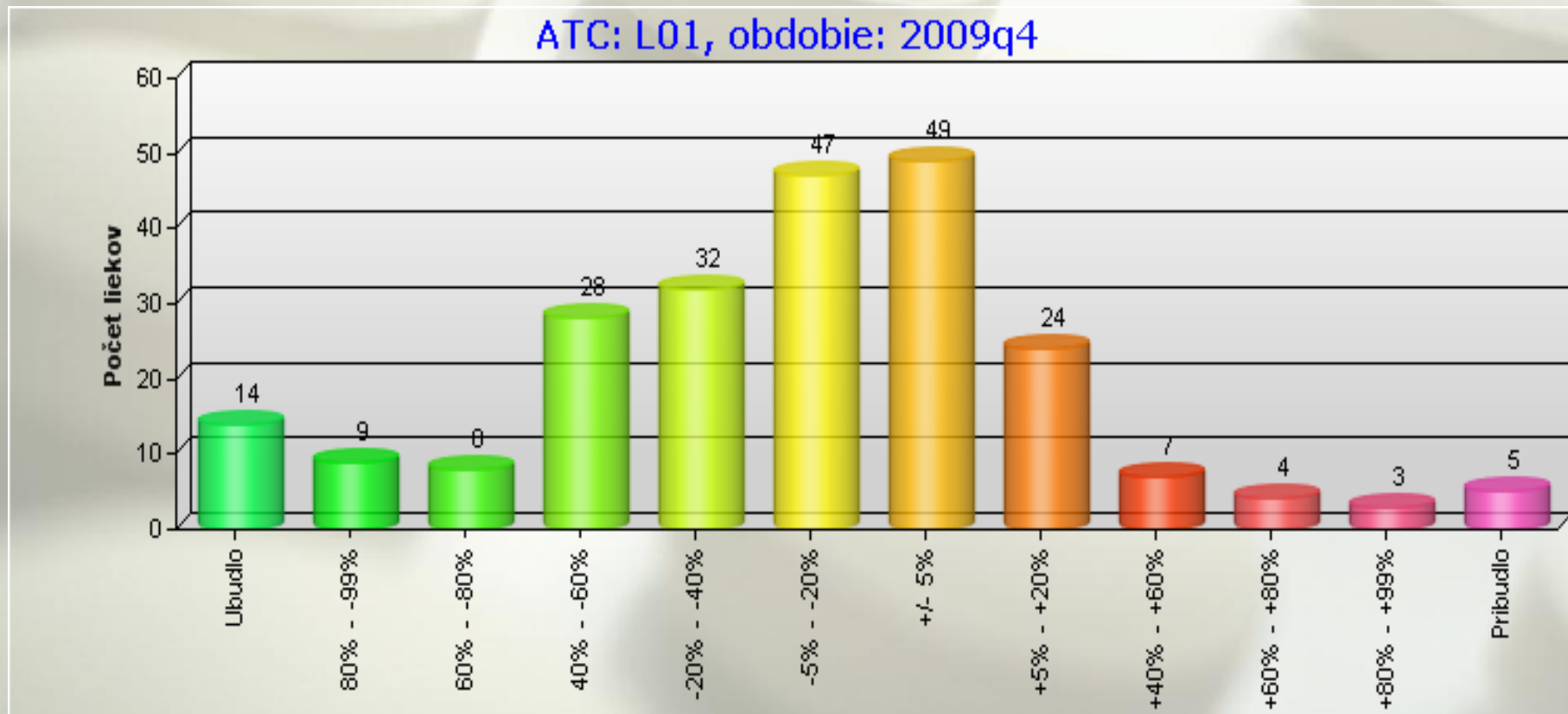
ks	354 501
Poist. EUR	46 512 861
Pac. EUR	468 815
Spolu EUR fix.	46 964 541
Spolu EUR var.	46 964 541



ATC skupina: L
Úhrada poisťovne za spotrebované množstvo lieku podľa údajov zo spotreby
(v Euro)

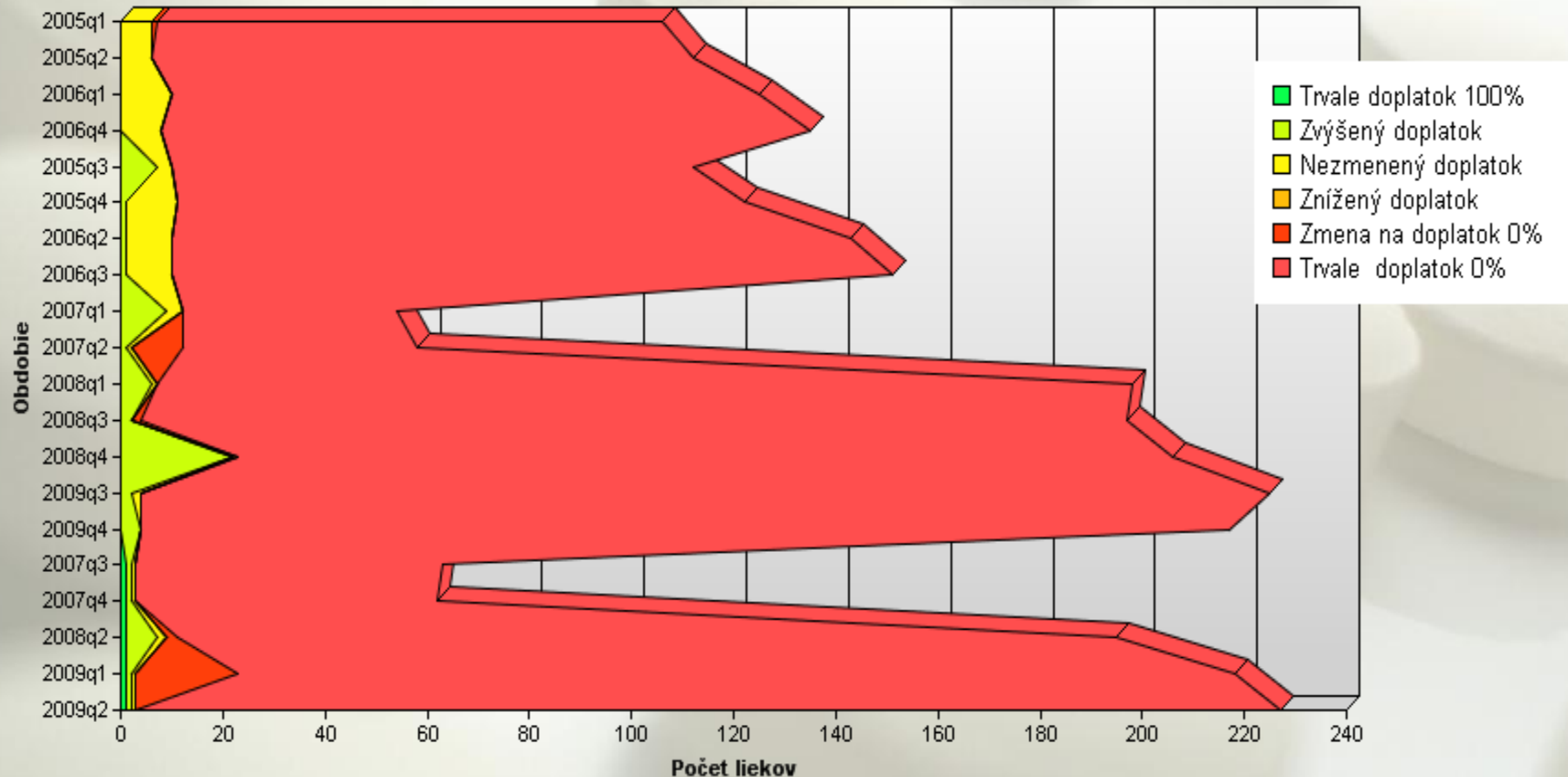


Rozdelenie liekov podľa zmeny konečnej hodnoty spotreby za použité množstvo lieku podľa údajov zo spotreby.

