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Massachusetts Department of Public Health
Minutes of the Drug Formulary Commission
Meeting of Thursday, April 7, 2016
Henry I. Bowditch Public Health Council Room, 2nd Floor
250 Washington Street, Boston, MA

Date of Meeting: Thursday, April 7, 2016
Beginning Time: 2:04 PM
Ending Time: 4:00 PM

Advisory Council Members Present: The following eleven (11) appointed members of the Drug Formulary Commission attended on March 17, 2016, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Interim Director Bureau Health Care Safety and Quality Eric Sheehan (Chair); Dr. Douglas Brandoff; Ray Campbell; Dr. Daniel Carr; Dr. Joanne Doyle-Petrongolo; Stephen Feldman; Dr. Paul Jeffrey; Cindy Steinberg; Dr. Jeffrey Supko; Dr. Theoharis Theoharides; and Dr. Alexander Walker.

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1. Welcome and Introductions

Department of Public Health (DPH) Bureau of Health Care Safety and Quality Interim Director Chair Eric Sheehan called the meeting to order at 2:04PM and provided brief introductory remarks.

Mr. Sheehan reminded the attendees that this is a recorded, public hearing, and confirmed that no one in audience was recording.

Mr. Sheehan summarized the March 17, 2016 meeting. He noted that the Commission at its last meeting laid the groundwork to begin crosswalking the Abuse Deterrent Property (ADP) drug products it approved as potential substitutes with the drug products it determined have a Heightened Public Health Risk. The Commission also approved a definition for Chemically Equivalent Substitution, and approved a form to determine the strength of evidence showing ADP Efficacy.

The work achieved at the April 7th meeting enables the Commission to begin the work of Component 3 of the Evaluation and Review Process. Referring to the overview slide for today's presentation, Mr. Sheehan noted that Component 1 (determining which groups of drugs should be designated as having a heightened public health risk), was complete. Moving on to Component 2, Mr. Sheehan noted that the Commission determined that five (5) drug products should be identified as potential substitutes for the drugs with a heightened public health risk.

Moving on to Component 3, Mr. Sheehan noted that the Commission will now complete the crosswalking process and develop a formulary of potential substitutes for drugs with a heightened public health risk. This work is possible since Components 1 and 2 have been completed, and the ADP efficacy form and the definition under which the Commission will operate have been finalized.

Mr. Sheehan reminded the Commission that the Formulary is guidance for prescribers and is not mandatory. It will be another tool that prescribers can use but it will not be mandated to substitute drugs just because the formulary recommends that action.

Mr. Sheehan called for approval of the minutes from the March 17, 2016 meeting.

- One change was noted on the incorrect date of the next meeting on page 6.
- Motion to approve: Mr. Feldman
- Second: Dr. Theoharides
- All in favor: 7 in favor; 0 opposed; 3 abstention.
  Dr. Carr, Dr. Supko and Dr. Walker abstained as they were not present at the March 17th meeting.

2. Opioid Bill- Chapter 52 of the Acts of 2016

Mr. Sheehan provided an overview presentation of Chapter 52 of the Acts of 2016, which the Governor signed on March 14, 2016.

Ms. Steinberg asked when the provisions in the bill were effective. Mr. Sheehan stated that most were effective immediately unless otherwise noted in the legislation.

3. Crosswalk

Mr. Sheehan noted that at the last meeting, the Commission approved a definition for the statutory term "Chemically Equivalent Substitution" as it applies to the creation of a drug formulary of abuse deterrent substitutes. Following the vote to approve the definition, it was determined that the definition requires a very small edit. A member noted that, although the statute uses the term "opiates", it should use the more inclusive term "opioids".

Because the definition was approved by a vote of the members, the Commission voted on the updated definition with the edit included.

Mr. Sheehan called for approval of the revised definition.

- Motion to approve: Mr. Feldman
- Second: Dr. Theoharides
- All in favor: 11 in favor; 0 opposed; 0 abstention.

Next, Mr. Sheehan reviewed the drugs on the 28 Heightened Public Health Risk drugs on List A and the five potential formulary substitutes on List B. He noted that as the Commission has progressed, more drug products have been proceeding through the FDA approval process. Not long after the initial work of this group is complete, the Commission will reconvene to consider adding more potential substitutes to List B.

Mr. Sheehan explained that the goal of the Crosswalk in Component 3 is to determine whether a drug product on List B should be a substitute for one or more drug products on List A. The Commission members were provided with complete lists, with accompanying cost and utilization data.

Mr. Sheehan stated that Section 13 of Chapter 17 of the General Laws guides the Commission's work in Component 3 by offering four criteria by which we determine that a drug is a chemically equivalent substitution. In addition to the definition of the term "chemically equivalent substitution" itself, the Commission must consider accessibility, cost, drug effectiveness, and ADP efficacy. As the Commission evaluates each pairing based on these criteria, it is important to note that the totality of the factors should determine whether a List B drug product should substitute for a List A products. Factors should be considered in order for the Commission to meet its goal of finding safer alternatives for Heightened Public Health Risk Drugs. This is especially true of cost.

Next, Mr. Jonathan Mundy introduced the potential pairing of Embeda, one of the List B drug products, and Morphine extended-release 24 hour capsule, a List A drug product. Mr. Mundy described the following information for each drug product: active ingredient; strength; dosage form; route of administration; dosing schedule; cost per unit; units dispensed in 2015; the approximate cost paid for these units; and the ADP efficacy category.

