



Modular Program Report

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview	
Request Description	<p>FDA has requested execution of Modular Program #1 (MP1), version 2, to investigate prevalent and incident use of lapatinib, ticlopidine, telithromycin, allopurinol, diclofenac, and isoniazid (oral routes only for all drug products). This involved one run of MP1. The query was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of January 1, 2004 to December 31, 2011. The package was distributed to Data Partners on December 6, 2012.</p> <p>Results provide counts of new users, dispensings, total days supplied, eligible members, and member-days. Total days supplied are from the Mini-Sentinel Common Data Model (MSCDM) outpatient pharmacy table for records identified using specified NDCs. A "MULT" incidence type for the exposure was used, meaning that the program considers all incident dispensings during the query period for each member. A 183-day washout period was used to define incident use, meaning that a user was considered a new user if he/she was not exposed to the drug of interest in the 183 days prior to the dispensing.</p>
Request ID	msy4_mpr06_v1

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Notes:	Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

MSY4_MPR06_v1 Specifications

FDA has requested execution of Modular Program #1 (MP1), version 2, to investigate prevalent and incident use of lapatinib, ticlopidine, telithromycin, allopurinol, diclofenac, and isoniazid (oral routes only for all drug products). The query period was from January 1, 2004 to December 31, 2011. The enrollment gap was set at 45 days, and age groups were stratified as follows: <20, 20-44, 45-64, 65+ years. In total, 6 different scenarios were examined. See below for a description of each of these scenarios.

Scenario	Drug/Exposure Criteria			
	Prevalent/Incident exposure	Incident w/ respect to (incidence criteria):	Washout (days)	Incidence type*
1	Allopurinol	Allopurinol	183	MULT
2	Diclofenac	Diclofenac	183	MULT
3	Isoniazid	Isoniazid	183	MULT
4	Lapatinib	Lapatinib	183	MULT
5	Telithromycin	Telithromycin	183	MULT
6	Ticlopidine	Ticlopidine	183	MULT

*A "MULT" incidence type for the exposure will consider all dispensings for each member that meet the 183 washout period. There can be more than one incident dispensing per member. The enrollment requirement is based on the number of days in the washout.

**Modular Program 1 will consider those members with at least drug coverage.

Glossary of Terms in Modular Program 1*

Eligible Members (incidence-based cohort) - Number of members eligible for incident exposure (defined by the washout period) with drug and medical coverage during the query period.

Eligible Members (prevalence-based cohort) - Number of members with at least one day of drug and medical coverage** during the query period.

Enrollment Gap - Number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled” sequence.

Incidence Type (event/outcome)- *Minimum incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple incidence type* uses the washout period to establish incidence and considers all qualifying incident treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident episode.

Member-Days (incidence-based cohort) - Sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period.

Member-Days (prevalence-based cohort) - Sum of all days members are enrolled with drug and medical coverage** during the query period.

New Starts- Number of incident exposures during the query period. User must have no prior exposures in the washout period. For a minimum incidence type, an individual may have no more than one new start. For a multiple incidence type, an individual may have more than one new start.

New Users - Number of members with incident exposure during the query period. Member must have no evidence of exposure (s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

Query Period - Period in which the modular program looks for exposures of interest.

Washout Period (drug/exposure) - Number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage.

*all terms may not be used in this report

**in cases where only NDCs are used to identify exposure, only drug coverage is required

Table 1a. Summary of Prevalent Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug Product

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Allopurinol	1,054,452	11,594,239	527,542,467	115,766,695	97,771,706,059	9.11	500.30	11.00	45.50
Diclofenac	2,238,259	6,786,946	214,558,969	115,766,695	97,771,706,059	19.33	95.86	3.03	31.61
Isoniazid	103,823	347,444	15,738,078	115,766,695	97,771,706,059	0.90	151.59	3.35	45.30
Lapatinib	3,434	20,801	613,260	115,766,695	97,771,706,059	0.03	178.58	6.06	29.48
Telithromycin	295,197	368,480	2,231,988	115,766,695	97,771,706,059	2.55	7.56	1.25	6.06
Ticlopidine	17,387	162,145	6,708,840	115,766,695	97,771,706,059	0.15	385.85	9.33	41.38

Figure 1a1. Number of Prevalent Users and Dispensings between January 1, 2004 and December 31, 2011, by Drug Product