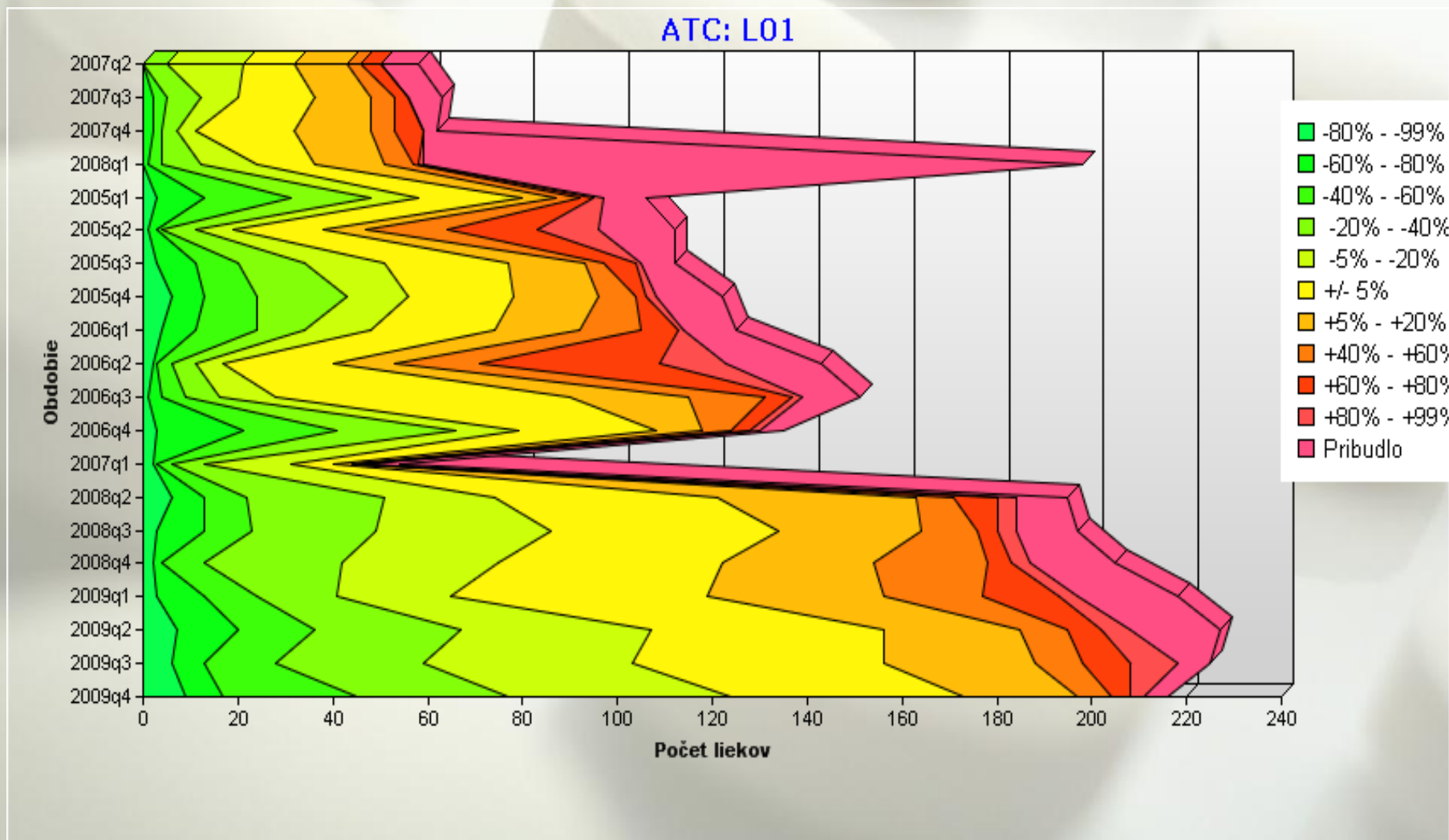


Zmeny skutočného % doplatku pacienta za balenie vypočítané podľa údajov zo spotreby

ATC: L01

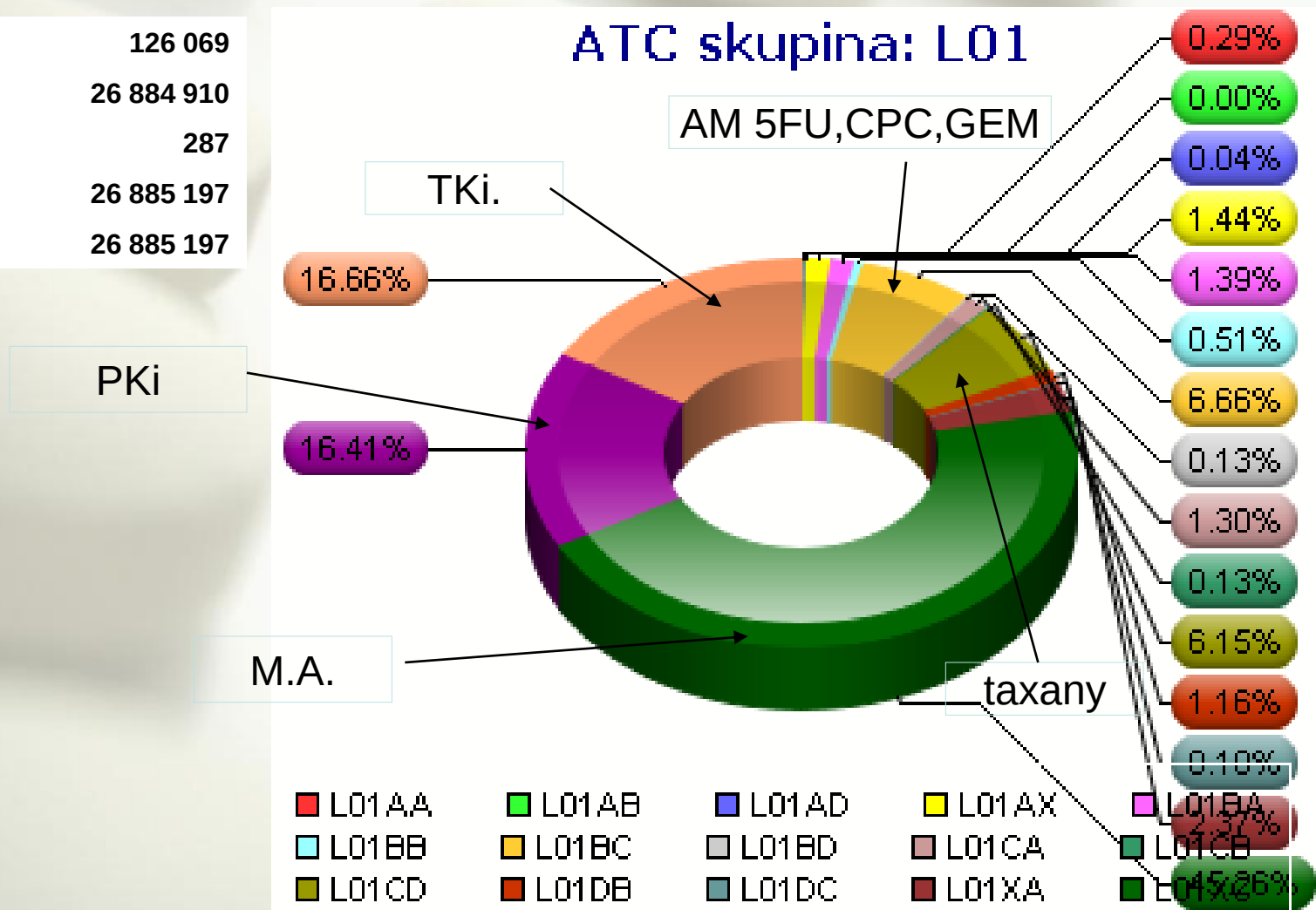


Rozdelenie liekov podľa zmeny konečnej hodnoty spotreby za použité množstvo lieku podľa údajov zo spotreby v skupine L01.

