Overview of the Drug Formulary Commission and Statutory Objectives

Bureau of Health Care Safety and Quality
Department of Public Health

August 6, 2015

Topics

- Commission Background
- MA Prescription Monitoring Program (PMP) Overview
- PMP Dispensing and Reporting Data: Schedule II and III Opioids
- New Mission
- Factors for Consideration

Commission Background

The Drug Formulary Commission (Commission) is a body comprised of members appointed by the Governor who are charged with developing a list of those drug products (from the Massachusetts List of Interchangeable Drugs) that are safely interchangeable (i.e., equivalent to each other in all significant respects).

The Commission is charged with:

- Ensuring that drug products meet applicable standards for strength, quality, purity and identity, and are bioequivalent.
- Assessing the therapeutic equivalence of drug products.
- Maintaining the MA list of interchangeable drugs of pharmaceutically equivalent drug products.

MA PMP Overview

- The MA Prescription Monitoring Program (PMP) receives dispensing data on Schedule II - V (e.g., narcotic, stimulant, sedative) prescriptions dispensed by MA community, clinic and outpatient pharmacies as well as out-of-state mail order pharmacies that deliver to MA residents. The PMP has been in operation since 1992.
- The Massachusetts Online Prescription Monitoring Program (MA Online PMP) is a secure website that supports safe prescribing and dispensing and allows an authorized account holder to view the prescription history of a patient for the past year. The Online PMP has been operational since December 2010.
- Over 12 million prescription records reported to MA PMP in Calendar Year (CY) 2014.

SOURCE: A Report to the Massachusetts General Court, February 2015, "The Massachusetts Prescription Monitoring Program: Addendum to Update Trends with 2014 Data"

New Mission

- Chapter 258 of the Acts of 2014 created an additional mandate for the Commission including:
  - Preparing a drug formulary of chemically equivalent substitutions for drugs that are opiates, as defined in Section 1 of Chapter 94C, and contained in Schedule II or III that the Commission has determined have a heightened level of public health risk due to the drugs' potential for abuse and misuse.
- Additionally, Chapter 258 expanded the composition of the Commission to include individuals with experience in addiction and chronic pain medicine, insurance pharmacy benefit design and pharmaceutical manufacturing, and established term limits of three years for each Commission member.

PMP Dispensing and Reporting Data: Schedule II and III Opioids

Schedule II Opioid Drug Products	Schedule III Opioid Drug Products
Generic Cross Reference Name	Generic Cross Reference Name
Oxycodone Hydrochloride	Buprenorphine/Naloxone
Acetaminophen/Oxycodone Hydrochloride	Acetaminophen/Codeine Phosphate
Acetaminophen/Hydrocodone Bitartrate	Buprenorphine Hydrochloride
Morphine Sulfate	Buprenorphine
Hydromorphone hydrochloride	APAP/Butalbital/Caff/Codeine Phos
Fentanyl	Aspirin/Butalbital/Caffeine/Codeine Phosphate
Methadone Hydrochloride	Acetaminophen/Caffeine/Dihydrocodeine Bitartrate
Hydrocodone Bitartrate/Ibuprofen	Aspirin/Carisoprodol/Codeine Phosphate
Oxymorphone Hydrochloride	Aspirin/Caffeine/Dihydrocodeine Bitartrate
Tapentadol Hydrochloride	
Codeine Sulfate	
Meperidine Hydrochloride	
Levorphanol Tartrate	
Fentanyl Citrate	
Hydrocodone Bitartrate	
Aspirin/Oxycodone Hydrochloride	
Morphine Sulfate/Naltrexone Hydrochloride	
Belladonna Alkaloids/Opium Alkaloids	
Ibuprofen/Oxycodone Hydrochloride	

Source: BHCSQ, MA PMP. This list is derived from all prescriptions dispensed and reported to the Prescription Monitoring Program during CY 2014. This list represents 100% of all Schedule II and III opioids, and 68% of all of the Schedule II and III drug products (including opioids and non-opioids), dispensed and reported to the PMP.

Factors for Consideration

- To complete the work assigned to the Commission, there are four sources of information that should be initially considered. These will be reviewing in the upcoming slides.
  - Opioid Drug Products Approved by the FDA to Include Abuse-Deterrent Claims on their Label.
  - Abuse Deterrent Properties.
  - Drug Formulary Requirements, as outlined in Chapter 258.
  - Definitions of “Extended Release Long-Acting Opioid” and “Non-abuse Deterrent Opioid”, as established by Chapter 258.

