South Carolina
Department of Health and Human Services
Post Office Box 8206
Columbia, South Carolina 29202-8206

Pharmacy and Therapeutics (P&T) Committee Meeting
February 2, 2005
MINUTES

1. Call To Order

A meeting of the P&T Committee convened at 4:00 p.m. on Wednesday, February 2, 2005.

2. Welcome

Mr. Kerr welcomed those in attendance and thanked the Committee for the work performed on the PDL. He also extended his appreciation to DHHS staff and representatives of pharmaceutical manufacturers for their assistance in the PDL process. He noted that the February 2, 2005 meeting marked a milestone in the initial review of PDL therapeutic classes; the final group of drug classes for inclusion on the South Carolina Medicaid PDL will be reviewed at this meeting. He noted that the Committee would now move into "maintenance mode" with the Committee providing DHHS with clinical expertise on PDL issues as well as assistance with opportunities for other projects.

Mr. Kerr also asked the Committee to provide input on the possibility of DHHS allowing the use of "specialty pharmacies" where physicians could make arrangements with pharmacies to purchase and bill Medicaid for medications administered in the physician's office.

Additionally, Mr. Kerr informed the Committee that the upcoming changes with Medicare Part D are currently under evaluation at DHHS.

Dr. LaCroix opened the meeting by stating that the P&T Committee meetings are held in compliance with the Freedom of Information Act's (FOIA) mandate that the public is notified when the public's business is being done, and that furthermore, the public has been notified that this facility is accessible to individuals with disabilities, and special accommodations could have been provided if requested in advance.

Chairperson LaCroix introduced the newest Committee members, Dr. Gregory Browning, M.D. and Dr. Kelly Jones, Pharm.D.

Committee Members Present:

J. Kevin Baugh, M.D.	Kelly Jones, Pharm.D.	Mark A. O'Rourke, M.D.
Edward M. Behling, M.D.	Jerome E. Kurent, M.D.	Thomas Phillips, R.Ph.
Gregory V. Browning, M.D.	Robin K. LaCroix, M.D.	Deborah J. Tapley, R.Ph.
Joseph A. Horvath, M.D.	James M. Lindsey, M.D.	Harry H. Wright, M.D.

Committee Members Absent:
Matthew K. Cline, M.D.
Albert Humphrey, M.D.
George E. Vess, Pharm.D.

DHHS Staff Present:

Robert Kerr	Byron Roberts, J.D.
James Assey, R.Ph.	Caroline Sojourner, R.Ph.
Marion Burton, M.D.	Linda Van Hoose

Other Representation:
First Health Services Corporation – Mary Roberts, R.Ph., Danielle Stroup

Pharmaceutical Industry Representatives

5. Discussion Topics

A. Committee Meeting Minutes, Wednesday, December 1, 2004.

Minutes from the previous P&T Committee meeting were approved.

B. General Issues

Dr. LaCroix advised the speakers that presentations are limited to three (3) minutes in duration. Dr. LaCroix reminded attendees that information regarding a speaker's name, title, credentials, or curriculum vitae should be submitted to DHHS no later than seven (7) days prior to the meeting date.

C. Public Comment

The following speakers discussed the drugs listed below:

	Company	Speaker	Drug
1)	Janssen	Richard Druckenbrod, Pharm.D. Regional Medical Services Manager, Janssen Medical Affairs	Reminyl®
2)	Novartis	W. Andrew Johnson, III, M.S. Novartis Regional Scientific Director for Gulf States	Exelon®
3)	Pfizer	Walter J. Evans, M.D. Practicing neurologist with Comprehensive Neurological Services, Florence, S.C. Assistant Clinical Professor, Neurology, Medical University of South Carolina	Aricept®

	Company	Speaker	Drug
4)	Novartis	Raymond E. Lancaster, Pharm.D. Novartis Associate Director of Regional Scientific Operations, Specialty-Internal Medicine, Cardiovascular, Infectious Disease and Pharmacokinetics	Elidel®
5)	GlaxoSmithKline	Mark G. Buchanan, M.D., Urologist, Charleston, S.C.	VESIcare®
6)	McNeil Consumer & Specialty Products	Andrew Chen, M.S. Manager, Medical Affairs, Ortho Urology	Ditropan XL®
7)	Novartis	Raymond E. Lancaster, Pharm.D. Novartis Associate Director of Regional Scientific Operations, Specialty-Internal Medicine, Cardiovascular, Infectious Disease and Pharmacokinetics	Enablex®
8)	Pfizer	Ross Alan Rames, M.D., MUSC Urology Services, Charleston, S.C.	Detrol LA®

Following the period of public comment, Dr. LaCroix thanked each speaker for his or her individual presentation. Dr. LaCroix also reminded Committee members of the requirement to disclose any potential conflicts of interest at this time, prior to discussion of PDL selections.