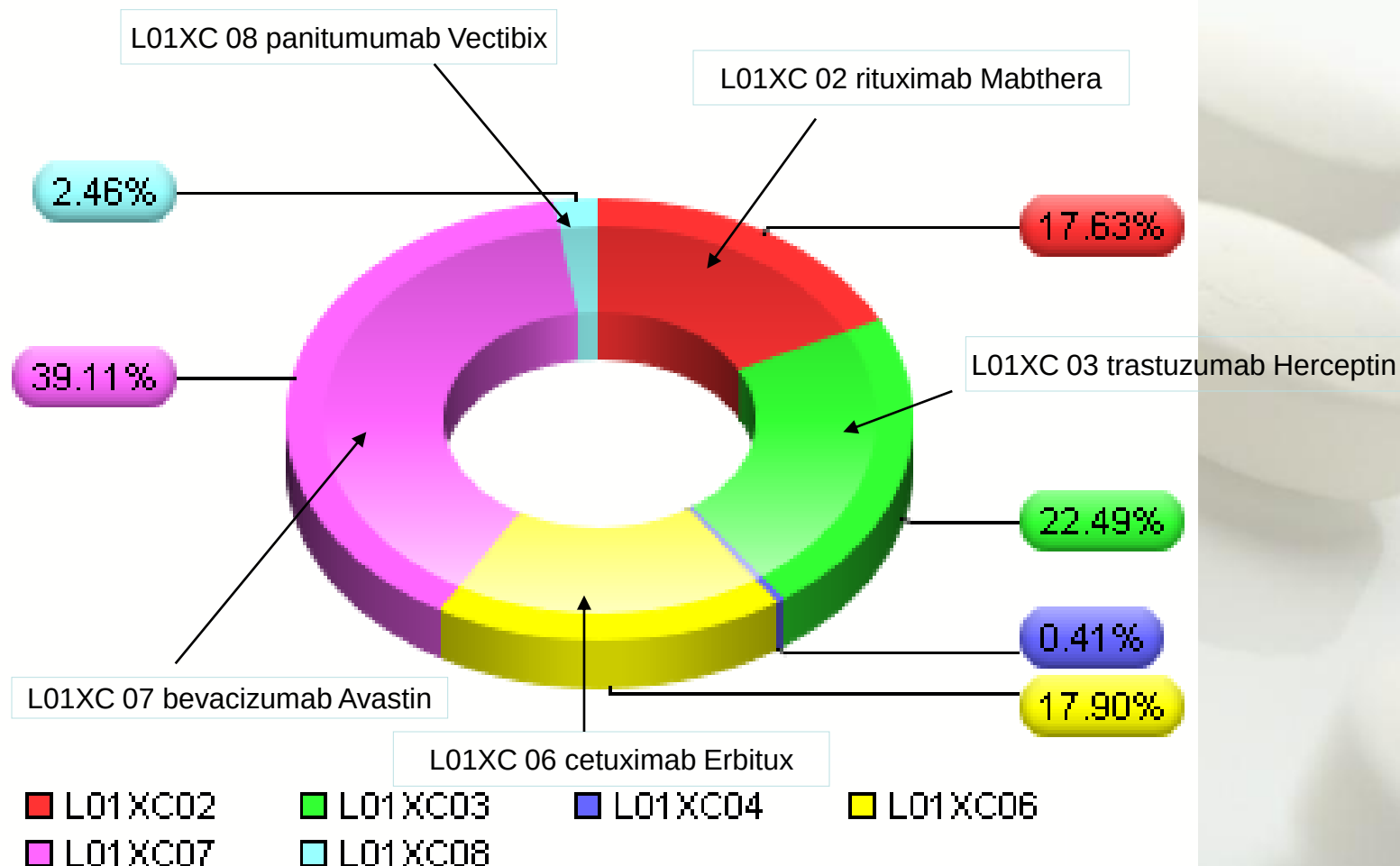


Obdobie 4 štvrťrok 2009 - štruktúra ATC L01

ks	126 069
Poist. EUR	26 884 910
Pac. EUR	287
Spolu EUR fix.	26 885 197
Spolu EUR var.	26 885 197

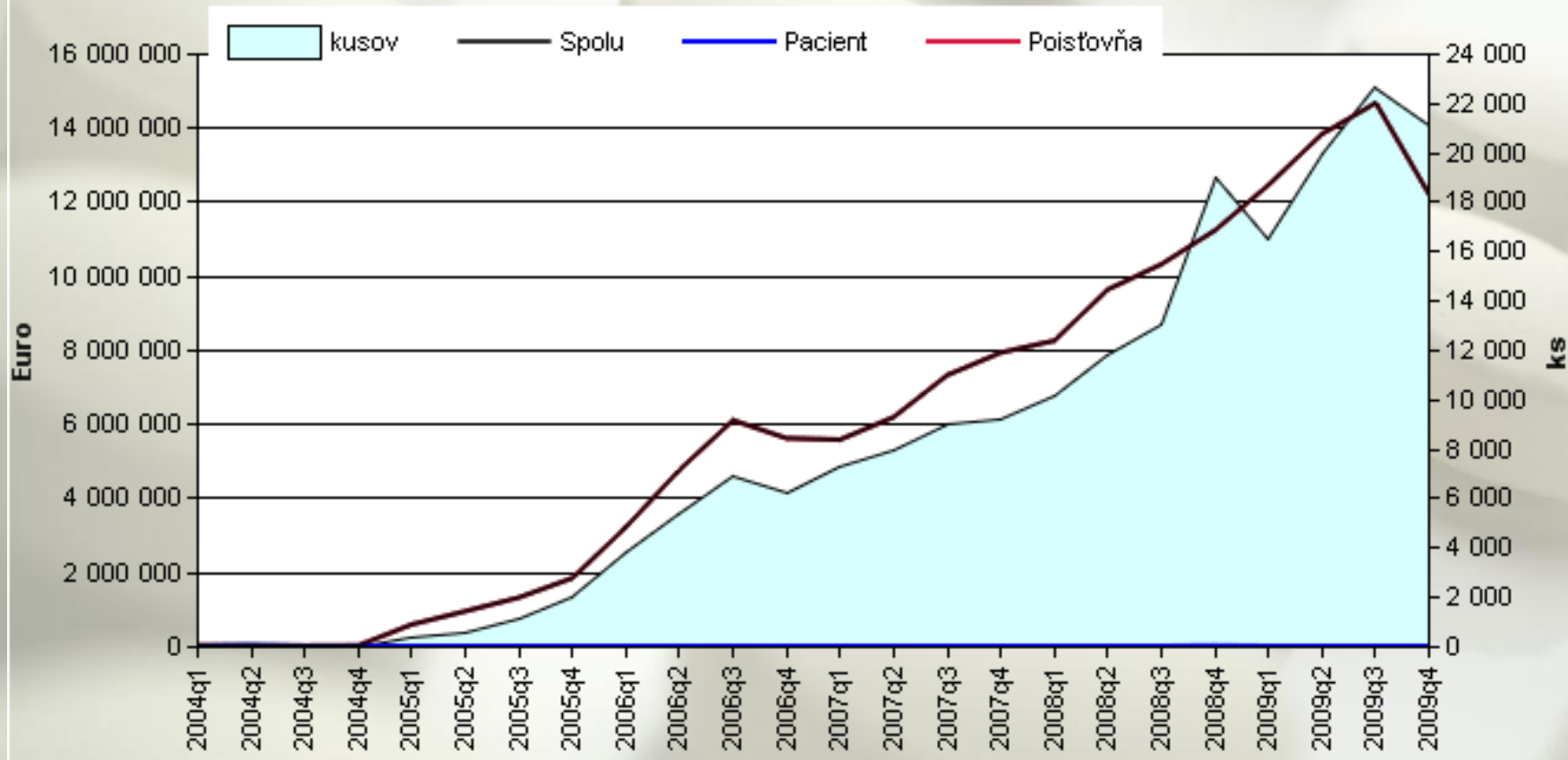


ATC skupina: L01XC



Vývoj spotreby monoklonálnych protilátok

Vývoj spotreby liekov pre ATC L01XC



Obdobie 2 štvrťrok 2009 – štruktúra ATC L01XC monoclonal antibodies

Rank	ATC	Spolu	%	Poistovňa	Pacient	Kusov
1	L01XC07	5 322 841	38,53%	5 322 841	0	5 743
2	L01XC03	3 310 452	23,96%	3 310 452	0	3 770
3	L01XC02	2 912 743	21,08%	2 912 743	0	1 984
4	L01XC06	1 975 245	14,30%	1 975 243	2	8 000
5	L01XC08	273 008	1,98%	273 008	0	480
6	L01XC04	21 516	0,16%	21 516	0	15

L01XC 07 Avastin, bevacizumab
 L01XC03 Herceptin, trastuzumab
 L01XC02 Mabthera, rituximab
 L01XC06 Erbitux , cetuximab
 L01XC08 Vectibix, panitumumab
 L01XC04 MabCampath, alentuzumab