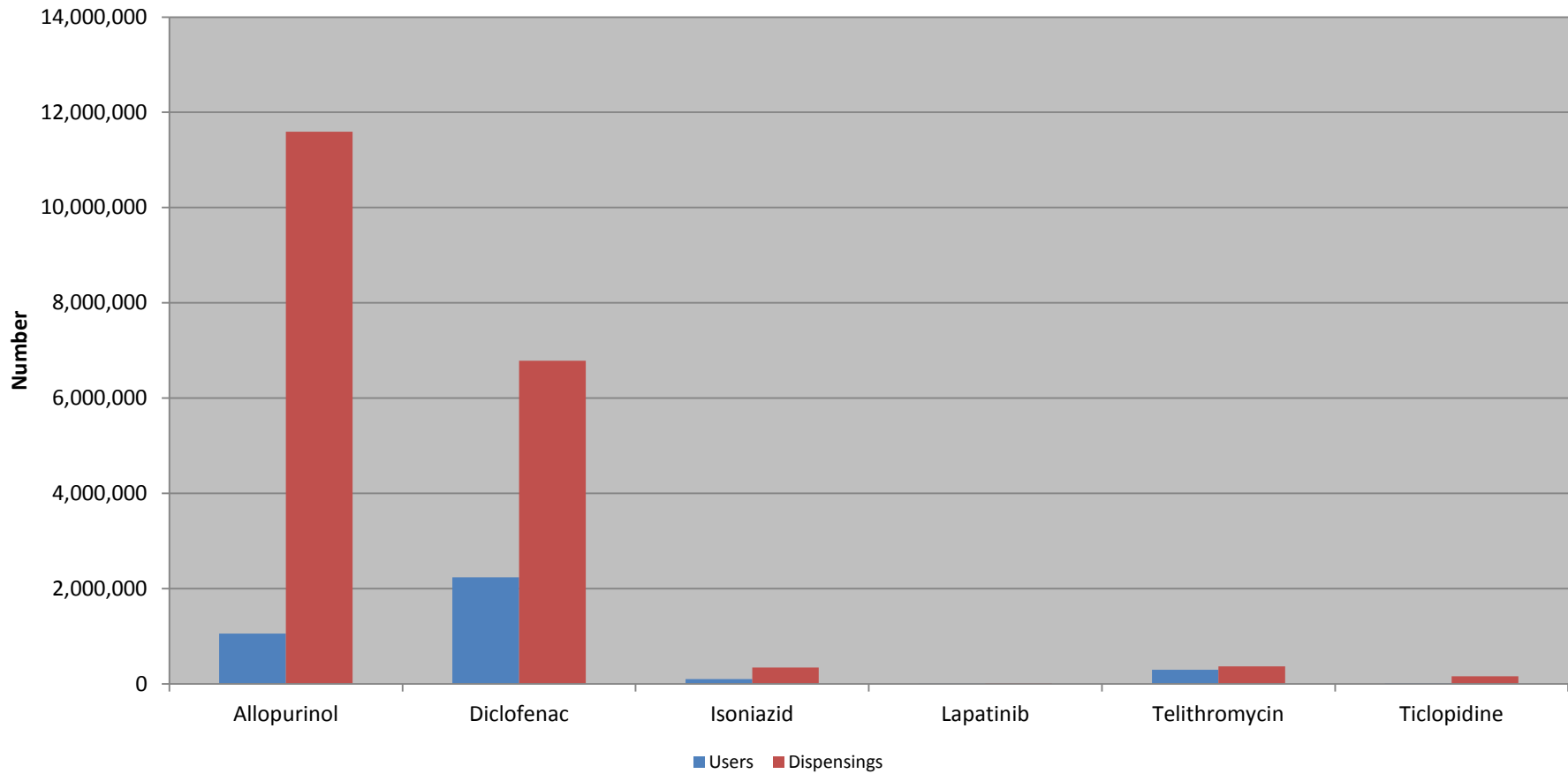


Figure 1a2. Prevalent Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing between January 1, 2004 and December 31, 2011, by Drug Product

