

**Preferred Drug List Committee Meeting
Meeting Minutes, Open Session
September 14, 2011**

<p>Preferred Drug List Committee Meeting Minutes, Open Session HP Enterprise Services Capital / Cedar Crest Room Topeka, KS</p>	<p>Members Present: Michael Burke, M.D, Ph.D., Chair Robert Haneke, Pharm.D. Glenn Harte, Pharm.D. Landa Colvin-Marion, M.P.H., Pharm.D. Donna Sweet, M.D. Matthew Schlotterback, M.D.</p> <p>KHPA Staff Present: Kelley Melton, Pharm.D. Shelly Liby Shea Robinson Dr. Margaret Smith</p> <p>HP Staff Present: Nicole Churchwell, Pharm.D. Karen Kluczykowski, R.Ph. Lisa Todd, R.Ph.</p> <p>ACS Staff Present: Bethany Noble, C.Ph.T</p>	<p>Representatives: Nick Boyer - AstraZeneca Jim Graham - J & J Derek Terada - Boehringer-Ingelheim Julie McDavitt - Boehringer-Ingelheim Barbara Felt - GlaxoSmithKline Diptesh Patel - GlaxoSmithKline Katie Klockarr – KU Student Phil King -Pfizer Jeff Knappen - Allergan Scott Maurice - Boehringer-Ingelheim Joe Summers - Takeda Matthew Stafford -Merck Teresa Blair - Amgen Jim Bauman - Pfizer Jared Lurk - Novartis</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>I. Welcome and Announcements</p>	<p>Dr. Haneke called the meeting to order at 10:03 am. Dr. Burke attended the meeting by phone. Dr. Melton provided general parking instructions for those in attendance, advised attendees of the five minute limit per drug for Public Comments, and requested that a Conflict of Interest Disclosure form be completed by those individuals planning to speak. Dr. Melton introduced herself to the PDL Board. She also introduced Bethany Noble, Affiliated Computer Services (ACS). Bethany manages the recently implemented SMART PA program. Dr. Landa Colvin-Marion was introduced as our new PDL Board member.</p>	
<p>II. Review and Approval of Feb. 17, 2010, Meeting Minutes</p>	<p>The draft minutes from the Feb. 17, 2011, meeting were reviewed and approved as written.</p>	<p>Dr. Sweet moved to approve the minutes.</p> <p>Dr. Harte seconded the motion.</p> <p>The motion carried unanimously.</p>

<p>III. Bisphosphonates - (Class previously Reviewed; New Agent in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: There is a new agent in this class approved by the FDA in October 2010, Atelvia (risendronate). Risendronate is already available for the treatment of osteoporosis under the trade name Actonel. The Bisphosphonate class was last reviewed August 2006, and also in February and June of 2005. The committee found all drugs in this class to be equivalent at all three meetings.</p> <p>Public Comment: No comments.</p> <p>Board Discussion: Dr. Haneke asked if there were any drug representatives at the meeting that would like to speak on behalf of Atelvia</p> <p>Dr. Sweet suggested for the purposes of this committee, these drugs continue to be considered clinically equivalent.</p>	<p>Dr. Sweet made a motion to continue considering these drugs equivalent.</p> <p>Dr. Burke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>IV. Ophthalmic Antihistamine/Mast Cell Stabilizers – (Class previously reviewed; New Agent in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: In July of 2010, the FDA approved alcaftadine (Lastacaft), a new agent in this therapeutic class. This class was first reviewed at the previous PDL meeting on June 2, 2010 and the agents in this class were found to be clinically equivalent.</p> <p>Public Comments: No comments.</p> <p>Board Discussion: Dr. Sweet was impressed by how quickly the class is expanding. She saw nothing in the literature that suggests one is superior over the other.</p>	<p>Dr. Sweet made a motion to consider the new agent as previously considered equivalent in this class.</p> <p>Dr. Harte seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>V. Triptans – (Class Previously Reviewed; New Agents in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: There are three new products for the subcutaneous delivery of sumatriptan now available –Alsuma, Sumavel DosePro, and Imitrex StatDose. This class was last reviewed in June of 2008, and it was found that all Triptans were clinically equivalent, with the exception of combination products such as Treximet (sumatriptan/naproxen).</p> <p>Public Comment: No comments.</p> <p>Board Discussion: Dr. Schlotterback asked if it's the same medicine but different delivery method. Basically, it's a needle free injection.</p>	<p>Dr. Sweet made a motion that these agents be considered clinically equivalent.</p> <p>Dr. Burke seconded the motion.</p> <p>The motion carried unanimously.</p>