Factors for Consideration

Opioid Drug Products Approved by the FDA to Include Abuse-Deterrent Claims on their Label

- The FDA has permitted the following products to include on their respective labels, descriptions of their product's abuse-deterrent properties. These abuse-deterrent properties are consistent with the FDA's 2013 draft guidance for industry, Abuse-Deterrent Opioids – Evaluation and Labeling.
  - OxyContin (Extended release [ER] oxycodone) – Approved by FDA in April 2010; introduced into market in August 2010.
  - Targiniq ER (ER/LA) – Approved by FDA in July 2014.
  - Embeda (ER morphine sulfate and naltrexone hydrochloride) – Approved by FDA in October 2014; FDA approved an updated label for EMBEDA® extended-release (ER) capsules, for oral use, CII, to include abuse-deterrence studies.
  - Hysingla ER (hydrocodone bitartrate) – Approved by FDA in November 2014.

Source: Communication with Christopher Jones, PharmD, MPH. Senior Advisor, U.S. Food and Drug Administration. July 29, 2015.

Factors for Consideration

Abuse Deterrent Properties

As outlined in Chapter 258 of the Acts of 2014 and codified in M.G.L. c. 17, § 13 (b), the formulary shall include formulations of drugs that the Commission has determined may be appropriately substituted and that incorporate any of the following abuse deterrent properties:

(1) a physical or chemical barrier that (i) prevents chewing, crushing, cutting, grating, grinding, melting or other physical manipulations that enable abuse or (ii) resists extraction of the opioid by common solvents such as water, alcohol or other organic solvents;

(2) an agonist or antagonist combination that interferes with, reduces or defeats the euphoria associated with abuse;

(3) an aversion quality that produces an unpleasant effect if the dosage form is manipulated or altered or a higher dose than directed is used;

(4) a delivery system that, under United States Food and Drug Administration guidance, offers resistance to abuse;

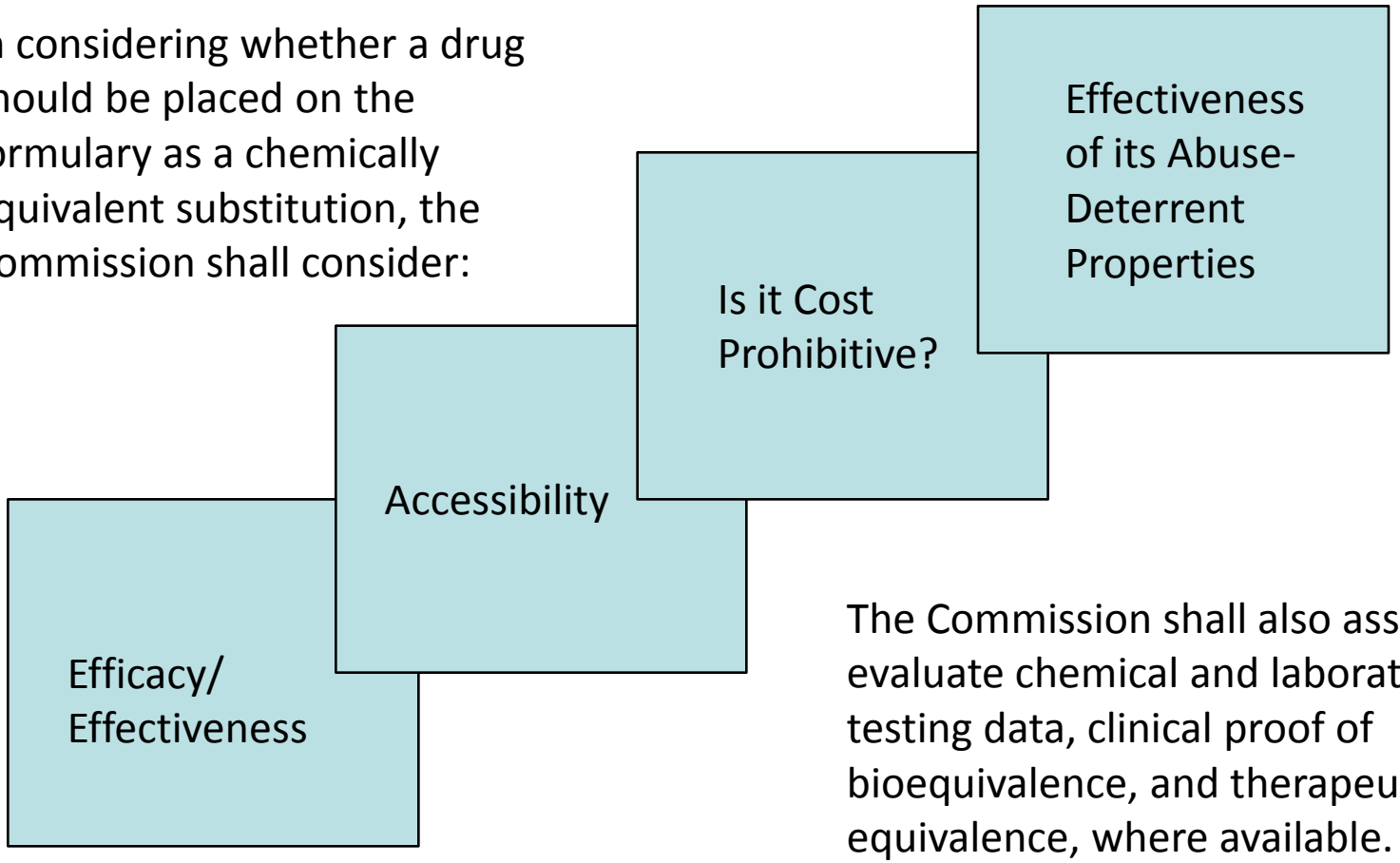
(5) a prodrug technique that limits opioid activity until transformed in the gastrointestinal tract; or

