Corrections - Page 7 amended to correct prices for formoterol and salmeterol, following initial dissemination of these minutes on 13 May 2004

The next meetings of the DoD P&T Committee have been changed to Tuesday 13 July and Wednesday 14 July, 2004.

Department of Defense Pharmacoeconomic Center

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Fort Sam Houston, TX 78234-5081

MCCS-GPE **20 April 2004**

MEMORANDUM FOR: Executive Director, TRICARE Management Activity (TMA)

SUBJECT: Minutes of the Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Executive Council Meeting

1. The DoD P&T Executive Council convened at 1300 hours on 20 April 2004 at the DoD Pharmacoeconomic Center, Fort Sam Houston, Texas.

2. VOTING MEMBERS PRESENT

COL Daniel D. Remund, MS	DoD P& T Committee Co-chair
CDR Terrance Egland, MC (Via VTC)	DoD P& T Committee Co-chair
COL Joel Schmidt, MC	Army
COL Doreen Lounsbery, MC	Army
MAJ Travis Watson, MS (Via VTC)	Army
LtCol Gordon Wright Bates, Jr., MC	Air Force
Col Phil Samples, BSC	Air Force
CAPT Matt Nutaitis, MC	Navy
CDR Mark Richerson, MSC	Navy
CDR Patrick Marshall	Coast Guard
Joe Canzolino	Department of Veterans Affairs

VOTING MEMBERS ABSENT

COL James E. Cox, Jr., MC	Air Force

OTHERS PRESENT

COL William Davies, MS	DoD Pharmacy Program Director, TMA
CAPT Patricia Buss, MC	Deputy Chief Medical Officer Representative, TMA
COL Mike Heath, MS, USA (Via VTC)	Army Pharmacy Consultant, Chairman Pharmacy Board of Directors
CAPT Betsy Nolan, MSC (Via VTC)	Navy Pharmacy Specialty Leader
COL James Young, BSC, USAF (Via VTC)	DoD Pharmacy Program Assistant Director, TMA
COL Kent Maneval, MS	Joint Readiness Clinical Advisory Board
CDR Don Nichols, MC	DoD Pharmacoeconomic Center
CDR Denise Graham, MSC	DoD Pharmacoeconomic Center
CDR Ted Briski, MSC	DoD Pharmacoeconomic Center
LtCol Dave Bennett, BSC	DoD Pharmacoeconomic Center
LtCol Barb Roach, MC	DoD Pharmacoeconomic Center
CPT Jill Dacus, MC	DoD Pharmacoeconomic Center
Shana Trice	DoD Pharmacoeconomic Center
Dave Bretzke	DoD Pharmacoeconomic Center
Angela Allerman	DoD Pharmacoeconomic Center
Eugene Moore	DoD Pharmacoeconomic Center
Elizabeth Hearin	DoD Pharmacoeconomic Center
Elaine Furmaga	Department of Veterans Affairs
Four pharmacists	Iraq Ministry of Health

3. REVIEW MINUTES OF LAST MEETING

The minutes from the last meeting were accepted as written.

4. INTERIM DECISIONS/ADMINISTRATIVE ISSUES

None.

5. NATIONAL PHARMACEUTICAL CONTRACTS AND BLANKET PURCHASE AGREEMENT (BPA) AWARDS, RENEWALS AND TERMINATIONS

A. *New Contracts Awarded* – tramadol (Caraco) and ranitidine (Golden State Medical). The Council encourages MTF pharmacies to order these products from the contracted companies.

B. *Changes to Existing Contracts*

1) The next option year was exercised for contracts on the following drugs: 35 mcg ethinyl estradiol/1 mg ethynodiol diacetate (Pharmacia/Pfizer), zolmitriptan (AstraZeneca), etodolac (Taro), hydrochlorothiazide (Ivax), and glyburide (Pharmacia/Pfizer).

2) Additional NDCs were added to existing contracts for metoprolol 50 mg (Caraco), NDC# 57664-0477-08, and tramadol 50 mg (Caraco), NDC# 57664-0377-13.

3) Contracts for insulin syringes (BD), isosorbide mononitrate (Schwarz), and capsaicin cream (Qualitest) were extended.

4) The contracts for levobunolol, timolol, prazosin, verapamil and nortriptyline have no more options years left. They will be reevaluated for resolicitation.