	<p>Dr. Melton mentioned in the past new dosage forms haven't necessarily been brought to PDL for review, but in this case the Alsuma is a little different in how it functions. Dr. Sweet asked if we were looking at adding the new injectable agents to the sumatriptans. Dr. Melton confirmed that was correct. Dr. Sweet suggested we continue to use the sumatriptans and consider them clinically equivalent. Dr. Burke clarified that Sumavel is clinically equivalent to the Imitrex brand of sumatriptan.</p>	
<p>VI. Antiemetics - (5-HT3) Receptor Antagonist) – (Class Previously Reviewed; New Agent in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: In June 2010, the FDA approved a new product in this class, Zuplenz (ondansetron orally dissolving film). This class was last reviewed in June 2009, and at that meeting it was found that all antiemetics were clinically equivalent. This class was also reviewed in 2008 and 2006.</p> <p>Public Comments: No Comments</p> <p>Board Discussion: Dr. Sweet noted the form may be appropriate for a few people, but one could get that through very easily.</p>	<p>Dr. Sweet made a motion that Zuplenz is clinically equivalent to the other drugs in the class of 5-HT3 receptor antagonists.</p> <p>Dr. Schlotterback seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>VII. NSAIDs – (Class Previously Reviewed; New Agent in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: An NSAID overlooked in previous reviews (diflunisal (Dolobid)) has been included for review. The NSAID class was reviewed in 2002, 2004, and 2009; all agents were determined clinically equivalent. The class was last reviewed in June 2010, at which time the PDL Committee determined that Topical NSAIDs (diclofenac drops, patch, and gel) should be in a separate class.</p> <p>Public Comments: No Comments</p> <p>Board Discussion: Dr. Sweet asked if we were looking at the old diflunisal. Dr. Melton responded that it was included in order to get a comprehensive review by the committee with all the materials available.</p> <p>Dr. Haneke added that this NSAID is a little different but Dr. Sweet said it was clinically equivalent.</p>	<p>Dr. Sweet made a motion to that diflunisal is clinically equivalent to the other products in NSAIDs class.</p> <p>Dr. Harte seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>VIII. Fixed Dose Combination Products for Arthritis – (Class Previously Reviewed; New Agent Class)</p> <p>a. Public Comment</p>	<p>Background: The Fixed Dose Combination Products for the Arthritis Class was created at the February 2011 PDL Meeting. At that time, Vimovo (naproxen/esomeprazole) was deemed clinically equivalent to its individual agents. Prior to this, at the June 2010 meeting, Vimovo was</p>	<p>Dr. Harte made a motion that Duexis is clinically equivalent to the co-use of its individual components.</p>

<p>b. Committee Discussion and Recommendations</p>	<p>approved as a part of the NSAID class. To be considered today is Duexis, a fixed-dose combination of famotidine and ibuprofen approved by the FDA in April of 2011.</p> <p>Public Comments: No Comments</p> <p>Board Discussion: Dr. Sweet wanted to know what we did with Vimovo. Dr. Melton responded it is currently in a fixed dose class for arthritis.</p> <p>Dr. Burke added the combination offers no advantage.</p>	<p>Dr. Sweet seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>IX. Topical NSAIDs – (Class Previously Reviewed; New Agent in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: In May 2010, the FDA approved a new NSAID - Sprix (ketorolac nasal spray). In June 2010, the PDL Committee determined that Topical NSAIDs (diclofenac drops, patch, and gel) should be in a separate class. Prior to this, they had been approved for inclusion in the NSAID class at the June 2009 meeting.</p> <p>Public Comment: Phil King (Pfizer) stated, currently the only preferred agent is the gel (Voltaren). He asked the committee to share their views on the clinical equivalence of those agents. He didn't know if that had been established previously.</p> <p>According to Dr. Burke, in June 2010, the PDL determined topical NSAIDs should be in a separate class.</p> <p>Dr. Melton read the June 2010 minutes in which Dr. Sweet moved to separate the NSAID category by delivery system into the topical NSAID and oral NSAID classes. Dr. Sweet made a new motion, to determine that all topical delivery NSAIDs are clinically equivalent for analgesia. Dr. Haneke seconded the motion and the motion passed by unanimous vote.</p> <p>Phil King wanted to make sure the PDL committee ruled on the equivalency standards so the state can entertain bids. Dr. Melton confirmed that this had been done in a previous meeting.</p> <p>Board Discussion: Dr. Burke asked if the nasal solution is transdermal, is this the best place for Sprix to be? Dr. Sweet added that it is a topical. Dr. Schlotterback stated that maybe Sprix should be moved to the oral Ketorolac. Dr. Melton mentioned oral Ketorolac is a part of the oral NSAID class and we don't have an injectable Ketorolac because the PDL refers to outpatient dispensing and it won't be dispensed as outpatient. Do</p>	<p>Dr. Sweet moved to consider Sprix clinically equivalent.</p> <p>Dr. Schlotterback seconded the motion.</p> <p>The motion carried unanimously.</p>