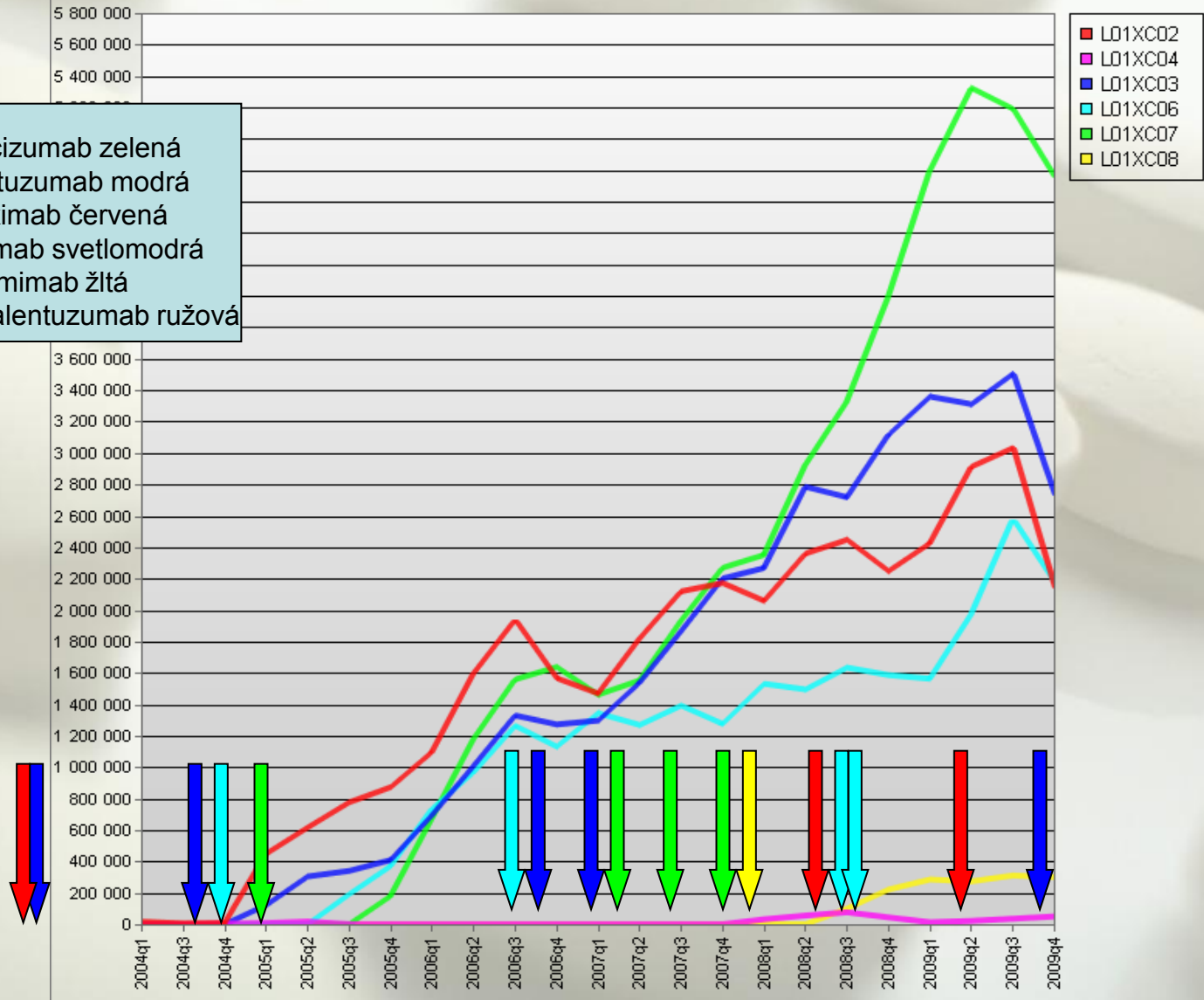
Obdobie 4 štvrťrok 2009 – štruktúra ATC L01XC monoclonal antibodies

Rank	ATC	Spolu	%	Pistovňa	Pacient	Kusov
1	L01XC07	4 759 432	39,11%	4 759 432	0	5 291
2	L01XC03	2 736 869	22,49%	2 736 869	0	4 037
3	L01XC06	2 178 447	17,90%	2 178 447	0	9 225
4	L01XC02	2 145 513	17,63%	2 145 513	0	1 969
5	L01XC08	299 549	2,46%	299 549	0	553
	L01XC04					
6		49 453	0,41%	49 453	0	63

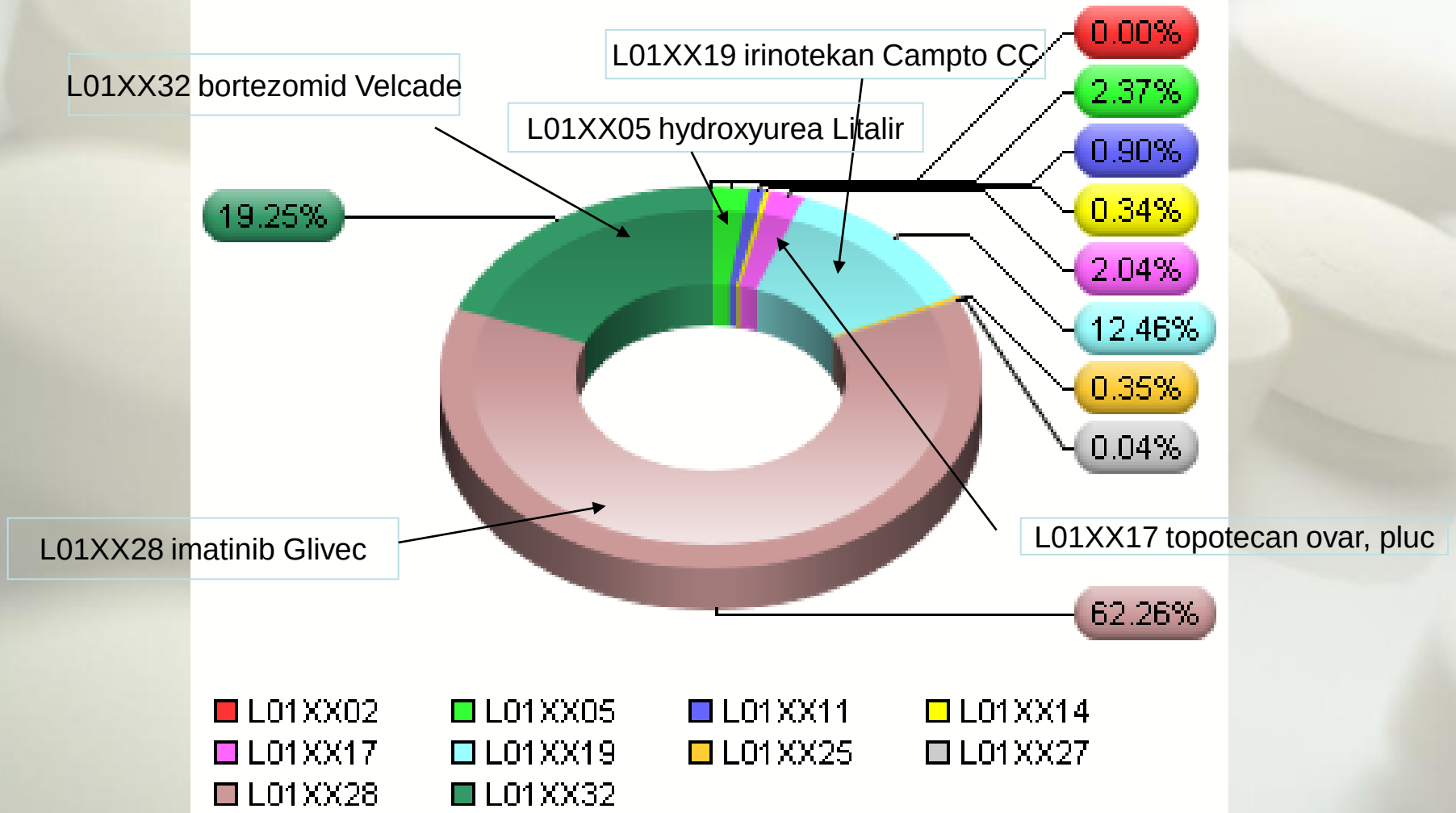
L01XC 07 Avastin, bevacizumab
 L01XC03 Herceptin, trastuzumab
 L01XC02 Mabthera, rituximab
 L01XC06 Erbitux, cetuximab
 L01XC08 Vectibix, panitumimab
 L01XC04 MabCampath, alemtuzumab

ATC skupina: L01XC
Úhrada poisťovne za spotrebované množstvo lieku podľa údajov zo spotreby
(v Euro)

L01XC 07 Avastin, bevacizumab zelená
L01XC03 Herceptin, trastuzumab modrá
L01XC02 Mabthera, rituximab červená
L01XC06 Erbitux, cetuximab svetlomodrá
L01XC08 Vectibix, panitumimab žltá
L01XC04 MabCampath, alentuzumab ružová

