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**Minutes of the Drug Formulary Commission**

**Meeting of Thursday, May 18, 2017**

Henry I. Bowditch Public Health Council Room, 2nd Floor

250 Washington Street

Boston, MA 02114

**Date of Meeting:** **Thursday, May 18, 2017**

**Beginning Time:** 9:05 AM

**Ending Time:** 11:15 AM

**Advisory Council Members Present:** The following (14) appointed members of the Drug Formulary Commission attended on December 15, 2016, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Bureau of Health Care Safety and Quality Director Eric Sheehan (Chair); Dr. Shihab Ahmed, Dr. Douglas Brandoff; Dr. Daniel Carr; Dr. Joanne Doyle-Petrongolo; Stephen Feldman; Dr. Kenneth Freedman (9:10AM); Dr. Paul Jeffrey; Logan Leslie; Tracey McMillan; Dr. Jeffrey Supko; Cindy Steinberg; Dr. Theoharis Theoharides; and Dr. Alexander Walker.

**1. Welcome and Introductions**

Eric Sheehan called the meeting to order at 9:05AM

Mr. Sheehan thanked everyone for being here today, and reminded everyone that the meeting was being recorded. He then asked if anyone was recording, receiving no affirmative response.

Mr. Sheehan began the meeting by recapping the March 20th meeting. At this meeting, the Commission approved Troxeca ER as an Interchangeable Abuse Deterrent (IAD) drug product, and reviewed and scored the ADP Efficacy of the drug product. The Commissioner also had an opportunity to discuss the CHIA Benefits Review, which is now online at their website; and Commission staff presented the timeline for continued review of the proposed amendments to 105 CMR 720, including the first draft formulary.

Next, Mr. Sheehan called for approval of the minutes from the March 20, 2017, meeting. Dr. Doyle-Petrongolo requested revision to her comment on page 5 on training and education of the regulatory requirements. Dr. Jeffrey asked that “Mr. Tyson Thompson” but changed to “Dr. Tyson Thompson”.

* Motion to Approve: Dr. Jeffrey
* Second: Mr. Feldman
* All in favor: 12; Opposed: 0; Abstentions: Ms. Steinberg

**2. IAD Drug Product Evaluations**

Mr. Sheehan introduced the next agenda item. In September 2016, the Commission began the task of evaluating more drug products for the second abuse deterrent formulary by approving Xtampza ER as an Interchangeable Abuse Deterrent (IAD). The Commission then approved Troxyca ER as an IAD drug product. At today’s meeting, the Commission will continue with this process by presenting Morphabond ER® and Arymo ER®.

To do this, the Commission will revisit Component 2 to evaluate its claims of ADP technology using the approved monograph. The Commission does not need to revisit Component 1 again, as its vote on October 15, 2015, to include all Schedule II and III opioids on the Heightened Public Health Risk (HPHR) list, allows all new opioids to automatically be placed on the HPHR opioid list upon FDA approval, until approved as IAD drug products by the Commission.

Dr. Tyson Thompson gave a presentation on Morphabond ER®. Following the presentation, there was discussion by the members.

Dr. Ahmed asked if the peak plasma is unusual. Dr. Thompson noted that it was not unusual and it is similar to MS Contin®.

Ms. Steinberg asked if the food effect was noteworthy. Dr. Thompson noted that at peak, there is a 33% higher impact but overall exposure shows that not a concern that would warrant additional direction to the patient.

Mr. Sheehan requested a motion to approve Morphabond ER® as an IAD Drug Product.

* Motion to Approve: Dr. Theoharides
* Second: Ms. Steinberg
* All in favor: 13; Opposed: 0; Abstentions: 0

Mr. Tyson Thompson gave a presentation on Arymo ER®. Following the presentation, there was discussion by the members.

Dr. Jeffrey asked if this is the first time the Commission has seen this study on smoking. Dr. Thompson noted that it is not the first time. The dossier showed everything that they did. Dr. Jeffrey asked why the manufacturer may have felt obligated to include it. Dr. Thompson responded that it may not be an issue of obligation but just that other manufacturers may not put it in there.

Dr. Ahmed asked about the drug’s efficacy compared to other existing drugs. Dr. Thompson noted that these drugs did not have to do a phase 3 clinical trial and could compare to MS Contin®.

Mr. Sheehan requested a motion to approve Morphabond ER® as an IAD Drug Product.