	<p>we want to fit in with where oral Ketorolac is,? Dr. Haneke asked if we are looking at a gel that is used topically for inflammatory pain.</p> <p>Dr. Sweet thinks it should stay in the Topical NSAIDs and utilization can be monitored.</p> <p>Dr. Melton mentioned there is a 5 day supply limit.</p>	
<p>X. Adjunct Antiepileptics – (Class Previously Reviewed: New Agents in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: Potiga (ezogabine), a new antiepileptic to be used as an add-on medication to treat seizures associated with epilepsy in adults, was approved by the FDA in June of 2011. The adjunct antiepileptics were last reviewed in June of 2009, when Vimpat (lacosamide), Banzel (rufinamide), and Keppra XR (levetiracetam XR) were determined to be equivalent to existing members of this class. The class was established in February of 2006.</p> <p>Public Comment: Barbara Felt, GSK, stated Potiga was approved on July 10, 2011. The FDA requested the drug be scheduled, so right now the FDA is reviewing the medication and determining what classification the drug will go into. Once that process is complete, the package inserts and packing information will be finalized and the drug will be available for use. There are no head to head trials at this time.</p> <p>Dr. Melton had a meeting with the GSK representatives last month. They did tell her the drug will be scheduled and that it should not be discussed yet because it's not on the market yet. We did find an example, pitavastatin (Livalo), which was approved for the PDL before it was on the market so there is precedent that we have done that before. Dr. Sweet asked why Potiga is being controlled. Barbara Felt, GSK, stated this product doesn't have a package insert yet and no finalized prescribing information because of the potential controlled substance. That may be a difference between this drug and other previous agents reviewed. In the terms of controlled substance, if a medication crosses the blood brain barrier and has been shown in studies to cause euphoria-related adverse events, then via the Control Substances Act, it needs to be evaluated for potential scheduling. When that happens, you have to do two things: (1) The sponsor has to do a drug abuse liability study. That has been completed and it didn't show a difference when compared to alprazolam or Keppra. There was a difference versus placebo but no difference between those two drugs. (2) The second thing that the DEA has to do is an eight</p>	<p>Dr. Sweet motioned to table Potiga until the package insert is available.</p> <p>The motion was seconded by Dr. Harte.</p> <p>The motion carried unanimously.</p>

	<p>factor analysis.</p> <p>Barbara Felt added the package inserts are not available for Potiga and won't be until the finalized package insert is available for review.</p> <p>Dr. Harte suggested we table the motion until we have the package insert.</p>	
<p>XI. DPP-4 Inhibitors-(Class Previously Reviewed; New Agent in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: Established in December of 2009, the DPP-4 Inhibitors class already includes Januvia (sitagliptin) and Onglyza (saxagliptin). With the May, 2011 approval of Tradjenta (linagliptin), this class is up for re-review.</p> <p>Public Comments: Derek Terada, Boehringer-Ingelheim, informed the board that Tradjenta is available as a single dose 5mg tablet; it can be administered with or without food. It's the only DPP-4 Inhibitor that does not require a dosage adjustment for patients with renal impairment. The dosage is also independent of Body Mass Index, weight, age, gender or ethnicity. As far as a comparative head to head study, at this moment, no head to head studies exist. However, they do have a head to head comparative study in a non-inferiority active control trial against glimepiride in patients with inadequate glycemic control despite the fact they were on background metformin therapy. In that trial, in a prespecified 52 week interim analysis, both treatment groups had a decrease in A1c from baseline. With Tradjenta they found a decrease of about .4%, with glimepiride it was a decrease of about .6% from baseline. That view of the mean treatment difference of plus .2% of glimepiride. However, if you look at the upper bound of the 97.5% of the confidence interval of the difference between treatment groups, it was less than the prespecified non-inferiority margin of 3.5% so in actuality it met the non-inferiority criteria. In that study also, patients on Tradjenta experienced a significant weight loss of 1.1kg versus a significant weight gain of 1.4kg with glimepiride. There were also significantly fewer episodes of hypoglycemic events on Tradjenta; 5.4% versus 31.8% with glimepiride. Some safety information - although the drug can be given with an insulin secretagogue, the dose of insulin secretagogue may have to be decreased to reduce the risk of hypoglycemia when concomitantly given with Tradjenta. Pancreatitis has been reported as one patient case per 538 patient years with Tradjenta on therapy versus none per 433 patient years with the comparator. The only other significant drug interaction is that the efficacy of Tradjenta may be decreased when it is given concomitantly with a strong Pglyco protein. Or CYP 3A4 inducer, as tested by use with rifampin. The board had no</p>	<p>Dr. Sweet motioned to continue to consider all agents in this class clinically equivalent.</p> <p>The motion was seconded by Dr. Burke.</p> <p>The motion carried unanimously.</p>