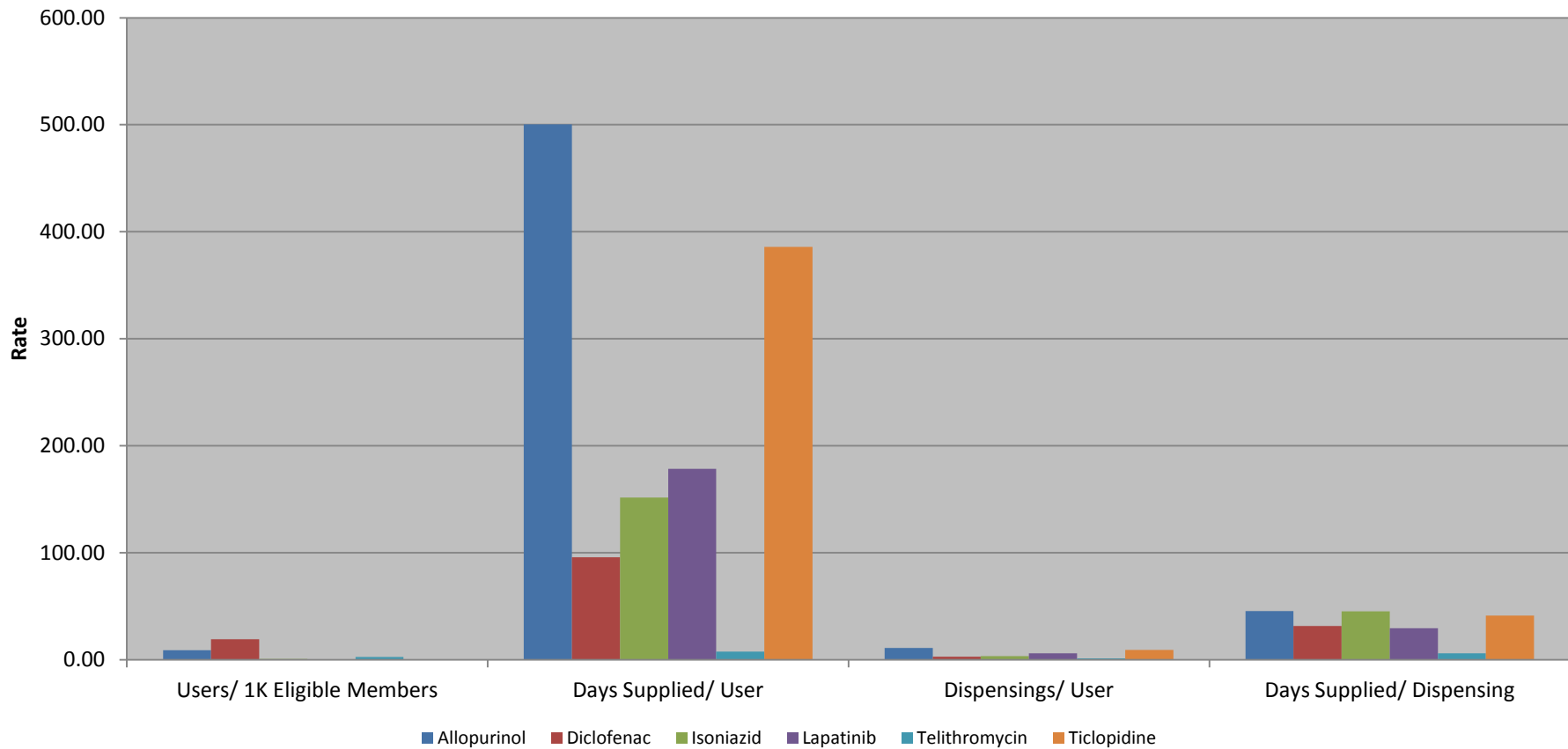


Table 1b. Summary of Incident Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug Product

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Allopurinol	564,119	720,603	4,284,122	201,513,634	94,881,124	77,649,308,704	5.95	357.22	7.59	47.04
Diclofenac	1,660,873	1,898,527	3,996,896	118,944,177	95,067,729	77,705,165,135	17.47	71.62	2.41	29.76
Isoniazid	71,168	74,883	235,917	11,323,312	95,195,260	78,209,985,802	0.75	159.11	3.31	48.00
Lapatinib	2,487	2,632	14,626	426,295	95,199,771	78,233,212,250	0.03	171.41	5.88	29.15
Telithromycin	247,693	263,370	309,904	1,867,478	95,196,714	78,182,460,522	2.60	7.54	1.25	6.03
Ticlopidine	9,314	10,465	57,668	2,495,169	95,196,409	78,225,971,045	0.10	267.89	6.19	43.27

Figure 1b1. Number of New Users, New Starts, and Dispensings between January 1, 2004 and December 31, 2011, by Drug Product

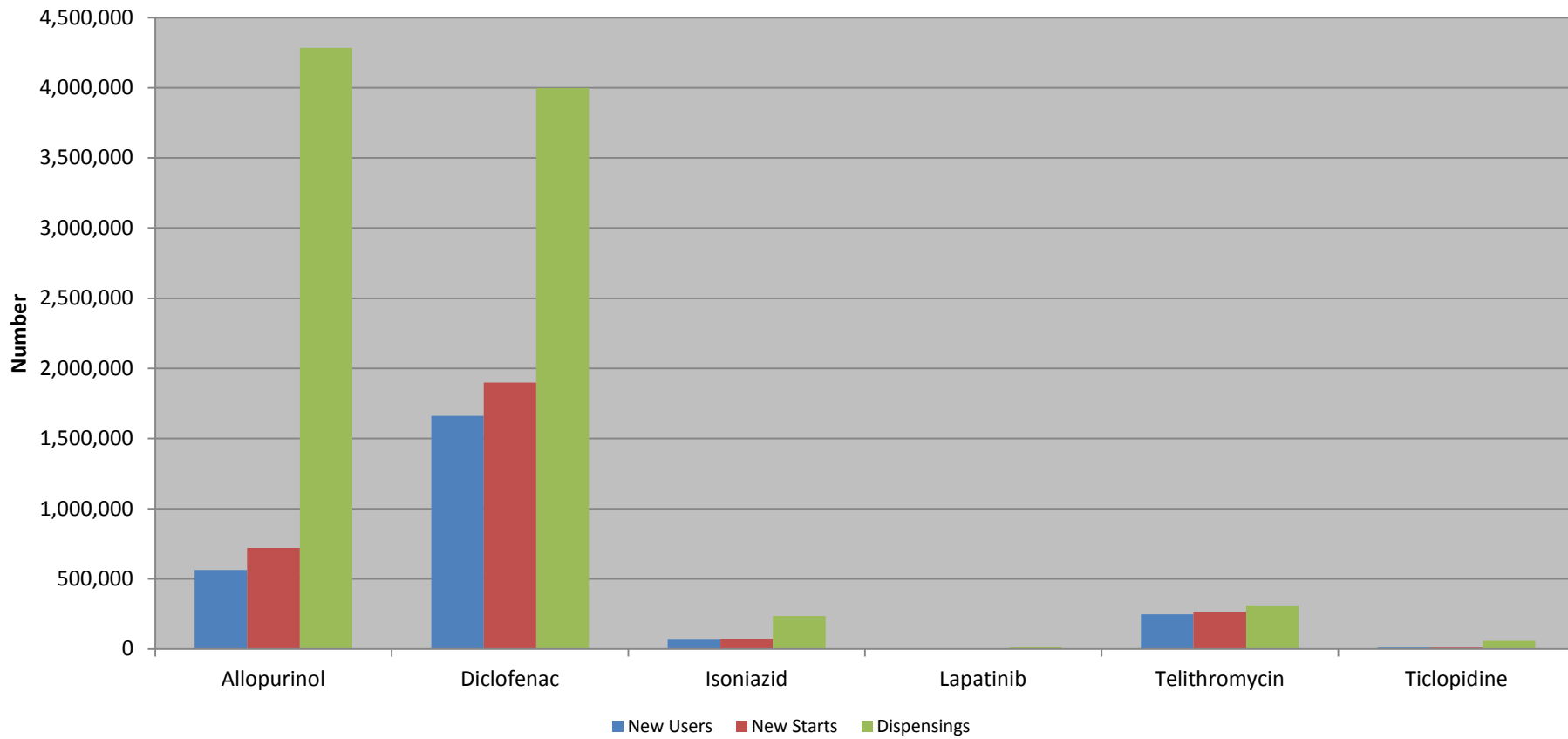


Figure 1b2. Incident Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, and Days Supplied per Dispensing between January 1, 2004 and December 31, 2011, by Drug Product