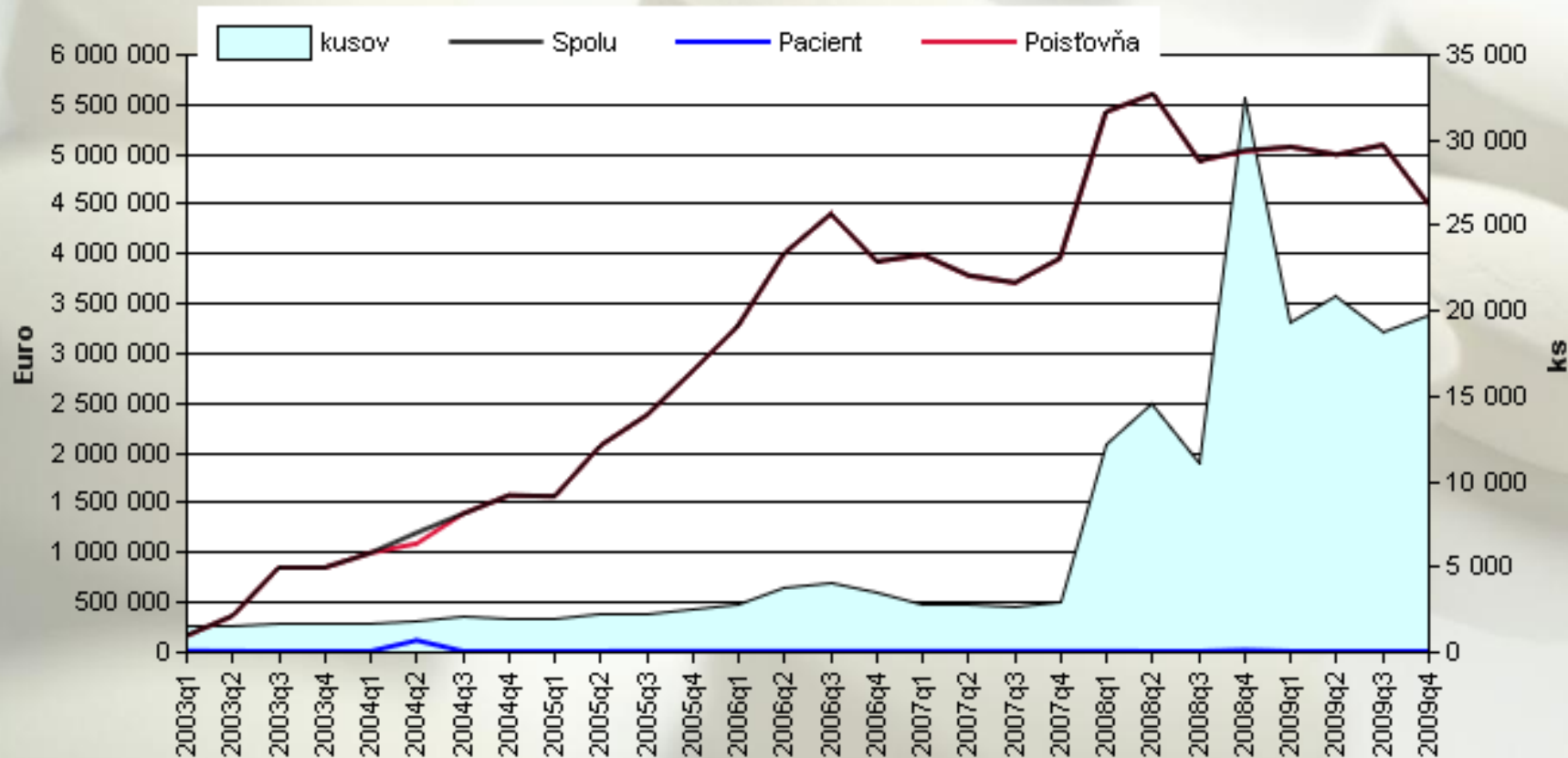


ATC skupina: L01XX



Vývoj spotreby ATC L01XX

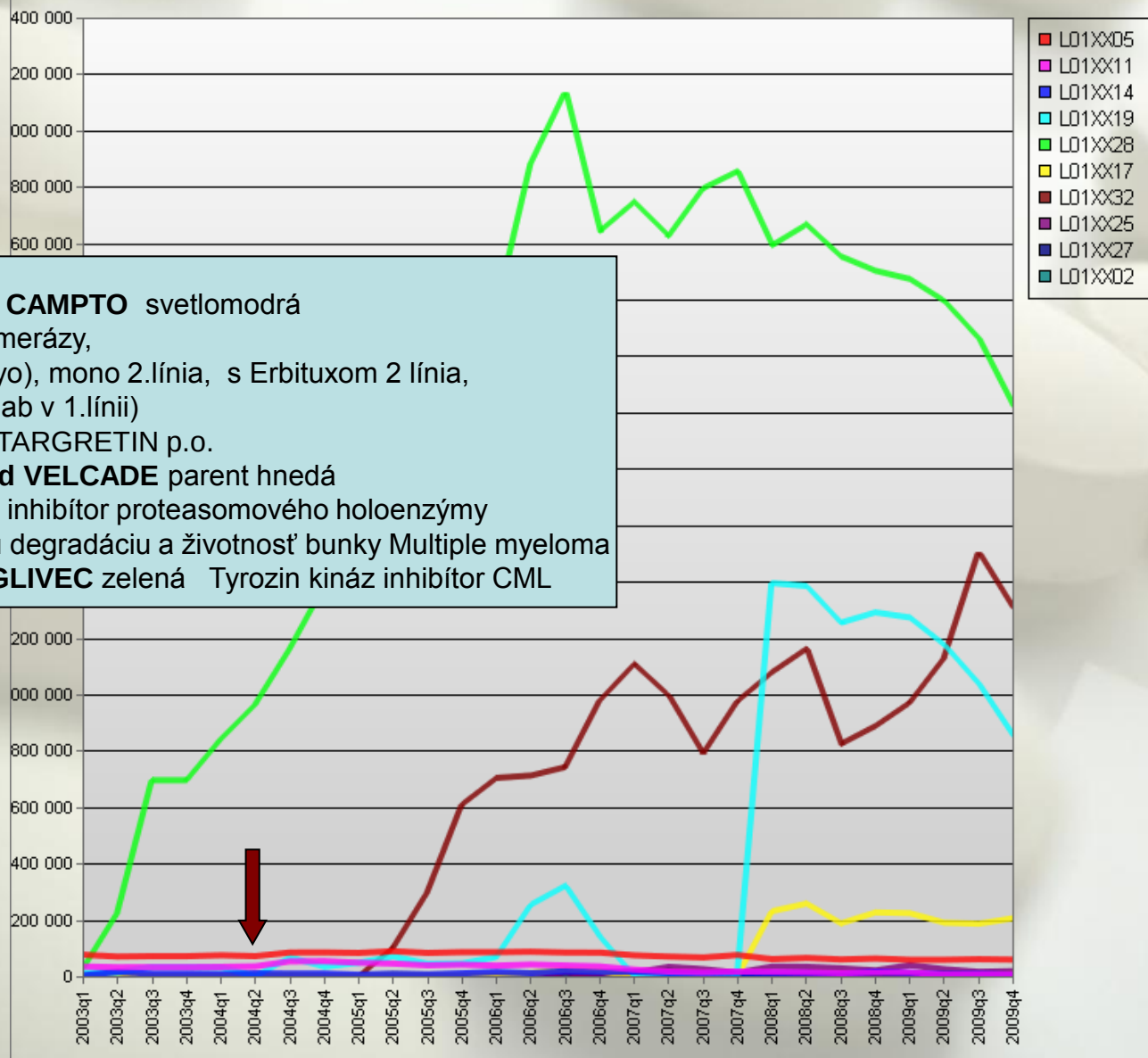
Vývoj spotreby liekov pre ATC L01XX



Obdobie 4 štvrťrok 2009 – štruktúra ATC L01XX

Rank	ATC	Spolu	%	Poistovňa	Pacient	Kusov
1	L01XX28	2 023 965	45,19%	2 023 965	0	1 033
2	L01XX32	1 307 215	29,19%	1 307 215	0	1 169
3	L01XX19	854 034	19,07%	854 034	0	15 278
4	L01XX17	205 473	4,59%	205 473	0	738
5	L01XX05	58 725	1,31%	58 682	43	1 355
6	L01XX25	18 061	0,40%	18 061	0	14
7	L01XX11	5 920	0,13%	5 920	0	67
8	L01XX14	5 217	0,12%	5 217	0	25
9	L01XX02	341	0,01%	341	0	1

ATC skupina: L01XX
Úhrada poisťovne za spotrebované množstvo lieku podľa údajov zo spotreby
(v Euro)



L01XX19 **irinotekan CAMPTO** svetlomodrá
inhibitor DNA topoizimerázy,
CC s 5FU + FA (Mayo), mono 2.línia, s Erbituxom 2 línia,
5FU+FU+Bevacizumab v 1.línii)
L01XX25 bexaroten TARGRETIN p.o.
L01XX32 **bortezomid VELCADE** parent hnedá
selektívny reverzibilný inhibitor proteasomového holoenzýmy
kontroluje proteínovú degradáciu a životnosť bunky Multiple myeloma
L01XX28 **imatinib GLIVEC** zelená Tyrozin kináz inhibitor CML