* Motion to Approve: Mr. Feldman
* Second: Dr. Walker
* All in favor: 13; Opposed: 0; Abstentions: 0

Next, Mr. Sheehan noted that while Morphabond ER® and Arymo ER® are the only newly approved drug products to be presented today, there are several others that may be ready for presentation in the coming months:

* FDA Approved products include Vantrela ER® and RoxyBond®
* Drugs in development tentatively include Egalet-002, KP201/IR, NKTR-181

Dr. Carr asked why a drug would do a phase 3 study. Dr. Thompson noted that the information came off of the manufacturer’s website.

**3. Chemically Equivalent Substitutions**

Next, Mr. Sheehan stated that with two approved IAD Drug Product, DFC staff will also present the ADP Efficacy evidence and crosswalk data for the Commission’s consideration of potentially Chemically Equivalent Substitutions.

Both of the IAD Drug Products include Morphine ER as their active ingredient. Like Embeda ER, which is listed on the formulary, there are five non-abuse deterrent Morphine ER drug products available as substitutes for these IAD Drug Products.

Mr. Sheehan reminded the Commission of the process and considerations under the law. He reviewed the definition the Commission drafted to guide its determination whether an IAD Drug Product is a Chemically Equivalent Substitution and went over the statutorily mandated criteria that must be considered in this determination. Mr. Sheehan also reviewed the cost impact method.

The Commission took a break at 9:35AM and came back into session at 9:48AM.

Dr. Thompson presented the ADP Efficacy of Morphabond ER® and information for consideration of the drug as a Chemically Equivalent Substitute. Following the presentation, there was discussion by the members.

Dr. Carr stated that the evaluation includes aspects that were not part of other comparisons and he thinks it’s a good idea. Dr. Thompson noted that he didn’t recall the other morphine drugs doing this evaluation but it certainly is relevant.

Mr. Feldman stated that we haven’t defined at which point something is cost prohibitive, right? Dr. Thompson noted that it is his understanding that the Commission has not defined this term.

Ms. Lauren Nelson reminded the Commission that it approved Embeda with similar cost impacts.

Dr. Ahmed asked where the number of usage come from and how the cost was calculated. Dr. Thompson explained that it comes from the Prescription Monitoring Program (PMP) and the cost was based on straight cost of the medication since it would be difficult to look at it from a co-pay perspective. We are looking at the cost to system versus cost to patient.

Dr. Jeffrey stated that the estimate is based on pricing as reported by manufacturer- not based on what the payer would pay. We are talking about acquisition cost versus utilization cost. The point about identifying a threshold related to when a drug is cost prohibitive is a good point.

Mr. Sheehan noted that the Commission can put a discussion on cost threshold on a future agenda if it wants to further discuss criteria. It is important to remember that the potential of multiple crosswalked drugs is not part of cost analysis and would likely impact the cost estimates.

Ms. Steinberg asked if we looked at the cost to the state. Ms. Nelson stated that the CHIA benefits review provided broad estimates and the ICER study, which is draft, did go into some Massachusetts numbers.

Dr. Carr stated that putting pricing on a future agenda is good as it is outside of my expertise. There may be some methodologies out there to help clarify. We should also discuss how this may be paid for. Mr. Sheehan noted that putting it on a future agenda allows us time to look at our statutory authority as a Commission to do that.

Dr. Walker noted that we can’t look at cost as a vacuum. We would like to have competition to give incentive to negotiate. Dr. Thompson replied that what is further complicating cost estimates is that we don’t know what others are paying for the drug—it’s proprietary. This is a rough approximation. Dr. Walker stated that these estimates are a worst case scenario.

Dr. Carr stated that the Commission also needs to look at the cost of sparing one overdose or death but that is a difficult calculation. We want to show that we have considered this even if it is difficult to calculate.

Mr. Feldman noted that he is not aware of data that shows that ADP has impact on addiction rates, treatment for addiction or overdose deaths but there is strong data that demonstrates a shortage of funding for addiction treatment so need to take that into consideration if we advocate for a substitution that will cost a lot of money.

Dr. Jeffrey stated that the Commission has been asked what is cost prohibitive and we have been making decisions up to today. Can we delay determining if this is cost prohibitive? Would this force us into re-considering previous decisions?

Mr. Sheehan noted that it would be great to have a future conversation on this topic but as a reminder, the statute says to take all four aspects into consideration. Ms. Nelson added that the Commission already approved a drug that is similar costs on the Formulary. If the Commission approved drugs that would not meet a future established threshold, the Formulary is evolving document and drugs could be added or taken off.

Mr. Feldman stated that if the Commission is looking at one drug at a time, we see a number but we need to look at all the drugs that we have approved and see the total cost impact. If utilization or cost changes, will need to know the overall picture and establish an overall cap.