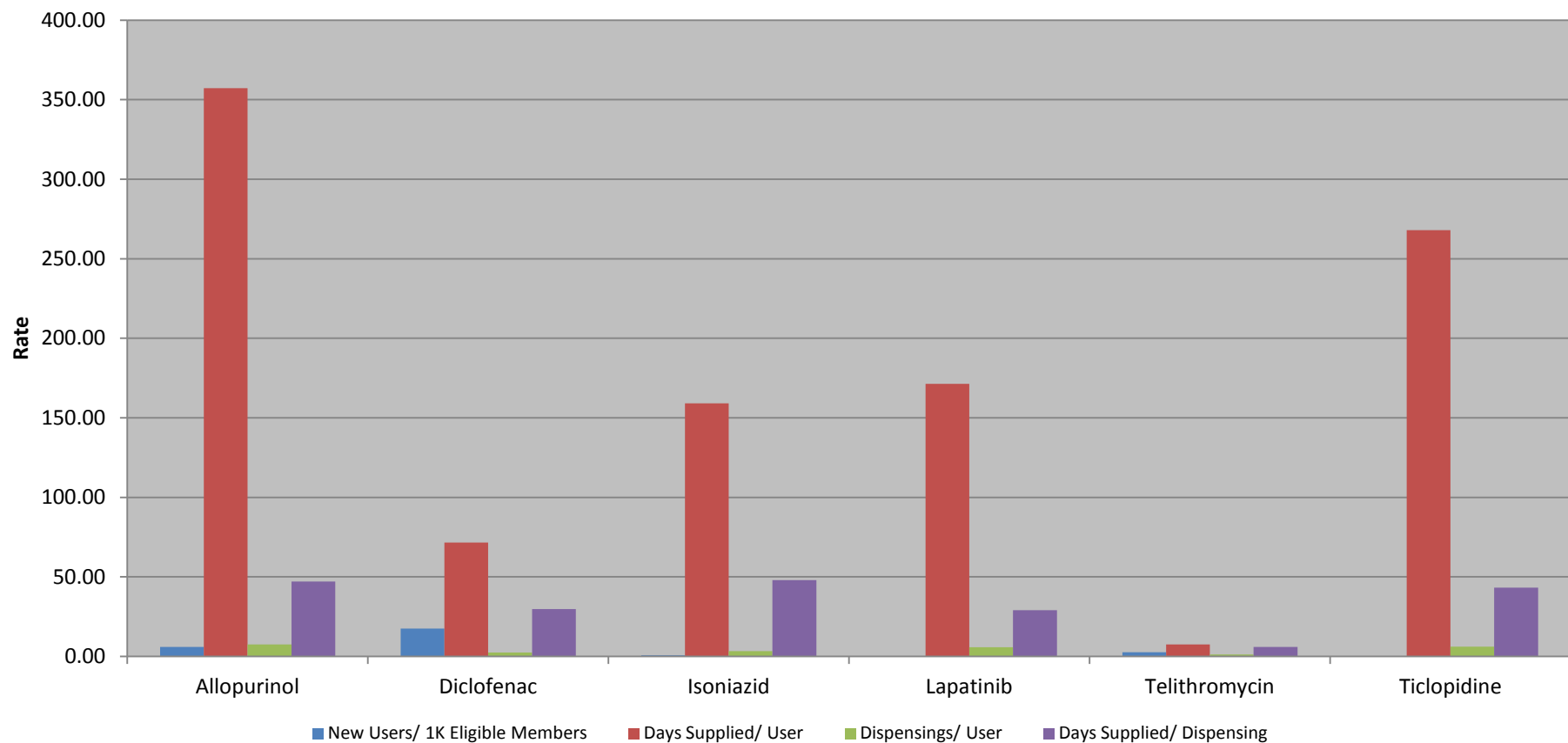


Table 2a. Summary of Prevalent Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug Product and Age Group