C. *Contracts Pending Award* – amantadine, enalapril, salsalate, and insulin

D. More information about DoD and DoD/VA national pharmaceutical contracts may be found on the Defense Supply Center Philadelphia (DSCP) DMM-Online website at http://dmmonline.dscp.dla.mil/pharm/contractlist.asp. Contract guidance for the oral fluoroquinolones, statins, leutinizing hormone releasing hormone (LHRH) agonists, and triptans are available on the PEC website at www.pec.ha.osd.mil/national_contracts.htm.

E. The Council reviewed the top 40 drug classes by MTF expenditure for FY 2003. National pharmaceutical contracts or incentive price agreements exist for medications in many of these drug classes. The remaining classes are likely targets for procurement initiatives in the future.

MTF Expenditures by Drug Class,* FY 2003**

Rank	Drug Class	$		Rank	Drug Class	$
1	Antihistamines †	$88 M		21	Metformin †	$22 M
2	NSAIDs †	$86 M		22	Leukotriene antagonists	$21 M
3	Lipotropics †	$83 M		23	Glucocorticoids	$20 M
4	SSRIs †	$64 M		24	Macrolides	$19 M
5	PPIs & H2 blockers †	$61 M		25	Antifungals	$19 M
6	Bisphosphonates †	$45 M		26	Antimalarials	$18 M
7	Calcium channel blockers†	$45 M		27	Hematinics †	$17 M
8	ACE inhibitors †	$43 M		28	Antimigraine agents †	$17 M
9	Vaccines (Hep A & B) †	$38 M		29	Beta-adrenergics (e.g., albuterol) †	$16 M
10	Anticonvulsants †	$37 M		30	Estrogenic agents †	$15 M
11	Salmeterol / fluticasone (Advair)	$31 M		31	Antipsychotics †	$15 M
12	Thiazolidinediones†	$30 M		32	Vaccines/Toxoids	$14 M
13	Quinolones †	$28 M		33	Vaccines, Gram (-) Bacilli	$13 M
14	Antiplatelet agents †	$27 M		34	Bupropion †	$13 M
15	Penicillins	$24 M		35	Miotics / intraocular pressure agents †	$13 M
16	Blood glucose diagnostics †	$24 M		36	Beta blockers †	$12 M
17	Contraceptives †	$23 M		37	Insulins †	$11 M
18	Narcotic analgesics	$22 M		38	ADHD drugs †	$10 M
19	Aqueous nasal steroids †	$22 M		39	Serotonin-norepi reuptake inhibitors	$10 M
20	ARBs	$22 M		40	Sedative/hypnotics	$10 M
Top 20 classes = $843 M 52% of total expenditures				**Top 40 classes = $1,148 M 70% of total expenditures**		

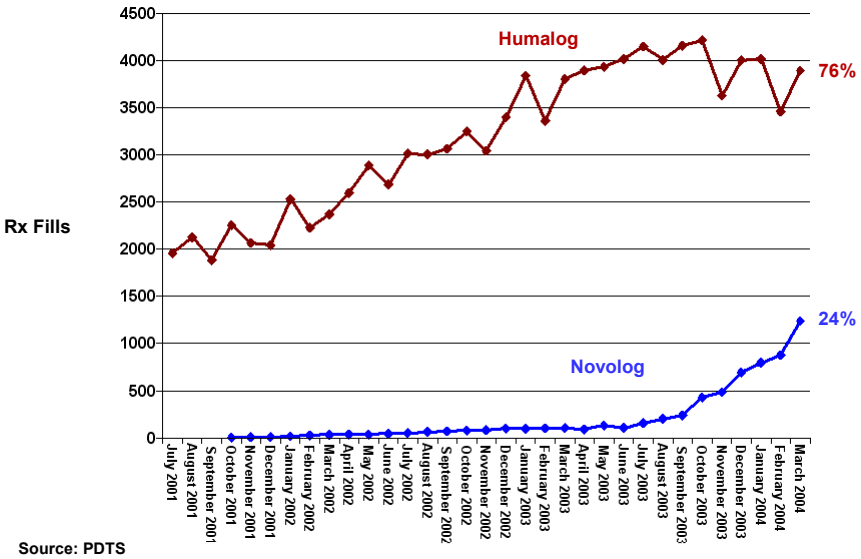
* Drug classes based on First Data Bank HIC-3 classifications

** Expenditures based on DoD Prime Vendor data. May underestimate expenditures in some drug classes, especially products not always ordered through the pharmacy prime vendor system (e.g., vaccines, blood glucose test strips)

† National pharmaceutical contracts or incentive price agreements exist.