ATC skupina: L01XE

L01XE08 nilotinim Tasigna CML po imat

L01XE07 lapatinib Tyverb mBC s capecX last 6/08

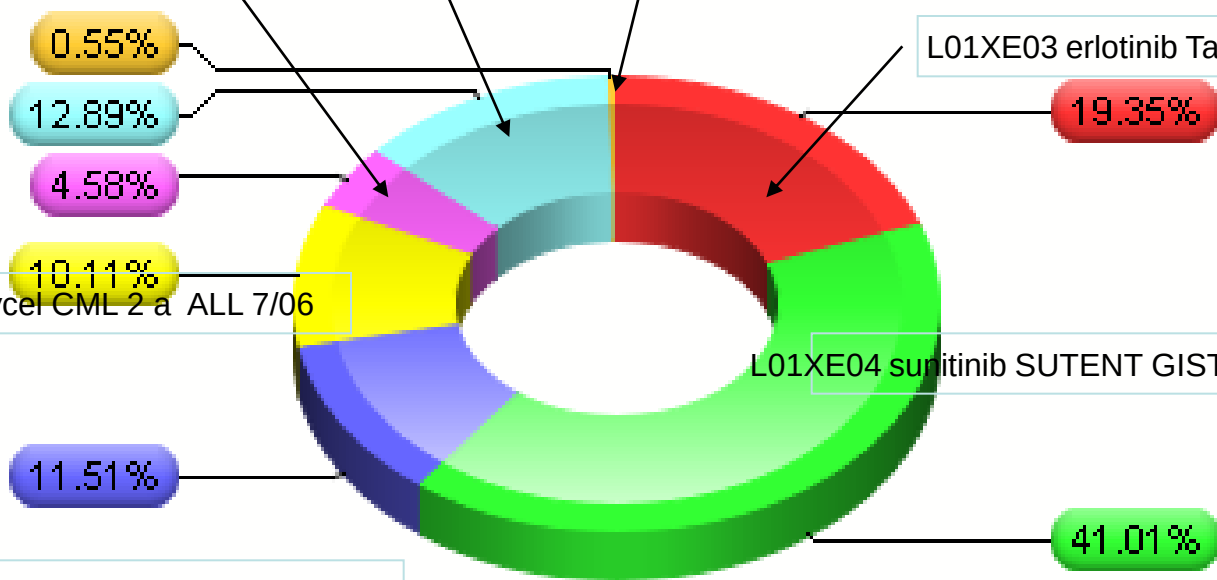
L01XE09 temsirolimus Torisel mRCC 1 9/07