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Allopurinol									
<20 years	2,065	8,411	295,375	30,728,470	24,546,240,775	0.07	143.04	4.07	35.12
20-44 years	132,190	946,783	35,988,342	48,333,642	33,122,875,176	2.73	272.25	7.16	38.01
45-64 years	451,419	4,702,907	203,877,970	31,797,880	27,174,122,518	14.20	451.64	10.42	43.35
≥65 years	521,274	5,936,138	287,380,780	13,599,233	12,928,467,590	38.33	551.30	11.39	48.41
Diclofenac									
<20 years	78,815	108,385	2,344,809	30,728,470	24,546,240,775	2.56	29.75	1.38	21.63
20-44 years	797,313	1,429,338	36,508,105	48,333,642	33,122,875,176	16.50	45.79	1.79	25.54
45-64 years	1,003,452	3,429,358	109,385,868	31,797,880	27,174,122,518	31.56	109.01	3.42	31.90
≥65 years	396,738	1,819,865	66,320,187	13,599,233	12,928,467,590	29.17	167.16	4.59	36.44
Isoniazid									
<20 years	25,891	89,059	4,135,364	30,728,470	24,546,240,775	0.84	159.72	3.44	46.43
20-44 years	46,822	146,912	6,659,841	48,333,642	33,122,875,176	0.97	142.24	3.14	45.33
45-64 years	23,576	80,514	3,666,063	31,797,880	27,174,122,518	0.74	155.50	3.42	45.53
≥65 years	8,756	30,959	1,276,810	13,599,233	12,928,467,590	0.64	145.82	3.54	41.24
Lapatinib									
<20 years	5	27	822	30,728,470	24,546,240,775	0.00	164.40	5.40	30.44
20-44 years	575	3,306	98,649	48,333,642	33,122,875,176	0.01	171.56	5.75	29.84
45-64 years	2,200	13,970	413,474	31,797,880	27,174,122,518	0.07	187.94	6.35	29.60
≥65 years	733	3,498	100,315	13,599,233	12,928,467,590	0.05	136.86	4.77	28.68
Telithromycin									
<20 years	17,043	20,217	125,773	30,728,470	24,546,240,775	0.55	7.38	1.19	6.22
20-44 years	139,458	167,936	996,211	48,333,642	33,122,875,176	2.89	7.14	1.20	5.93
45-64 years	117,813	152,137	939,274	31,797,880	27,174,122,518	3.71	7.97	1.29	6.17
≥65 years	21,992	28,190	170,730	13,599,233	12,928,467,590	1.62	7.76	1.28	6.06
Ticlopidine									
<20 years	7	31	1,010	30,728,470	24,546,240,775	0.00	144.29	4.43	32.58
20-44 years	468	2,716	94,490	48,333,642	33,122,875,176	0.01	201.90	5.80	34.79
45-64 years	5,720	46,652	1,790,418	31,797,880	27,174,122,518	0.18	313.01	8.16	38.38
≥65 years	11,689	112,746	4,822,922	13,599,233	12,928,467,590	0.86	412.60	9.65	42.78

Table 2b. Summary of Incident Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug Product and Age Group

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Allopurinol										
<20 years	1,524	1,685	5,346	191,206	24,765,774	19,344,143,443	0.06	125.46	3.51	35.77
20-44 years	78,053	97,943	436,018	16,992,672	38,338,905	25,347,216,901	2.04	217.71	5.59	38.97
45-64 years	235,342	298,028	1,741,651	77,542,282	26,853,520	22,323,396,637	8.76	329.49	7.40	44.52
≥65 years	256,812	322,947	1,982,146	100,731,313	12,007,626	10,634,551,723	21.39	392.24	7.72	50.82
Diclofenac										
<20 years	63,843	68,426	86,062	1,835,261	24,763,933	19,331,767,218	2.58	28.75	1.35	21.32
20-44 years	597,625	661,384	996,796	24,799,376	38,333,495	25,252,582,957	15.59	41.50	1.67	24.88
45-64 years	748,504	863,223	2,017,394	61,087,486	26,919,356	22,300,193,747	27.81	81.61	2.70	30.28
≥65 years	264,753	305,494	847,173	29,457,984	12,151,543	10,820,621,213	21.79	111.27	3.20	34.77
Isoniazid										
<20 years	16,404	17,583	56,740	2,742,043	24,764,601	19,338,539,078	0.66	167.16	3.46	48.33
20-44 years	31,686	33,147	97,819	4,748,618	38,364,200	25,385,022,567	0.83	149.86	3.09	48.54
45-64 years	17,198	17,929	58,455	2,818,661	26,990,258	22,549,322,796	0.64	163.89	3.40	48.22
≥65 years	6,033	6,224	20,947	923,309	12,198,450	10,937,101,361	0.49	153.04	3.47	44.08
Lapatinib										
<20 years	4	4	22	713	24,765,938	19,344,667,691	0.00	178.25	5.50	32.41
20-44 years	404	430	2,316	69,039	38,366,649	25,395,153,558	0.01	170.89	5.73	29.81
45-64 years	1,557	1,647	9,511	277,652	26,991,063	22,554,474,769	0.06	178.32	6.11	29.19
≥65 years	530	551	2,432	68,598	12,198,975	10,938,916,232	0.04	129.43	4.59	28.21
Telithromycin										
<20 years	14,653	15,318	17,447	107,530	24,765,691	19,341,848,319	0.59	7.34	1.19	6.16
20-44 years	114,156	120,452	137,890	814,129	38,364,364	25,371,936,468	2.98	7.13	1.21	5.90
45-64 years	101,338	108,452	130,859	802,386	26,990,013	22,533,401,077	3.75	7.92	1.29	6.13
≥65 years	18,221	19,148	23,253	139,663	12,198,741	10,935,274,658	1.49	7.66	1.28	6.01
Ticlopidine										
<20 years	1	1	1	30	24,765,937	19,344,667,467	0.00	30.00	1.00	30.00
20-44 years	281	298	1,459	50,090	38,366,639	25,395,162,112	0.01	178.26	5.19	34.33
45-64 years	3,111	3,402	19,346	751,006	26,990,152	22,552,798,689	0.12	241.40	6.22	38.82
≥65 years	5,952	6,764	35,759	1,640,337	12,196,250	10,933,342,777	0.49	275.59	6.01	45.87