F. The Council reviewed utilization of the rapidly-acting insulin analogue products, insulin lispro (Humalog) and insulin apart (Novolog). Due to a voluntary price reduction, Novolog costs only $17.16 per 10 mL vial while the FSS price for Humalog is $31.96 per 10 mL vial. MTFs are saving money by using Novolog rather than Humalog.

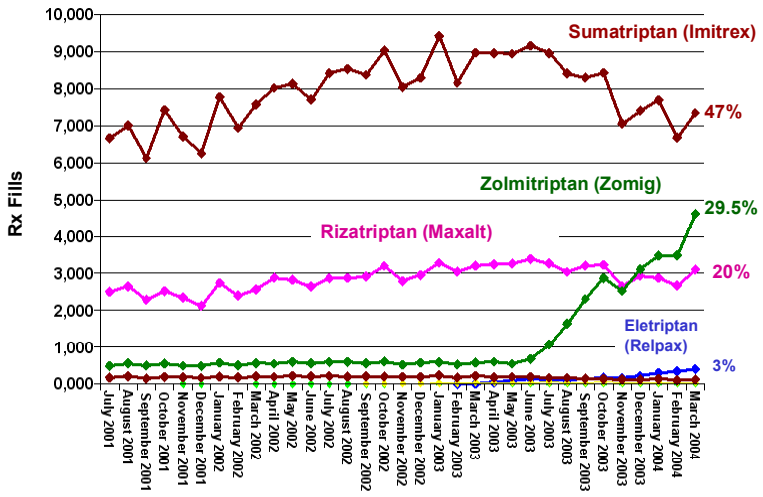
MTF Rx Fills, Humalog vs. Novolog, Jul 01 – Mar 04



Source: PDTS

G. The Council reviewed MTF utilization of the triptans and compliance with the joint DoD/VA contract for zolmitriptan. Zolmitriptan at $3.20 per tablet (contract price) costs at least 20% less than any other triptan. Zolmitriptan should be used as the first-line triptan for all new patient starts unless there is a medical necessity to use a different triptan.

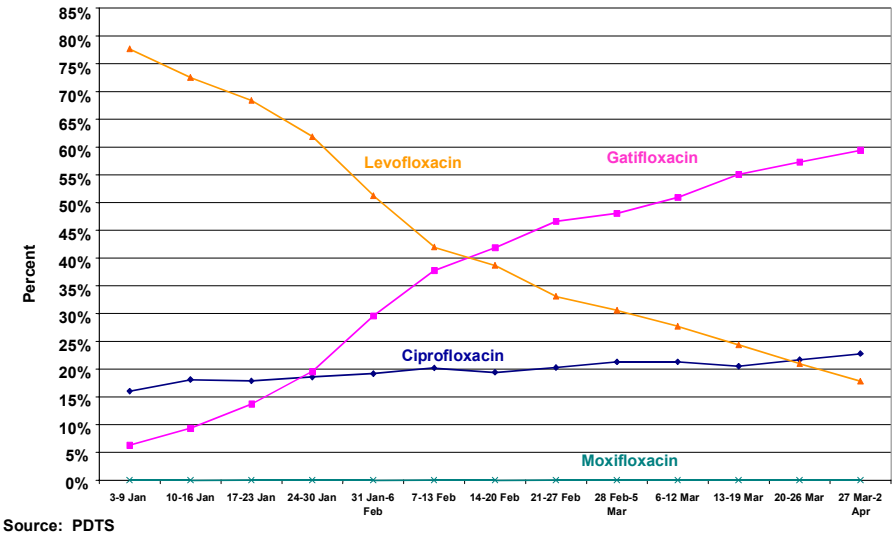
MTF Triptan Rx Fills, Jul 01 – Mar 04



Source: PDTS

H. The Council reviewed MTF utilization of the oral fluoroquinolones and compliance with the joint DoD/VA contract for gatifloxacin. Gatifloxacin is the contract oral fluoroquinolone for the treatment of community-acquired pneumonia and sinusitis. The contract price for gatifloxacin 400 mg is $1.35 per tablet, compared to the FSS price of $5.06 per tablet for levofloxacin 500 mg. The following graph shows the weekly MTF market share for each of the oral fluoroquinolones over the last 3 months. As of the week ending 2 April 2004, almost 60% of oral fluoroquinolone prescriptions were for gatifloxacin.