L01XE03 erlotinib Tarceva NSCL 3 linia

L01XE06 dasatinib Sprycel CML 2 a ALL 7/06

L01XE04 sunitinib SUTENT GIST 2 a mRCC 7/06

L01XE05 sorafenib Nexavar hepatoc a mRCC 7/06



■ L01XE03

■ L01XE04

■ L01XE05

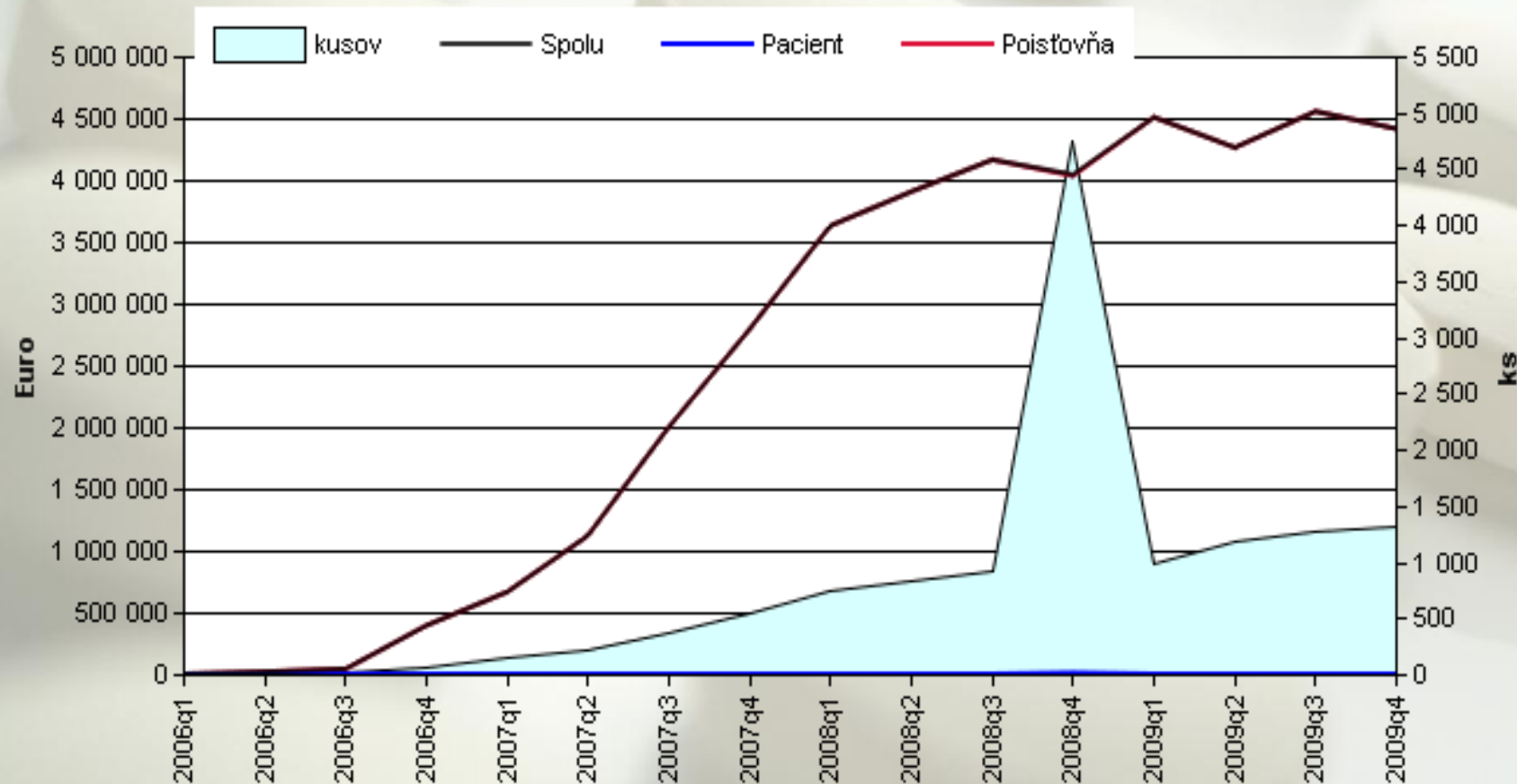
■ L01XE06

■ L01XE07

■ L01XE08

■ L01XE09

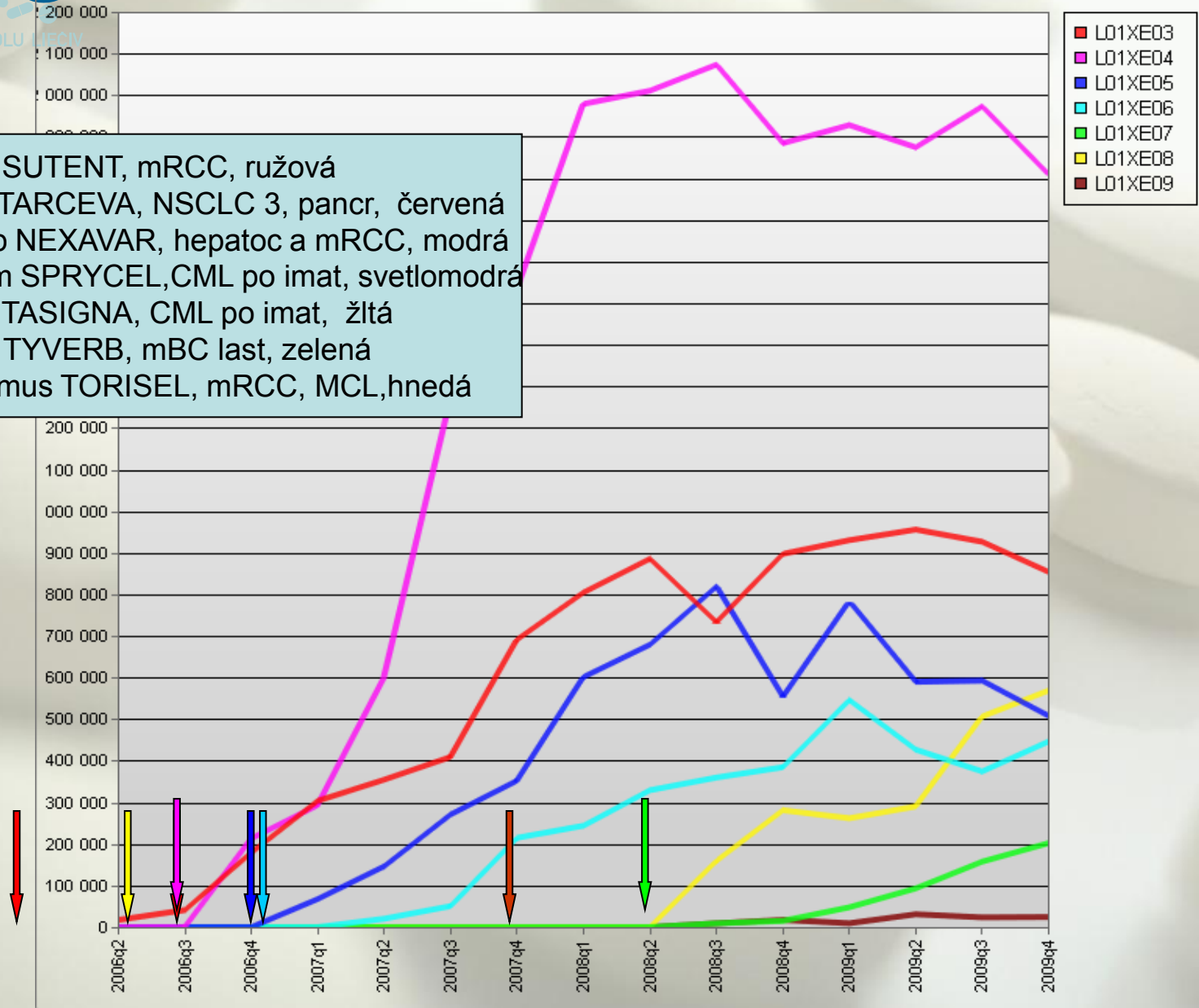
Vývoj spotreby liekov pre ATC L01XE



Obdobie 4 štvrťrok 2009 – štruktúra ATC L01XE

Rank	ATC	Spolu	%	Poist'ovňa	Pacient	Kusov
1	L01XE04	1 809 049	41,01%	1 809 049	0	405
2	L01XE03	853 690	19,35%	853 690	0	410
3	L01XE08	568 796	12,89%	568 796	0	100
4	L01XE05	507 718	11,51%	507 718	0	132
5	L01XE06	446 230	10,11%	446 230	0	93
6	L01XE07	201 973	4,58%	201 973	0	144
7	L01XE09	24 264	0,55%	24 264	0	29

L01XE04 sunitinib SUTENT, mRCC, ružová
L01XE03 erlotinib TARCEVA, NSCLC 3, pancr, červená
L01XE05 sorafenib NEXAVAR, hepatoc a mRCC, modrá
L01XE06 dasatinim SPRYCEL, CML po imat, svetlomodrá
L01XE08 nilotinim TASIGNA, CML po imat, žltá
L01XE07 lapatinib TYVERB, mBC last, zelená
L01XE09 temsirolimus TORISEL, mRCC, MCL, hnedá



COLORECTAL CARCINOM

Active substance	Indication and date of registration	Efficacy
capecitabin L01XE01 L01BC06 Xeloda Pro-drug 5-FU Orally admin. CVS preclinical better than 5-FU Dr. Jan Mazag	-- first-line monotherapy of patients with metastatic <u>colorectal cancer</u> → registered from <u>02/2001</u> -- adjuvant treatment of patients following surgery of stage III colon cancer → type II var <u>03/2005</u> -- treatment of metastatic colorectal cancer → type II var. <u>01/2008</u> -- first-line treatment of advanced gastric cancer in combination with a platinum-based regimen → type II var. <u>03/2007</u> -- the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy (in combination with docetaxel). -- as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of taxanes and an anthracycline containing chemotherapy regimen or for whom further anthracycline therapy is not indicated. → Type II var. <u>03/2002</u>	Colorectal CA – 376 000 new cases each year in Europe – 5% of EU population is affected during his life span Previous therapy – 5-fluorouracil, alone or in comb. with leucovorin Capecitabine non-inferiority proven 1. (PFS 241 days, OS-577days) vs 5 FU/leucovorin PFS-259 days, OS-549days) 2. ORR 25% capecitabin vs 16% MAYO) 3. QoL some tendency, no impressive 4. No cross comparison mon and others Breast CA – 300 000 new cases each year 1st line therapy – anthracyclines, then taxanes, then trastuzumab 1. Med surv 442 vs 352 days docetaxel 2. ORR 41% vs 30% in docetaxel 3. PFS 186 vs 128 taxanes 4. Med surv 163 a PFS 384 vs 93 in mono, 23% ORR, QoL higher

Active substance	Indication and date of registration	Efficacy
cetuximab L01XC06 ma Erbix	→registered from 06/2004 -- treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer (KRAS added 07/2008) • in combination with chemotherapy, • as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan -- treatment of patients with squamous cell cancer of the head and neck • in combination with radiation therapy for locally advanced disease,→ type II var. 03/2006 • in combination with platinum-based chemotherapy for recurrent and/or metastatic disease → type II var. 11/2008	Metastatic colorectal CA – 950 000 new cases per year Backbone therapy: 5-FU/leucovorin (LV) (including new variants), oxaliplatin and irinotecan -- patients lived for longer without their disease getting worse when they received cetuximab in addition to chemotherapy 9.9 months vs. 8.7 months (irinotecan); 7.7 months vs. 7.2 months (oxaliplatin) Squamous cell CA Mainstream therapy – radiotherapy, 5-FU, platinum analogues OS: 29.3 months (RT) vs. 49 months (RT+cetuximab) PFS: 12,4 months (RT) vs. 17,1 months (RT+cetuximab)

Active substance	Indication and date of registration	Efficacy
Panitumumab L01XC08 ma Vectibix	monotherapy for the treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) <i>KRAS</i> after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens → <u>registered 12/2007</u>	Colorectal CA – 700 000 new cases each year in the world – 5% of EU population is affected during his life span State of art therapies: irinotekan or oxaliplatin in comb. 5-FU/leucovorin (schema Mayo clinic) OS: 6,3 mo (best supportive care + panitumumab) vs. 6 mo (best supportive care) PFS: 8 weeks (best supportive care + panitumumab) vs. 7,3 weeks (best supportive care)

**bevacizumab
L01XC07 ma**

Avastin

-- in combination with fluoropyrimidine-based chemotherapy -- for treatment of patients with **metastatic carcinoma of the colon or rectum** → reg. 01/2005
 -- in combination with paclitaxel or docetaxel -- for first-line treatment of patients with **metastatic breast cancer** → Type II var. 03/2007
 -- in addition to platinum-based chemotherapy -- for first-line treatment of patients with unresectable advanced, metastatic or recurrent **non-small cell lung cancer** other than predominantly squamous cell histology → type II var 08/2007
 -- in combination with interferon alfa-2a -- for first line treatment of patients with advanced and/or metastatic **renal cell cancer** → type II var 12/2007

Colorectal CA – 334 000 new cases each year in Europe – 5% of EU population is affected during his life spam
 PFS: 6,24 mo (placebo) vs. 10,55 mo (bev.)
 OS: 15,6 mo (placebo) vs. 20,3 mo (bev.)
Breast CA –
 PFS: 8,2 mo (placebo) vs. 10,1 mo (bev.)
 OS: 89 mo (pl) vs. 92 mo (bev.)
Lung CA – 1 mil. of new cases each year
 Standard therapy: platinum-based
 PFS: 5,4 mo (placebo) vs. 10,2 mo (bev.)
 OS: 10,3 (pl) vs. 12,3 mo (bev.)
Renal CA – 2% from all solid tumors
 Incidence in EU – 11,04 (male) and 5,04 (female) per 100000
 Standard treatment: IFN-alpha with vinblastine
 PFS: 5,4 mo (placebo) vs. 10,2 mo (bev.)
 OS: 19,8 (pl) vs. N/A mo (bev.)

Active substance	Indication and date of registration	Efficacy
Sunitinib (Sutent)	→ registered from <u>07/2006</u> -- treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesilate treatment due to resistance or intolerance. -- treatment of advanced/metastatic renal cell carcinoma (MRCC) → Conditional approval changed into normal in <u>01/2007</u>	GIST: 1% of all GI tumors (incidence 7-15 cases per million) -- treatment: surgery, imatinib mesylate PFS: 24,6 weeks (sun) vs. 6,4 weeks (placebo) Renal cell CA: Incidence in EU – 11,04 (male) and 5,04 (female) per 100000 Therapy – IFN-alpha, IL-2 PFS: 47,3 weeks (sun) vs. 22 weeks (IFN-a)
Sorafenib (Nexavar) ORPHAN	→registered from <u>07/2006</u> for following indication: -- treatment of patients with advanced renal cell carcinoma who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy -- treatment of hepatocellular carcinoma → type II var. <u>10/2007</u>	Renal cell CA: 2% of all adult malignant tumors Therapy – IFN-alpha, IL-2 PFS: 84 days (pl) vs. 167 days (sor.) OS: 15,9 months (pl) vs. 19,3 months (sor.) Hepatocellular CA: 560 000 new cases/year Therapy: surgery, doxorubicine (not licensed, but used) OS: 34,4 weeks (pl) vs. 46,3 weeks (sor.) TTP: 12,3 weeks (pl) vs. 24,0 weeks (sor.)