Dr. Walker noted that Ms. Nelson’s point is important. This decision doesn’t mean that we can’t take action later and we could add and evaluate to make a decision to pull off a drug in the future. We may see that the costs didn’t go up to the estimated amount so it may help to see how it plays out.

Dr. Doyle-Petrongolo asked if at the next meeting, if the Commission can look at establishing definition similar to other definitions that we have created?

Dr. Theoharides noted that given that the Commission has approved a drug with similar costs, and that it may lower costs, and we can take up the cost at a future meeting, would like to call the question?

Mr. Sheehan stated that he will call the vote for each paring.

Mr. Sheehan asked if there was a motion to approve the pairing of MorphaBond ER® as a potential substitute for Morphine extended-release 24 hour capsule.

* Motion to approve: Dr. Walker
* Second: Dr. Theoharides
* All in favor: Unanimous

Mr. Sheehan asked if there was a motion to approve the pairing of MorphaBond ER® as a potential substitute for Kadian®.

* Motion to approve: Dr. Walker
* Second: Dr. Theoharides
* All in favor: Unanimous

Mr. Sheehan asked if there was a motion to approve the pairing of MorphaBond ER® as a potential substitute for Morphine extended-release 12 or 24 hour capsule.

* Motion to approve: Dr. Walker
* Second: Dr. Carr
* All in favor: Unanimous

Mr. Sheehan asked if there was a motion to approve the pairing of MorphaBond ER® as a potential substitute for MS Contin®.

* Motion to approve: Dr. Walker
* Second: Dr. Theoharides
* All in favor: Unanimous

Mr. Sheehan asked if there was a motion to approve the pairing of MorphaBond ER® as a potential substitute for Morphine ER tablets.

* Motion to approve: Dr. Walker
* Second: Mr. Feldman
* All in favor: 11; Opposed: Dr. Freedman, Dr. Supko

Next, Dr. Thompson went through the ADP Efficacy form for Arymo ER® and information for consideration of the drug as a Chemically Equivalent Substitute. Following the presentation, there was discussion by the members.

Dr. Carr stated that over the past years, data has shown that opioid prescribing is going down. If this is true, would it be possible to try to calculate for trends in prescribing rates decreasing and reductions in dosage? Assuming that a spreadsheet with formulas may exist—this may help with the cost estimates.

Ms. Nelson responded that whenever a new drug is presented to the Commission, we will use the most recent PMP data. Once the Formulary is promulgated, the data may change and give us more real time data. Dr. Carr noted that if we look at the beginning of trend data versus real-time, that may help.

Mr. Sheehan noted that in last round of Chapter 55 reporting, DPH Commissioner Bharel reported that prescribing of opioids has gone down. There are a number of triggers that could be behind that, including all the work that DPH and the entire Commonwealth has done.

Mr. Leslie asked how predictive are these costs are to the future? If building in trends on prescribing, we need to think about potential changes in cost. Does anyone have an idea of how much they will change? Dr. Jeffrey responded that there are some measures of cost predictability but the market is unpredictable.

Dr. Doyle-Petrongolo stated that we need to remember the cost to the patient. All the approved drugs that have high costs which will result in a higher cost for Medicare Part D patients and commercial patients. They will have higher co-pays. I have a hard time approving costs that may result in costs going to patient.

Ms. Nelson noted that once the drug is on the formulary, a commercial payer cannot pass the cost on to the patient. The statute places insurance protections on these drugs so they are equal for the coverage for the drugs that is being substituted. Also, the prescriber can do “no substitutions”. This applies to GIC and commercial payers but it is our understanding that Medicare Part D and MassHealth are not subject.

Dr. Doyle-Petrongolo stated that she wanted to change her earlier vote to no. Mr. Sheehan asked her to hold until this discussion was over.

Ms. Nelson noted that if a prescriber writes for a drug on a HPHR list, the pharmacy will contact them and the prescriber will be able to write for a ADP opioid or write no substitution. There will be a choice.

Dr. Jeffrey stated that the patient may be protected from a higher co-pay but the higher costs in the system will be passed on to the patient at some point in some other way. Rates may go up or the deductible.

Mr. Sheehan noted that there are estimated to be over 1,400 deaths related to opioid epidemic last year. We have an obligation to come up with a Formulary to help come up with a tool to address the epidemic. The Commission has also discussed the potential cost savings from avoiding addiction and overdose treatment. We need to consider that this is the worst case cost scenario.