	<p>questions for Mr. Terada.</p> <p>Board Discussion: Dr. Sweet commented that comparing this drug to sulfonyleureas and saying it's less toxic doesn't tell her anything and it needed to be compared to the other two in the class, which there is no significant difference in the three drugs. She feels duped when people tell her it's better than sulfonyleureas as though we don't know that already. It is not inferior. She continues to consider them clinically equivalent.</p>	
<p>XII. ARBs – (Class Previously Reviewed; New Agent in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: In February the FDA approved Edarbi (azilsartan), a new Angiotensin II Receptor Blocker. A re-review of this class of agents was done in March 2007. At that time, it was determined that all formulations of ARBs are clinically equivalent, and all combination ARBs are equivalent to single agents and HCTZ when taken in combination. Prior to that the class was reviewed in October 2004.</p> <p>Public Comment: No Comments</p> <p>Board Discussion: Dr. Harte commented that it falls in the category of clinically equivalent as the ones that fall before it.</p>	<p>Dr. Harte motioned to consider Edarbi clinically equivalent.</p> <p>The motion was seconded by Dr. Sweet.</p> <p>The motion carried unanimously.</p>
<p>XIII. Inhaled Beta 2 Agonists – Long-Acting (Class Previously Reviewed; New Agents in Class)</p> <p>a. Public Comments</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: Two Long-Acting Beta Agonists are available for potential inclusion in this class: Brovana (arformoterol), approved in October 2006, and Arcapta (indacaterol), approved in July 2011. This class was established in March of 2007.</p> <p>Public Comments: No Comments</p> <p>Board Discussion: Dr. Sweet could not find anything that made them different than what is currently available.</p>	<p>Dr. Sweet motioned to consider Brovana and Arcapta as clinically equivalent.</p> <p>The motion was seconded by Dr. Burke.</p> <p>The motion carried unanimously.</p>
XIV. Open Public Comment	There were no additional Public Comments.	
XV. Discussion of the Public Comment Policy	Dr. Melton introduced the Wyoming Pharmacy and Therapeutics (P&T) Committee Public Comment Policy. The policy was bought up in a discussion with manufacturers. The manufactures are not allowed to tell us anything unless we ask. They are only allowed to tell us what is published, which are package inserts, and the board already receives in advance of meetings. Wyoming posts their agenda a month in advance and representatives have two weeks to submit studies of head to head clinical trials as well as any evidence that is contrary to what they want the	.