Table 3a. Summary of Prevalent Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug and Sex

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Allopurinol									
Female	273,894	2,845,533	124,386,711	59,246,378	50,672,518,681	4.62	454.14	10.39	43.71
Male	780,124	8,744,044	402,974,179	56,401,844	46,956,619,284	13.83	516.55	11.21	46.09
Unknown	434	4,662	181,577	118,473	142,568,094	3.66	418.38	10.74	38.95
Diclofenac									
Female	1,300,936	4,091,823	130,442,458	59,246,378	50,672,518,681	21.96	100.27	3.15	31.88
Male	935,412	2,690,349	83,971,032	56,401,844	46,956,619,284	16.58	89.77	2.88	31.21
Unknown	1,911	4,774	145,479	118,473	142,568,094	16.13	76.13	2.50	30.47
Isoniazid									
Female	57,214	189,577	8,620,345	59,246,378	50,672,518,681	0.97	150.67	3.31	45.47
Male	46,552	157,602	7,109,764	56,401,844	46,956,619,284	0.83	152.73	3.39	45.11
Unknown	57	265	7,969	118,473	142,568,094	0.48	139.81	4.65	30.07
Lapatinib									
Female	3,364	20,569	606,267	59,246,378	50,672,518,681	0.06	180.22	6.11	29.47
Male	66	200	5,943	56,401,844	46,956,619,284	0.00	90.05	3.03	29.72
Unknown	4	32	1,050	118,473	142,568,094	0.03	262.50	8.00	32.81
Telithromycin									
Female	184,770	233,987	1,418,438	59,246,378	50,672,518,681	3.12	7.68	1.27	6.06
Male	109,880	133,843	809,942	56,401,844	46,956,619,284	1.95	7.37	1.22	6.05
Unknown	547	650	3,608	118,473	142,568,094	4.62	6.60	1.19	5.55
Ticlopidine									
Female	8,012	77,360	3,166,856	59,246,378	50,672,518,681	0.14	395.26	9.66	40.94
Male	9,369	84,731	3,540,304	56,401,844	46,956,619,284	0.17	377.87	9.04	41.78
Unknown	6	54	1,680	118,473	142,568,094	0.05	280.00	9.00	31.11

Table 3b. Summary of Incident Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug and Sex

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Allopurinol										
Female	154,307	187,481	1,121,575	51,506,238	48,943,888	40,529,117,864	3.15	333.79	7.27	45.92
Male	409,539	532,768	3,160,198	149,918,357	45,828,802	37,008,365,773	8.94	366.07	7.72	47.44
Unknown	273	354	2,349	89,039	108,434	111,825,067	2.52	326.15	8.60	37.91
Diclofenac										
Female	962,618	1,106,082	2,370,285	71,052,025	48,939,604	40,353,233,012	19.67	73.81	2.46	29.98
Male	696,761	790,760	1,623,599	47,809,148	46,019,673	37,240,310,123	15.14	68.62	2.33	29.45
Unknown	1,494	1,685	3,012	83,004	108,452	111,622,000	13.78	55.56	2.02	27.56
Isoniazid										
Female	39,545	41,667	129,750	6,247,931	49,017,059	40,654,196,207	0.81	158.00	3.28	48.15
Male	31,583	33,176	105,973	5,069,526	46,069,713	37,443,747,715	0.69	160.51	3.36	47.84
Unknown	40	40	194	5,855	108,488	112,041,880	0.37	146.38	4.85	30.18
Lapatinib										
Female	2,433	2,576	14,453	421,062	49,019,230	40,666,628,264	0.05	173.06	5.94	29.13
Male	51	52	143	4,243	46,072,052	37,454,528,757	0.00	83.20	2.80	29.67
Unknown	3	4	30	990	108,489	112,055,229	0.03	330.00	10.00	33.00
Telithromycin										
Female	155,059	165,511	196,914	1,188,263	49,017,390	40,634,882,945	3.16	7.66	1.27	6.03
Male	92,188	97,395	112,452	676,296	46,070,844	37,435,611,200	2.00	7.34	1.22	6.01
Unknown	446	464	538	2,919	108,480	111,966,377	4.11	6.54	1.21	5.43
Ticlopidine										
Female	4,093	4,703	24,139	1,051,272	49,017,730	40,663,675,380	0.08	256.85	5.90	43.55
Male	5,217	5,757	33,511	1,443,297	46,070,191	37,450,241,780	0.11	276.65	6.42	43.07
Unknown	4	5	18	600	108,488	112,053,885	0.04	150.00	4.50	33.33