Active substance	Indication and date of registration	Efficacy
Temsirolimus (Torisel) ORPHAN	-- first-line treatment of patients with advanced renal cell carcinoma who have at least three of six prognostic risk factors → registered from <u>11/2007</u> -- treatment of adult patients with relapsed and/or refractory mantle cell lymphoma (MCL) → type II var. <u>10/2009</u>	Renal cell CA: 2% of all adult malignant tumors Therapy – IFN-alpha, IL-2 PFS: 5,6 months (torisel) vs. 3,2 months (IFN-a) OS: 10,9 months (torisel) vs. 7,3 months (IFN-a) MCL: 8% of all lymphoma diagnosis Therapy – alkylating agent, anthracycline, vinca alkaloids, antimetabolites-no single-agent treatment available PFS: 4,8 months (torisel) vs. 1,9 months (other ther.) OS: 12,8 months (torisel) vs. 10,3 months (other ther.)
Everolimus (Afinitor) ORPHAN Dr. Jan Mazag	-- treatment of patients with advanced renal cell carcinoma, whose disease has progressed on or after treatment with VEGF-targeted therapy → registered <u>08/2009</u>	Renal cell CA: more than 208 000 cases/ year worldwide Therapy – IFN-alpha, IL-2 PFS: 4,90 months (everolimus) vs. 1,87 months (placebo)

Authorised products in Renal cell carcinoma : overview of licensed products and outcomes from clinical trials

	Indication	Basis_efficacy	Efficacy_long
Afinitor (everolimus L01XE10) PKi	RCC 2nd line after TKI (from August, 3, 2009)	Ph3, RCT placebo- controlled (n=416) all risks Cross-over 80%	PFS 4.9 vs 1.9 months HR 0.33 (0.25-0.43) P>0.001 OS 14.8 vs 14.4 m
Torisel (temsirolimus L01XE09) PKi	RCC 1st line (from November, 19, 2007)	Ph3, RCT, 3arm vs IFN (and IFN/ Torisel) (n=626) Poor risk NO cross-over	OS 10.9 vs 7.3 m HR 0.66 (0.53-0.81) p= 0.008 PFS 5.5 vs. 3.1 m HR 0.63 (0.53 – 0.81) p<0.001
Nexavar (sorafenib L01XE05) PKi	RCC 2nd line (from July, 19, 2006)	Ph3, RCT placebo-contr. (n=903) cross-over 48%	PFS 5.5 vs 2.8 m HR 0.44 (0.35-0.55) p<0.01 OS (prior to cross-over) P=0.02 OS (final) 17.8 vs 15.2 m HR 0,88 (0.74-1.04) p= 0.146
Sutent (sunitib L01XE04) PKi	RCC 2nd line (conditional approval) (from July 19, 2006)	2 Ph2 single arm uncontrolled	ORR 25 % per independent review
Sutent (sunitinib L01XE04) PKi	RCC 1st line (from January, 10, 2007)	Ph3 RCT vs IFN (n= 750) Cross-over 33%	PFS 11 vs 5 m HR 0.42 (0.32-0.54) p<0.001 OS 26.4 vs 21.8 m HR 0.82 (0.67-1.00) P= 0.051
Avastin (bevacizumab L01XC07) Monoclonal antibody	RCC 1st line (from December 2007)	Ph3, RCT Avastin/ IFN vs IFN (n=649) Cross-over: yes	PFS 10.2 vs 5.4 m HR 0.63 (0.52-0.75) p<0.001 OS NR vs 19.8 m HR 0.79 (0.62-1.02) P= 0.067

Dr. Jan Mazag

Active substance	Indication and date of registration	Efficacy
Trastuzumab L01XC03 ma Herceptin	-- <u>HER2 positive Metastatic Breast Cancer (MBC)</u> a) as monotherapy for the treatment of those patients who have received at least two chemotherapy regimens for their metastatic disease → registered 05/2000 b) in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease and for whom an anthracycline is not suitable → registered 05/2000 c) in combination with docetaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease → type II var. 06/2004 d) in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer, not previously treated with trastuzumab → type II var. 4/2007 -- <u>treatment of HER 2 positive early breast cancer (EBC)</u> following surgery, chemotherapy and radiotherapy → type II var. 5/2006 -- in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of patients with <u>HER2 positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction</u> who have not received prior anti-cancer treatment for their metastatic disease → type II var. 01/2010	Breast CA: <u>Monotherapy herceptin</u> -- TTP: 3,2 mo; OS: 16,4 mo <u>In comb. with paclitaxel:</u> TTP: 3 mo (pac) vs. 7,1 mo (pac+herc) OS: 17,9 mo (pac) vs. 24,8 mo (pac+herc) <u>In comb. with docetaxel:</u> TTP: 6,1 mo (doc) vs. 11,7 mo (doc+herc) OS: 22,74 mo (doc) vs. 31,2 mo (doc+herc) <u>In comb. with anastrozole:</u> PFS: 2,4 mo (ana) vs. 4,8 mo (ana+herc) OS: + 4,6 mo in ana+herc. group Gastric CA: PFS: 5,5 mo (stand. treatm.) vs. 6,7 mo (st. tr.+herc) OS: 11,1 mo (stand. treatm) vs. 13,8 mo (st. tr.+herc)

Active substance	Indication and date of registration	Efficacy
lapatinib L01XE07 Tyverb	-- in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumours overexpress ErbB2 (HER2). Patients should have progressive disease following prior therapy which must include anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting → registered <u>06/2008</u>	Breast CA: incidence – 350 000 new cases/year in EU Standard therapy: taxanes, anthracyclines, antimetabolites, aromatase inhibitors, antibodies TTP: 18,3 weeks (capecitabine) vs. 23,9 w (cap.+lapat.) OS: 65,9 weeks (capecitabine) vs. 74,0 w (cap.+lapat.)
toremifen L02BA02 antiestrogén Fareston	First line hormone treatment of hormone-dependent metastatic breast cancer in postmenopausal patients. Fareston is not recommended for patients with estrogen receptor negative tumours → registre <u>02/1996</u>	
fulvestrant L02BA03 Faslodex	Faslodex is indicated for the treatment of postmenopausal women with estrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-estrogen therapy or disease progression on therapy with an anti-estrogen.→ registered <u>03/2004</u>	Breast CA: incidence – 350 000 new cases/year in EU Standard therapy: taxanes, anthracyclines, antimetabolites, aromatase inhibitors, antibodies OS: 27,4 mo (fulvest) vs. 27,6 mo (anastorzole) TTP: 166 days (fulvest) vs. 126 days (anastorzole)

Imatinib
L01XX28

(Glivec)

1) treatment of

- a) adult patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy → registered **07/2001**
- b) adult and paediatric patients with newly diagnosed Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) for whom bone marrow transplantation is not considered as the first line of treatment → type II var. **12/2002**
- c) adult and paediatric patients with Ph+ CML in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis. → type II var. **12/2002**
- d) adult patients with relapsed or refractory Ph+ ALL as monotherapy. → type II var. **09/2006**
- e) adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements. → type II var. **11/2006**
- f) adult patients with advanced hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukaemia (CEL) with FIP1L1-PDGFRα rearrangement. → type II var. **11/2006**

2) is indicated for

- a) the treatment of adult patients with Kit (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours (GIST) → type II var. **05/2002**
- b) the treatment of adult patients with unresectable dermatofibrosarcoma protuberans (DFSP) and adult patients with recurrent and/or metastatic DFSP who are not eligible for surgery → type II var. **09/2006**
- c) the adjuvant treatment of adult patients who are at significant risk of relapse following resection of Kit (CD117)-positive GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment. → type II var. **04/2009**

CML: incidence – 1 case/100 000 people per year

Standard therapy: bone marrow transplantation, IFN-alpha, cytosine-arabinese

Efficacy:

Indication 1a: -- 65% of pts. achieved major cytogenetic response

Indication 1c: Median survival 8 months with imatinib

Indication 1d: Major cytogenetic response rate 90%

Indication 1e: Overall survival 65 months since diagnosis

Indication 1f: 21 from 65 pts achieved complete molecular remission with a median follow-up of 28 months

GIST: Incidence: 0,06 in 10 000 persons in the EU

Standard treatment: surgical, no approved specific drug therapy

Efficacy

Indication 2a:

TTF: 1,2 months (placebo) vs. 6 months (imatinib)

Indication 2b: data on OS not sufficient, PFS more than 18 months after imatinib

Indication 2c: Risk of recurrence reduced by 89% as compared to pl.

Active substance	Indication and date of registration	Efficacy
dasatinib L01XE06 Sprycel ORPHAN	→ registered 11/2006 for following indications: -- for the treatment of adults with chronic, accelerated or blast phase chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy including imatinib mesilate. -- for the treatment of adults with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.	CML: Incidence – 1case/100 000 people per year Standard therapy: bone marrow transplantation, IFN-alpha, cytosine-arabinoose, imatinib Efficacy: CML: 2 year survival – 91% of pts treated with 100 mg dasatinib PFS: 4 months; OS: 8 months ALL: 2year survival – 95% of pst treated with 100 mg dasatinib
nilotinib L01XE08 Tasigna ORPHAN	Tasigna is indicated for the treatment of adults with chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukaemia (CML) with resistance or intolerance to prior therapy including imatinib. → registered 11/2007	CML: incidence – 1case/100 000 people per year Standard therapy: imatinib 49% of patients had a major cytogenetic response

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