	<p>committee to consider. At the meetings, the representatives can only discuss studies that have been submitted to the board in advance, so the board can review it. The public comments are limited to three minutes. This process is working well for Wyoming - it cuts down on reading package inserts and manufactures are happy because they can discuss their studies without the committee asking at the beginning of every meeting. They haven't had an issue with the time limits because the board had time to look over the materials prior to the meeting. Dr. Melton asked the committee for their thoughts on this potential policy change?</p> <p>Dr. Harte thinks it sounds great. The last thing the committee wants to hear is regurgitation of the package inserts because committee members are familiar with it. What is needed is head to head or any data distinguishing that the drug as not being clinically equivalent to another drug in that class.</p> <p>Dr. Melton informed the drug manufacturer representatives that copies of the Wyoming policy were available for review and their feedback would be appreciated.</p> <p>Jim Baumann, Pfizer, stated that three minutes may be a little lean based on the questions asked. When it comes to comparative studies, he didn't hear anything about safety or side effects and would hope those things are looked at when the package inserts are reviewed. His other comment was about the public comment request form. He read it a couple of times and stated the pharmaceutical manufacturers are not required to do this. He would like to see the PDL committee and DUR Board members answer all the questions as well to make this a transparent process, everything needs to be out on the table.</p> <p>Dr. Melton stated the way the three questions Wyoming has written is fair and open ended. If the question is if the drug clinically equivalent, it will cover side effects and if the question is about taking another form of action, manufacturers can present anything that is related to that action and would be valuable for the committee to know.</p> <p>Barbara Felt, GSK, attends the Wyoming meetings. She stated there are actually two forms. This is the form for the non-PhRMA people who want to present to the board. There is another form that has the three questions that Dr. Melton presented. It's a form that the PhRMA companies have to</p>	
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	<p>use. The forms are posted on their website.</p> <p>Dr. Sweet advised these forms are for the doctors that have been solicited by PhRMA to come. She's not sure she'd need to have this form filled out but the committee has always asked and that's what the conflict of interests is. She stated that those individuals need to indicate who's paying them to be here and why they are here. She's personally not sure this form is necessary because she feels this is what the conflict of interest form does.</p> <p>Dr. Melton asked Dr. Sweet to clarify if she liked the questions but not the form. Dr. Sweet responded that she did like the questions. She understands what the form is about but thinks the Conflict of Interest form has worked well with PhRMA over the years. She doesn't think another barrier should be put up; the committee just wants to know who is paying the representatives to attend the meetings.</p> <p>Dr. Haneke added that the PDL committee members have to fill out a confidentiality form every year although he doesn't know if that form is publically available.</p> <p>Dr. Harte mentioned he doesn't mind the five minute time limit for the public comments portion; we've never held anyone to that. If you need to go over, the committee has been cordial.</p> <p>Phil King, Pfizer, said from an FDA stand point the manufacturers cannot go into any off label information that is outside the package insert unless it is an unsolicited request. Manufacturers will need to work with the committee to make sure the language is okay. Whenever that request comes out 30 days in advance, it allows the capability fulfill those needs. Making that change is a very important piece going forward. Mr. King also stated that some package insert standards will still have to be adhered to so he asks for the board's patience in providing this required information.</p> <p>Dr. Haneke asked Phil King if a there was a form that solicited certain studies, could you or your clinical person present the study? If so, then it could be decided by the committee. That may provide an avenue for the manufacturers to provide the information.</p> <p>Phil King responded that if the request is unsolicited then committee</p>	
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	<p>members can request whatever depth of information that is necessary.</p> <p>Barbara Felt, GSK, added she is on the research and development side of the business. The FDA rules are manufacturers cannot share anything off label proactively. That information has to be asked for.</p> <p>Dr. Melton asked Barbara Felt how does that works for GSK in Wyoming. She responded that the way they structured the questions are nice. The first question is, what are you asking us to do? The second question is about data that would support making that change, whatever it is. The way Wyoming worded the questions are broad and allows them to submit lots of different types of information, the goal is still the same. The third question is really good, what's the data that would say that that's not the case? The difficulty from their end is that it has to go through a legal process, so anything sent out has to have legal approval. They get a week turnaround time.</p> <p>Dr. Melton stated as she understands it, they post their agenda a month before the meeting and they want the data two weeks in advance of the meeting. Barbara Felt, GSK said it's been about three weeks in advance and then they want the information back two weeks before the meeting. They have seven to ten days to get the information in. It's a little tough to do.</p> <p>Dr. Burke asked if a phrase should be added that will permit the industry representatives to provide more information than they have seen on a website. They will still need to sign a conflict of interest form. He doesn't have any opposition to adding a few sentences that say we are interested and any information that will help clarify the uniqueness of the products being evaluated at the next meeting. He feels like the language should be broad and asked the other committee members is they had a problem with that approach. Dr. Haneke recommended that Dr. Melton and Dr. Churchwell develop some language and do a pilot.</p> <p>Dr. Melton suggested we use Wyoming's three questions but also add a fourth question specific to head to head trials? Several manufacturer representatives discussed whether these three questions would be specific enough to be able to allow them to provide this information. Dr. Burke stated that the considerations are focused on the label indications but head to head comparisons come up repeatedly.</p>	
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	<p>Dr. Melton and Dr. Churchwell will look into this. They will present the working documents to the PDL committee and DUR board.</p> <p>Dr. Melton asked what the committee thought about the Wyoming Policy for contacting P & T Committee Members. It limits the contact a PhRMA representative can make with a board member. Dr. Haneke stated in the last few years the PhRMA personal contacts are null. The committee members confirmed there is no need for this. They can work with the first page of Wyoming's Public Comment Policy and then our current conflict of interest statement. Dr. Haneke suggested the policy be worked on and brought back for review.</p> <p>Dr. Melton reminded everyone that provided public comments to fill out a conflict of interest form.</p>	
<p>XVI. Adjourn</p>	<p>The meeting adjourned.</p>	<p>Dr. Harte motioned to adjourn the meeting.</p> <p>The motion was seconded by Dr. Burke.</p> <p>The motion carried unanimously.</p>