MTF Oral Fluoroquinolone Rx Market Shares, Weeks Ending 8 Jan 04 – 2 Apr 04



Source: PDTS

6. BCF CHANGES AND CLARIFICATIONS

A. *Long Acting Beta Agonists*

CDR Denise Graham and CPT Jill Dacus (PEC) presented an analysis comparing the long-acting beta agonists salmeterol (Serevent Diskus), which is currently on the BCF, and formoterol (Foradil). The Council considered whether formoterol should be added to the BCF and whether salmeterol should be removed from the BCF.

Efficacy/Safety/Tolerability

Formoterol is a long acting beta-2 agonist indicated for the maintenance treatment of asthma, the prevention of bronchospasm in adults and children 5 years of age and older with reversible obstructive airways disease, acute prevention of exercise-induced bronchospasm, and maintenance treatment of bronchoconstriction in patients with Chronic Obstructive Pulmonary Disease (COPD). Clinical studies have shown comparable efficacy with formoterol compared to salmeterol in the maintenance treatment of asthma and the treatment of reversible obstructive airway disease. Safety and tolerability of the two drugs appear similar.

Formoterol has a faster onset of action than salmeterol, but this may not be a significant clinical advantage since salmeterol and formoterol are not indicated for acute bronchoconstriction. Acute bronchoconstriction should be treated with a

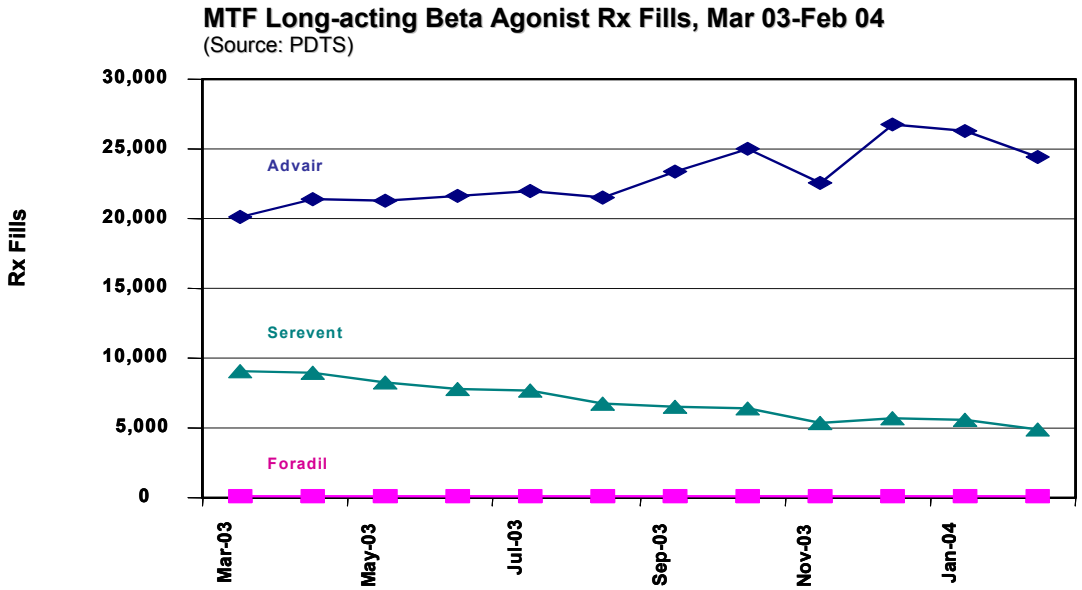
short-acting beta agonist (e.g., albuterol). Salmeterol and formoterol are typically used as adjunctive therapy with inhaled corticosteroids in patients with asthma and with ipratropium in patients with COPD.

Other Factors

- Fewer than 10% of MTFs (14/149) currently have formoterol on formulary. Salmeterol is on the BCF as a single agent (Serevent) and in combination with fluticasone (Advair).
- Patients may find the salmeterol inhaler device (Serevent Diskus) easier to use than the formoterol device (Foradil Aerolizer). Serevent Diskus is packaged as a self-contained dry powder inhaler device preloaded with 28 or 60 doses of 50 mcg of salmeterol. An indicator on top provides the number of doses remaining. Foradil Diskus is a small cylindrical device that is loaded by the patient with a capsule containing 12 mcg of formoterol and squeezed to pierce the capsule. The patient must open the device after inhaling to ensure that the entire dose was delivered. Formoterol capsules come in 12- or 60-count blister packs.
- Salmeterol may be stored at room temperature, and must be used within 6 weeks after opening the foil packet. Formoterol requires refrigeration while stored in the pharmacy, although the patient may store the product at room temperature for up to 4 months after dispensing.