Following this review, the floor was opened for discussion, Commission members offered the following observations, comments, suggestions and recommendations:

- Mr. Feldman asked for clarification on the approximate cost as there are two costs for each drug. Tyson Thompson explained that each cost matches up with the total dosage of the two different strengths noted for each drug.
- Mr. Feldman noted that the Commission hasn't defined "cost prohibitive" or a methodology to determine if a drug is or isn't.
- Ms. Steinberg commented that the Commission needs to consider who is bearing the cost if costs are expected to go up.
- Mr. Feldman noted that when he looks at the cost, if he thinks it is worth saving a life, then it's not prohibitive. There were comments to support this statement.
- Mr. Sheehan reminded the Commission members that they are tasked with looking at all the factors outlined in the legislation; not just cost.
- Dr. Brandoff stated that this comes down to what the drug costs and what is covered. A substitution may have a disproportionate effect on those paying out of pocket.
- Mr. Campbell asked if the cost of substitution between Embeda and morphine extended-release 24 hour capsule was $86,000 across the whole system? If so, the cost does not appear to be an issue. Mr. Thompson clarified that it was an estimate to apply to the whole system.

- Mr. Feldman noted that it will need to be communicated to insurance companies why the substitution is the right thing to do if they will experience higher costs.
- Dr. Jeffrey asked that we look at cost at an incremental basis. Does it double? Does that make it cost prohibitive? Also, we need to understand the methodology of the cost estimates. Does it consider a 100% conversation rate from the List A drug to the List B drug? Would be helpful to see estimates assuming 50% and 75% conversation rates.
- Dr. Walker stated that the Commission needs to look at the big picture. We need to ask questions about higher amounts but $86,000 to save a life is not an issue.
- Ms. Steinberg requested to gain an understanding of the total number of people impacted by a potential substitution.
- Dr. Carr stated that cost is a factor but may not be as significant if we know the number of people that were impacted.
- Mr. Thompson summarized that the Commission wanted to see updated cost data that included:
    - The difference in cost expressed as a percentage.
    - Cost assumptions assuming different conversation rates.
    - The number of impacted patients.
- Dr. Brandoff stated that he was still concerned about a patient being able to get the necessary prescription without problems.
- Mr. Sheehan went over the Commission's mandate and asked if the concerns being raised would preclude the members from voting on the potential substitutions involving Embeda.
- Mr. Campbell explained that the patient experience is important. Can we find out if other formularies have coverage issues? We need to think about communication.
- Mr. Sheehan went over the regulatory review process. After our crosswalk is complete, the Commission will vote on the final, draft formulary. Following this action, the Department will proceed with reviewing the draft formulary in the context of proposing amendments to 105 CMR 720.000. We need to promulgate the draft Formulary into regulation. The regulation process will consist of a presentation to the Public Health Council and public comment period, including a public hearing. The Department will consider this feedback and re-engage with the Commission if necessary. The final amended regulation will be proposed and promulgated. The Formulary will not be effective until the regulation is promulgated.
- Mr. Feldman asked if stakeholders should be engaged now to identify any issues with access for patients. The DEA is a big hurdle so should we reach out?
- Mr. Sheehan acknowledged the hurdles but stressed the importance of moving along a Formulary in this process.
- Dr. Doyle Petrongolo explained that the Commission wants to make sure it covered its basis knowing that the hurdles will exist or be addressed in other ways.
- Mr. Thompson stated that the vote that is before the Commission is to approve if the drug products are substitutable.
- Dr. Supko said that he would not be prepared to vote on the substitution unless pharmacokinetic data is provided. He would like to see actual data and not just summaries as he wants to determine if the drugs are therapeutically equivalent. The Commission does not have monographs for the drug products that are being substituted from List A and was told that the data would be available.
- Mr. Feldman noted that we need to look at the data to determine if the Commission needs to advise that the substitution happen with caution.
- Mr. Campbell asked if it was worth asking an outside group to do a review?
- Dr. Jeffrey stated that certain evidence may be challenging to find.

- Ms. Steinberg asked if the FDA looks at this type of data. Dr. Supko responded that they do but won't share that information.
- Dr. Theoharides stated that the decision was made to make the definition more flexible—that's why the phrase "comparable biological effect" was included. Is there data that indicates the peak and curve of the drugs that we are comparable?
- Dr. Carr noted that we need another layer of data to review.
- Mr. Sheehan asked the members what is needed to bring to the next meeting to move the Commission forward.
- Dr. Walker stated that we need to address how the substitution produces a comparable biologic effect and we need to define what to include.
- Dr. Supko stated that if the kinetics are comparable, could assume comparable biologic effects.
- Mr. Sheehan asked what data was needed to show this. Dr. Supko provided examples.
- Mr. Sheehan asked if there was a motion to defer the votes on Embeda until the next meeting once we provide additional information.

    - Motion to approve: Mr. Feldman
    - Second: Dr. Theoharides
    - All in favor: 11 in favor; 0 opposed; 0 abstention.

4. Next Steps

Mr. Sheehan went over the tasks that are still before the Commission including review of Oxaydo and the Commission's continuing review of new drugs with ADP.

Dr. Jeffrey brought up his observations on cost. He wanted to identify what would result in a "wow" effect, with respect to a significant cost impact in the aggregate. It would be helpful to see the cost for all the substitutions involving Embeda in the aggregate.

Mr. Sheehan noted that it's possible that we won't have quorum for the meeting currently scheduled for April 21 due to school vacation week. We will send out a doodle poll to see what other meeting options may be available the following week.

Having no further business before the Commission, Mr. Sheehan asked for a motion to adjourn.

- Motion: Dr. Jeffrey
- Second: Mr. Campbell
- All in favor: unanimous

The Drug Formulary Commission meeting concluded at 4:00 PM.

Documents Presented to DFC at the *March 17, 2016* Meeting

- DFC Minutes from March 17, 2016
- DFC PowerPoint presentation
- Cost Information on Short-Acting and Long-Acting Opioids
- Embeda ADF Efficacy Form

Documents can be found at:
http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/drug-formulary-commission.html