Table 4a. Summary of Prevalent Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Allopurinol									
2004	127,894	637,422	28,637,661	23,852,499	6,982,515,042	5.36	223.92	4.98	44.93
2005	135,776	653,109	29,689,178	24,633,783	7,156,323,614	5.51	218.66	4.81	45.46
2006	158,283	727,075	35,470,236	26,418,738	7,770,281,013	5.99	224.09	4.59	48.78
2007	294,639	1,304,770	57,676,606	33,458,715	9,227,354,654	8.81	195.75	4.43	44.20
2008	433,782	2,271,976	96,803,923	60,529,651	17,465,788,477	7.17	223.16	5.24	42.61
2009	414,022	2,041,607	91,519,138	56,696,940	16,885,622,636	7.30	221.05	4.93	44.83
2010	419,904	1,996,257	92,358,103	55,286,105	16,352,211,999	7.60	219.95	4.75	46.27
2011	443,734	1,962,023	95,387,622	54,239,888	15,931,608,624	8.18	214.97	4.42	48.62
Diclofenac									
2004	184,171	432,880	13,059,173	23,852,499	6,982,515,042	7.72	70.91	2.35	30.17
2005	227,702	531,367	16,118,462	24,633,783	7,156,323,614	9.24	70.79	2.33	30.33
2006	235,944	527,899	16,789,829	26,418,738	7,770,281,013	8.93	71.16	2.24	31.81
2007	313,717	741,316	23,482,796	33,458,715	9,227,354,654	9.38	74.85	2.36	31.68
2008	550,376	1,298,880	40,776,922	60,529,651	17,465,788,477	9.09	74.09	2.36	31.39
2009	522,780	1,160,710	36,787,345	56,696,940	16,885,622,636	9.22	70.37	2.22	31.69
2010	501,885	1,105,232	35,341,451	55,286,105	16,352,211,999	9.08	70.42	2.20	31.98
2011	456,207	988,662	32,202,991	54,239,888	15,931,608,624	8.41	70.59	2.17	32.57
Isoniazid									
2004	12,756	31,332	1,538,161	23,852,499	6,982,515,042	0.53	120.58	2.46	49.09
2005	13,648	34,752	1,643,957	24,633,783	7,156,323,614	0.55	120.45	2.55	47.31
2006	13,980	34,155	1,662,925	26,418,738	7,770,281,013	0.53	118.95	2.44	48.69
2007	16,021	40,054	1,929,928	33,458,715	9,227,354,654	0.48	120.46	2.50	48.18
2008	22,716	61,708	2,655,169	60,529,651	17,465,788,477	0.38	116.89	2.72	43.03
2009	20,634	55,252	2,395,342	56,696,940	16,885,622,636	0.36	116.09	2.68	43.35
2010	18,002	47,844	2,077,371	55,286,105	16,352,211,999	0.33	115.40	2.66	43.42
2011	16,088	42,347	1,835,225	54,239,888	15,931,608,624	0.30	114.07	2.63	43.34

Table 4a. Summary of Prevalent Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug and Year

	Users	Dispensings	Total Days Supplied	Eligible Members	Member-Days	Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Lapatinib									
2004	0	0	0	23,852,499	6,982,515,042	0.00	---	---	---
2005	0	0	0	24,633,783	7,156,323,614	0.00	---	---	---
2006	0	0	0	26,418,738	7,770,281,013	0.00	---	---	---
2007	657	2,323	67,541	33,458,715	9,227,354,654	0.02	102.80	3.54	29.07
2008	1,132	4,969	147,132	60,529,651	17,465,788,477	0.02	129.98	4.39	29.61
2009	1,034	4,542	133,012	56,696,940	16,885,622,636	0.02	128.64	4.39	29.28
2010	1,058	4,815	143,080	55,286,105	16,352,211,999	0.02	135.24	4.55	29.72
2011	968	4,152	122,495	54,239,888	15,931,608,624	0.02	126.54	4.29	29.50
Telithromycin									
2004	47,163	51,872	309,433	23,852,499	6,982,515,042	1.98	6.56	1.10	5.97
2005	159,951	185,522	1,083,571	24,633,783	7,156,323,614	6.49	6.77	1.16	5.84
2006	98,908	113,488	672,539	26,418,738	7,770,281,013	3.74	6.80	1.15	5.93
2007	10,585	12,354	84,859	33,458,715	9,227,354,654	0.32	8.02	1.17	6.87
2008	1,828	2,764	31,397	60,529,651	17,465,788,477	0.03	17.18	1.51	11.36
2009	598	1,136	19,482	56,696,940	16,885,622,636	0.01	32.58	1.90	17.15
2010	371	841	18,648	55,286,105	16,352,211,999	0.01	50.26	2.27	22.17
2011	237	503	12,059	54,239,888	15,931,608,624	0.00	50.88	2.12	23.97
Ticlopidine									
2004	2,873	14,584	589,592	23,852,499	6,982,515,042	0.12	205.22	5.08	40.43
2005	2,654	12,487	512,493	24,633,783	7,156,323,614	0.11	193.10	4.70	41.04
2006	2,363	10,244	464,484	26,418,738	7,770,281,013	0.09	196.57	4.34	45.34
2007	4,865	20,932	824,500	33,458,715	9,227,354,654	0.15	169.48	4.30	39.39
2008	6,272	33,294	1,283,677	60,529,651	17,465,788,477	0.10	204.67	5.31	38.56
2009	5,437	27,424	1,099,675	56,696,940	16,885,622,636	0.10	202.26	5.04	40.10
2010	5,208	25,244	1,102,836	55,286,105	16,352,211,999	0.09	211.76	4.85	43.69
2011	4,121	17,936	831,583	54,239,888	15,931,608,624	0.08	201.79	4.35	46.36