D. <u>PDL Discussions And Selections For The Following Drug Classes</u>

Mary Roberts, R.Ph., First Health Corporation led the discussion for the following drug classes:

Alzheimer's Agents – Cholinesterase Inhibitors

Onychomycosis Antifungals

Urinary Tract Antispasmodics

Herpes Antivirals

Topical Immunomodulators

The P&T Committee agreed to submit the following recommendations to DHHS:

No PA Required "Preferred"	PA Required
ALZHEIMER'S AGENTS CHOLINESTERASE INHIBITORS	
Aricept® Exelon® Reminyl®	Cognex®
HERPES ANTIVIRALS ORAL AGENTS	
Acyclovir Famvir® Valtrex®	Zovirax®
ONYCHOMYCOSIS ANTIFUNGALS ORAL AGENTS	
Gris-Peg® Grifulvin V® Lamisil®	Sporanox®
TOPICAL IMMUNOMODULATORS	
Elidel® Protopic®	
URINARY TRACT ANTISPASMODICS	
Detrol LA® Enablex® Oxybutynin Oxytrol®	Detrol® Ditropan® Ditropan XL® Sanctura® VESIcare®

6. Old Business

None.

7. New Business

A. Criteria for Re-review of Therapeutic Classes:

The Committee agreed that previously reviewed therapeutic classes from those PDL phases subject to re-review may be opened for re-review if one or more of the following has occurred:

a) New drug in the therapeutic class.
b) New indication for an existing drug in the therapeutic class.
c) New FDA-approved study or three peer-reviewed studies for a drug in the therapeutic class.

DHHS and First Health will examine the therapeutic classes from Phases 1, 2, and 3 to determine which classes meet the criteria and are therefore eligible for re-review at the next P&T Committee meeting.

B. General Discussion:

1) PDL Process - Discussion was held regarding the general PDL process and the P&T Committee's role in the PDL recommendations. As mentioned earlier, it was noted that the final group of drug classes for PDL inclusion were reviewed at this meeting. It was mentioned that it would be time-consuming and redundant to have all therapeutic classes re-reviewed. Therefore, it is prudent to use the re-review criteria to determine which classes will be opened for re-review. It was decided that the re-review criteria would be used.
2) Expert clinicians - A member discussed the value of having expert clinicians provide input for certain drugs such as the procedure followed for glaucoma drugs. At the time of that review, ophthalmologists were asked to evaluate and provide recommendations to the P&T Committee. No decisions were made on this discussion item.
3) Correspondence - Another member discussed the amount of correspondence being received from physicians and industry in regard to the pros and cons for certain drugs being considered for the PDL. Other members agreed that much information was being provided. No decisions were made on this issue.
4) Long Term Care Facilities - A member expressed concern about drug utilization in long term care facilities. Another member suggested that perhaps there were methods for changing practices without being enforcers. Discussion was held regarding the possibility of creating a website for treatment guidelines. It was suggested that a website could include "best practice" drugs for long term care patients. No decisions were made.
5) Disclosure - Discussion was held regarding whether speakers prior to their presentations should provide full financial disclosure. No decisions were made on this issue.
6) ARB's – Discussion was held regarding the need to re-review ARB's due to this class' impact upon stroke prevention. A member suggested use of a cost-averaging approach in making PDL recommendations. Discussion was then held regarding the Committee's direction from DHHS that P&T members examine clinical issues only. It will be determined if ARB's meet criteria and should be re-reviewed.

8. Resolved Items

Recommendations regarding PDL status for drugs in the following drug classes were approved for submission to DHHS:

Alzheimer's Agents
Herpes Antivirals
Onychomycosis Antifungals
Topical Immunomodulators
Urinary Tract Antispasmodics

9. Unresolved Items

None.

10. Closing Comments

Dr. LaCroix thanked the Pharmacy Association for hosting the P&T Committee meeting and announced that the next P&T Committee meeting will be held at the South Carolina Pharmacy Association office on Wednesday, May 4, 2005.

11. Adjournment

The meeting adjourned at 6:30 p.m.