Utilization

As of Feb 2004, MTFs were filling approximately 84 formoterol prescriptions per month, compared to 4,879 prescriptions per month for salmeterol. MTFs fill about 25,000 prescriptions per month for the combination salmeterol/fluticasone product (Advair).



Cost

Based on current FSS prices and recommended dosing regimens, salmeterol costs $44.57 per month compared to $32.63 per month for formoterol. The manufacturer of formoterol has offered a voluntary price reduction for formoterol to all DoD accounts at $31.50 per 60 doses regardless of BCF status. In addition they are offering a MTF based incentive agreement where MTFs can obtain a lower price in exchange for local formulary status and market share performance.

Conclusion

The Council voted unanimously not to add formoterol to the BCF. Long-acting beta agonist usage (as a single agent) is declining steadily. Formoterol may be more difficult for patients to use than salmeterol. Formoterol requires refrigeration prior to dispensing. Formoterol does not offer a significant clinical advantage over salmeterol. Although formoterol costs less than salmeterol, the Council doubted that MTFs would significantly shift usage from salmeterol to formoterol, especially in light of the overall decline in usage of long-acting beta agonists relative to the combination product (Advair). A formoterol/inhaled corticosteroid product (formoterol/budesonide) is not expected until 2006 or later.

The council voted not to remove salmeterol from the BCF in order to maintain uniform availability of a long-acting beta agonist product across MTFs.

7. ANGIOTENSIN RECEPTOR BLOCKERS (ARBS)

Bristol Myers Squibb submitted a "pre-award" GAO protest of the blanket purchase agreement (BPA) request for price quotes that the Defense Supply Center Philadelphia (DSCP) issued to pharmaceutical companies that market ARBs. Pending the resolution of this protest, the Council made no final decision regarding the addition of an ARB to the BCF.

8. SECOND-GENERATION ANTIHISTAMINES

The Claritin brand of loratadine is available through a joint DoD/VA blanket purchase agreement for $0.38 per 10-mg tablet. Generic loratadine is available at prices as low as $0.12 per 10-mg tablet and is expected to drop to as low as $0.07 per 10-mg tablet. Fexofenadine 180 mg costs $0.85 per tablet (incentive agreement price for having fexofenadine on the BCF). Fexofenadine 180 mg will likely increase to the FSS price of $1.42 per tablet if fexofenadine is removed from the BCF. The FSS price for cetirizine 10 mg is $0.96 per tablet.

At its February 2004 meeting the Council considered a proposal to remove fexofenadine from the BCF because some MTF pharmacy personnel had stated that the presence of fexofenadine on the BCF inhibits their ability to increase their use of the much less expensive loratadine. The Council voted at that time to keep fexofenadine on the BCF out of concern that MTFs may not shift enough of the market share to loratadine to offset the negative financial impact of a fexofenadine price increase. The Council did not want to remove fexofenadine from the MTF unless there was evidence that MTFs could shift more usage to loratadine.

The loratadine market share at MTFs has risen rapidly since the last meeting. Loratadine accounted for 14% of MTF prescription fills for second generation antihistamines in March 2004—nearly double the 7.5% market share that loratadine had in the first quarter of FY 2004. Loratadine accounted for over 20% of new MTF prescriptions for second generation antihistamines during the first two weeks of April 2004. An April 2004 PEC survey of 209 MTF providers indicated that 2 out of 3 would be willing to prescribe loratadine 1st line if the price was $0.10/tab or less. As of 1 May 2004, loratadine should be available from local wholesalers in bottles of 500 at $0.07/tab.

The Council reviewed several market-share and price scenarios and concluded that MTFs would likely need to achieve a loratadine market share of 25% to 32% in order to break-even financially in the second-generation antihistamine class (depending on the future prices of the second generation antihistamines and their market shares). Based on MTF performance over the last three months in shifting market-share to loratadine, the Council felt confident that MTFs will shift enough market share to loratadine to generate significant savings in this drug class. The Council voted to remove fexofenadine from the BCF, which means there is no longer a second generation antihistamine on the BCF. The BCF will now state that MTFs must have at least one second generation antihistamine on their formularies. The Council strongly encourages all MTFs to include loratadine on their formularies.

9. ADJOURNMENT

The meeting adjourned at 1730 hours. The next meeting is scheduled for 29 and 30 June at the PEC. All agenda items should be submitted to the co-chairs no later than 4 June 2004.

<signed>	<signed>
DANIEL D. REMUND	TERRANCE EGLAND
COL, MS, USA	CDR, MC, USN
Co-chair	Co-chair