(6) any other technique, as may be identified or recommended by the United States Food and Drug Administration, that offers significant abuse deterrence.

Factors for Consideration

Drug Formulary Requirements

In considering whether a drug should be placed on the formulary as a chemically equivalent substitution, the Commission shall consider:



The Commission shall also assess and evaluate chemical and laboratory testing data, clinical proof of bioequivalence, and therapeutic equivalence, where available.

Factors for Consideration

New Definitions

- Section 7 of Chapter 258 of the Acts of 2014 established a definition for the term, “extended release long-acting opioid.”
  - “…the term shall mean a drug that is subject to the United States Food and Drug Administration’s risk evaluation and mitigation strategy for extended release and long-acting opioid analgesics.”

Factors for Consideration

New Definitions

- Section 7 of Chapter 258 of the Acts of 2014 established a definition for the term, “non-abuse deterrent opioid.”
  - “…the term shall mean an opioid drug product that is approved for medical use, but does not meet the requirements for listing as a chemically equivalent substitute pursuant to Section 7.”

PMP Dispensing and Reporting Data: Schedule II and III Opioids

Schedule II Opioid Drug Products	Schedule III Opioid Drug Products
Generic Cross Reference Name	Generic Cross Reference Name
Oxycodone Hydrochloride	Buprenorphine/Naloxone
Acetaminophen/Oxycodone Hydrochloride	Acetaminophen/Codeine Phosphate
Acetaminophen/Hydrocodone Bitartrate	Buprenorphine Hydrochloride
Morphine Sulfate	Buprenorphine
Hydromorphone hydrochloride	APAP/Butalbital/Caff/Codeine Phos
Fentanyl	Aspirin/Butalbital/Caffeine/Codeine Phosphate
Methadone Hydrochloride	Acetaminophen/Caffeine/Dihydrocodeine Bitartrate
Hydrocodone Bitartrate/Ibuprofen	Aspirin/Carisoprodol/Codeine Phosphate
Oxymorphone Hydrochloride	Aspirin/Caffeine/Dihydrocodeine Bitartrate
Tapentadol Hydrochloride	
Codeine Sulfate	
Meperidine Hydrochloride	
Levorphanol Tartrate	
Fentanyl Citrate	
Hydrocodone Bitartrate	
Aspirin/Oxycodone Hydrochloride	
Morphine Sulfate/Naltrexone Hydrochloride	
Belladonna Alkaloids/Opium Alkaloids	
Ibuprofen/Oxycodone Hydrochloride	

Source: BHCSQ, MA PMP. This list is derived from all prescriptions dispensed and reported to the Prescription Monitoring Program during CY 2014. This list represents 100% of all Schedule II and III opioids, and 68% of all of the Schedule II and III drug products (including opioids and non-opioids), dispensed and reported to the PMP.