Table 4b. Summary of Incident Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Allopurinol										
2004	30,639	31,422	73,644	3,557,741	19,284,780	4,254,211,498	1.59	116.12	2.40	48.31
2005	43,439	44,868	119,312	5,364,455	21,246,746	6,115,978,853	2.04	123.49	2.75	44.96
2006	48,638	50,107	133,344	6,260,570	22,882,487	6,418,431,476	2.13	128.72	2.74	46.95
2007	57,156	58,997	150,132	7,198,760	28,913,369	7,013,809,553	1.98	125.95	2.63	47.95
2008	115,840	118,713	319,468	13,665,716	50,250,504	11,736,037,881	2.31	117.97	2.76	42.78
2009	134,641	138,569	382,266	16,721,661	50,203,725	14,503,861,580	2.68	124.19	2.84	43.74
2010	135,762	139,774	384,207	17,290,206	48,261,314	13,999,707,811	2.81	127.36	2.83	45.00
2011	134,632	138,153	366,573	17,181,231	47,505,819	13,607,270,052	2.83	127.62	2.72	46.87
Diclofenac										
2004	87,604	88,303	137,974	3,633,545	19,323,705	4,257,604,943	4.53	41.48	1.57	26.33
2005	159,866	162,437	276,781	7,574,616	21,286,801	6,109,080,590	7.51	47.38	1.73	27.37
2006	154,679	157,032	242,989	6,701,437	22,931,281	6,414,251,511	6.75	43.32	1.57	27.58
2007	159,433	162,036	246,299	6,845,782	29,011,161	7,016,775,878	5.50	42.94	1.54	27.79
2008	301,456	305,258	468,687	12,980,911	50,402,757	11,748,837,519	5.98	43.06	1.55	27.70
2009	361,788	367,559	563,008	15,674,488	50,350,817	14,513,763,584	7.19	43.33	1.56	27.84
2010	347,186	352,792	544,651	15,256,407	48,412,461	14,013,513,988	7.17	43.94	1.57	28.01
2011	299,134	303,110	460,834	12,881,660	47,674,880	13,631,337,122	6.27	43.06	1.54	27.95
Isoniazid										
2004	6,684	6,730	14,348	834,227	19,361,683	4,277,356,717	0.35	124.81	2.15	58.14
2005	7,996	8,080	20,157	991,339	21,327,018	6,149,189,311	0.37	123.98	2.52	49.18
2006	7,807	7,876	18,370	951,913	22,977,853	6,454,224,858	0.34	121.93	2.35	51.82
2007	8,781	8,845	20,794	1,108,858	29,125,455	7,059,910,956	0.30	126.28	2.37	53.33
2008	11,126	11,222	27,078	1,317,612	50,529,746	11,833,298,065	0.22	118.43	2.43	48.66
2009	12,160	12,268	31,693	1,434,548	50,450,639	14,611,556,905	0.24	117.97	2.61	45.26
2010	10,603	10,675	27,358	1,254,844	48,505,937	14,105,911,254	0.22	118.35	2.58	45.87
2011	9,121	9,187	23,157	1,065,804	47,767,401	13,718,537,736	0.19	116.85	2.54	46.03

Table 4b. Summary of Incident Drug Use in the MSDD between January 1, 2004 and December 31, 2011, by Drug and Year

	New Users	New Starts	Dispensings	Total Days Supplied	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Lapatinib										
2004	0	0	0	0	19,364,026	4,279,326,789	0.00	---	---	---
2005	0	0	0	0	21,329,348	6,151,750,007	0.00	---	---	---
2006	0	0	0	0	22,980,366	6,456,762,225	0.00	---	---	---
2007	467	468	1,746	50,937	29,128,993	7,062,548,474	0.02	109.07	3.74	29.17
2008	498	501	1,678	47,948	50,534,211	11,836,785,042	0.01	96.28	3.37	28.57
2009	584	590	2,138	61,990	50,453,804	14,615,373,500	0.01	106.15	3.66	28.99
2010	572	575	2,133	62,425	48,508,528	14,109,164,999	0.01	109.13	3.73	29.27
2011	495	498	1,675	48,635	47,769,874	13,721,501,214	0.01	98.25	3.38	29.04
Telithromycin										
2004	42,141	42,141	46,512	277,573	19,362,183	4,276,847,118	2.18	6.59	1.10	5.97
2005	134,754	137,363	154,963	898,186	21,320,368	6,126,761,603	6.32	6.67	1.15	5.80
2006	73,192	74,274	82,313	478,507	22,972,811	6,437,545,231	3.19	6.54	1.12	5.81
2007	7,671	7,741	8,596	55,992	29,126,812	7,058,282,607	0.26	7.30	1.12	6.51
2008	958	978	1,309	14,488	50,534,398	11,836,632,326	0.02	15.12	1.37	11.07
2009	423	432	685	11,086	50,454,090	14,615,448,342	0.01	26.21	1.62	16.18
2010	280	283	562	12,100	48,508,850	14,109,295,826	0.01	43.21	2.01	21.53
2011	155	158	313	6,951	47,770,182	13,721,647,469	0.00	44.85	2.02	22.21
Ticlopidine										
2004	812	834	1,949	87,339	19,362,437	4,278,728,031	0.04	107.56	2.40	44.81
2005	1,016	1,037	2,884	112,829	21,327,999	6,151,045,188	0.05	111.05	2.84	39.12
2006	788	804	2,349	95,760	22,979,084	6,456,195,114	0.03	121.52	2.98	40.77
2007	859	879	2,436	99,068	29,125,552	7,061,963,079	0.03	115.33	2.84	40.67
2008	1,870	1,907	5,430	202,687	50,530,979	11,835,468,489	0.04	108.39	2.90	37.33
2009	1,890	1,923	5,694	222,932	50,451,164	14,614,108,411	0.04	117.95	3.01	39.15
2010	2,042	2,093	6,809	318,689	48,506,299	14,107,947,554	0.04	156.07	3.33	46.80
2011	971	988	2,455	120,371	47,767,769	13,720,515,179	0.02	123.97	2.53	49.03