Dr. Brandoff stated that he appreciates any clarifications that state that we have to consider the statutory elements equally. It’s a lot more straightforward to talk about the other elements than deal with the cost. With the climate in Washington DC, we don’t know what systems will be covering what. It’s fine for the people that are trying to misuse the products but if people are just looking to swallow it in mass, that won’t be a cost saving because it is taken as prescribed, in excess. If looking at the four components equally, it still doesn’t solve everything.

Ms. Steinberg noted that we all know how bad the crisis is and that we are here for a purpose. There are also people living with pain and the inability to access medication is high. The crisis as we know has moved to illegal drugs and overdose data is due to that. We have made it harder to get to these medications. Simply limiting medications is causing suffering and that is a factor.

Mr. Sheehan stated that he will call the vote for each paring.

Mr. Sheehan asked if there was a motion to approve the pairing of Arymo ER® as a potential substitute for Morphine extended-release 24 hour capsule.

* Motion to approve: Dr. Walker
* Second: Dr. Theoharides
* All in favor: Unanimous

Mr. Sheehan asked if there was a motion to approve the pairing of Arymo ER® as a potential substitute for Kadian®.

* Motion to approve: Dr. Walker
* Second: Dr. Theoharides
* All in favor: Unanimous

Mr. Sheehan asked if there was a motion to approve the pairing of Arymo ER® as a potential substitute for Morphine extended-release 12 or 24 hour capsule.

* Motion to approve: Dr. Walker
* Second: Dr. Theoharides
* All in favor: Unanimous

Mr. Sheehan asked if there was a motion to approve the pairing of Arymo ER® as a potential substitute for MS Contin®.

* Motion to approve: Dr. Walker
* Second: Dr. Theoharides
* All in favor: Unanimous

Mr. Sheehan asked if there was a motion to approve the pairing of Arymo ER® as a potential substitute for Morphine ER tablets.

* Motion to approve: Dr. Walker
* Second: Mr. Feldman
* All in favor: 9; Opposed: 4-Dr. Brandoff, Dr. Doyle-Petrongolo, Dr. Freedman, and Dr. Supko.

Mr. Sheehan stated that we can go back to Morphabond ER® pairings and asked Dr. Doyle-Petrongolo if she was looking to change your vote on all of the pairings. Dr. Doyle-Petrongolo clarified that it was just the pairing with the Morphine ER tablets. Her basis for the change in vote is cost and access.

Mr. Sheehan stated that for the record, Dr. Brandoff also changed his vote on this pairing from yes to no. The new vote tally is:

Mr. Sheehan asked if there was a motion to approve the pairing of MorphaBond ER® as a potential substitute for Morphine ER tablets.

* Motion to approve: Dr. Walker
* Second: Mr. Feldman
* All in favor: 9; Opposed: 4-Dr. Brandoff, Dr. Doyle-Petrongolo, Dr. Freedman, and Dr. Supko.

**4. Draft Formulary**

Mr. Sheehan stated that although we have experienced some delays in getting this regulation before the Public Health Council, these delays have opened up some opportunities for us.

Since the initial regulation proposal, the Commission has approved several new IAD Drug Products that can be included now. While adding these new drugs will further delay the promulgation, it will only be by about one month, which is preferable to waiting for an updated regulation to be proposed later this year or next year. Final promulgation is expected this summer.

DPH will also continue to coordinate the education and guidance to prescribers and pharmacists with promulgation of the regulation to assure a smooth implementation and appropriate compliance. This updated promulgation schedule provides us with more time to be responsive to the needs of the prescribers and pharmacies in this regard as well.

**5. Next Steps**

Today, the Commission approved MorphaBond ER® and Arymo ER® an IAD Drug Products and approved both drugs as potential substitutes for:

* Morphine Extended-Release 24-Hour Capsule
* Kadian®
* Morphine Extended-Release 12 or 24 Hour Capsule
* MS Contin®
* Morphine Extended-Release Tablet

As the Commission discussed, the second draft Formulary will be an evolving document. As the FDA continues to review and approve drugs with ADP properties, and more of these drug products are brought to the US market, the Commission will need to determine how these drugs may interact on the Formulary.

Additionally, the review of the non-opioid pain management list is an annual task for the Commission, with an updated list due to be published by September 1 of each year. The Commission may also see more tasks assigned to it by the Legislature that we will need to be prepared to respond to in a timely manner.

Mr. Sheehan noted that the Commission does not need to meet in June or July. In light of discussion on agenda items, that will give us time to engage experts. We will also be in touch with updates related to the presentation of the draft regulation to the Public Health Council.

Mr. Sheehan asked for any final discussion or questions, then called for a motion to adjourn.

* Motion to Adjourn: Dr. Ahmed
* Second: Dr. Brandoff
* All in favor: Unanimous