**Section 790.40 Consideration of Drug Products for Inclusion in the Illinois Formulary**

a) Drug products for inclusion in the Illinois Formulary shall be approved and recommended to the Director of Public Health by a Technical Advisory Council according to the notice and hearing provisions of this Section. The Council is composed of 7 members, each of whom has extensive experience in pharmaceutical affairs. Products for Council consideration shall be researched and presented by Department staff following consideration of recommendations by the federal Food and Drug Administration (FDA), of recognized drug reference sources, of published research, and of qualified consultants.

b) No product shall be considered for inclusion in the Illinois Formulary unless each individual dosage form, dosage strength and manufacturer has been recommended for drug product selection use by the FDA. Each product considered must be verified by the FDA as being marketed under currently approved drug applications, as meeting required manufacturing standards and chemical identity standards, and as being cleared of any issues involving the bioequivalence or bioavailability of the product. Prior to being sanctioned for DPS use, the product must pass FDA criteria specific for DPS approval which criteria may be more stringent than that required for general marketing approval. "Bioequivalence" and "bioavailability" have the meanings prescribed under 21 CFR 320.1, April 1, 1999.

c) Generic Drug Products.

1) *Drug products previously approved by the Technical Advisory Council for generic interchange may be substituted in the State of Illinois without further review subject to the conditions of approval in the State before September 1, 2000 (the effective date of Public Act 91-766)* (Section 3.14 of the Illinois Food, Drug and Cosmetic Act [410 ILCS 620/3.14]). Drug products requiring approval by the Council on or after September 1, 2000, for generic interchange are subject to the notice and hearing provisions of this Section.

2) If not subject to a hearing under subsection (c)(5) or if not specifically prohibited, then generic drug products determined to be therapeutically equivalent by the FDA shall be available for substitution in this State no sooner than 60 days after the submission of the prescribed notification under subsection (d) to the Council. "Therapeutic equivalence" has the meaning prescribed under the current edition or supplement of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations", 21 CFR 314.3, April 1, 1999.

3) Manufacturers of the generic drug products shall submit to the Council the notification described in subsection (d) at least 60 days before the scheduled substitution of the drug product. During the 60-day notification period, the Council shall determine, based upon a preponderance of the evidence, whether the generic drug product has issues related to the practice of medicine or the practice of pharmacy.

4) If the Council determines that the generic drug product does not have issues related to the practice of medicine or pharmacy, then the Council shall issue its recommendation of approval of the generic drug product to the Director. If included on the Drug Products Selection Formulary by the Director under subsection (f), then the drug product may be substituted in the State after either the 60-day notification period, the date of the Director's approval, or the date of the product's full approval for safety and efficacy by the FDA, whichever date is later.

5) If the Council determines that the generic drug product has issues related to the practice of medicine or pharmacy, then:

A) a hearing on the drug product shall be held under subsection (e) at the Council's next regularly scheduled meeting;

B) the Council's hearing determination shall be reviewed by the Director under subsection (f); and

C) the drug product may not be substituted in the State unless included in the Drug Products Selection Formulary by the Director.

d) The 60-day notification shall be submitted in writing to the Technical Advisory Council at the following address:

Administrator, Drug Product Selection Program

 Illinois Department of Public Health

 Office of Health Protection

 Division of Food, Drugs and Dairies

 525 W. Jefferson Street

 Springfield, Illinois 62761-0001

1) The notification to the Council shall consist of 9 complete copies of all the following items:

A) All testimony (plus one copy of the testimony that has individual identifying information redacted) and data upon which comment or reference to may be made, whether published or unpublished.

B) The drug product's technical bioequivalence and therapeutic equivalence information, including documentation of the required testing to support FDA product approval.

C) The information required in subsection (b).

2) The Department shall notify all other manufacturers of products within a specific generic entity that a hearing will be held on the drug product. The notification may be posted on the Department's Internet Website at www.idph.state.il.us. These manufacturers shall provide 9 copies of all testimony (plus one copy of the testimony that has individual identifying information redacted) and 9 copies of all data upon which comment or reference to may be made, whether published or unpublished, in writing to the Department within 30 days before the regularly scheduled meeting should they wish to be heard on the specific issue at the Council meeting. Nine copies of all rebuttal comments from any concerned manufacturer shall be submitted in writing to the Department within 14 days after the regularly scheduled meeting, should a company wish to respond to its competitor's submission.

e) The Director may designate an individual to conduct the hearing and make a recommendation to the Council on a generic drug product that has issues related to the practice of medicine or pharmacy. The Council shall make the final recommendation. Hearings shall be conducted according to the Rules of Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100) under Article 10 of the Illinois Administrative Procedure Act [5 ILCS 100/Art. 10]. Determinations shall be accompanied by a written detailed explanation of the decision's basis. The Council shall make its recommendation of approval or disapproval of the generic drug product to the Director within 20 business days after the public hearing.

f) After the Council's recommendation for approval or disapproval of the drug product is submitted to the Director, the Director may approve or prohibit the drug product's inclusion in the Drug Products Selection Formulary. Only if the Director decides that, based upon a preponderance of the evidence, the generic drug is not bioequivalent, is not therapeutically equivalent, or could cause clinically significant harm to the health or safety of patients, may the Director prohibit the drug product from inclusion in the formulary. The Director's decision to prohibit a drug product from inclusion in the formulary shall be accompanied by a written detailed explanation of the decision's basis. Decisions under this subsection constitute a final administrative decision within the meaning of Section 22.2 of the Illinois Food, Drug and Cosmetic Act [410 ILCS 620/22.2] and Section 3-101 of the Administrative Review Law [735 ILCS 5/3-101] and are subject to judicial review under Article III of the Administrative Review Law [735 ILCS 5/Art. III].

g) Exclusive indications and unique product packaging, whether patented or unpatented, do not constitute criteria for inclusion of a drug entity in the Illinois Formulary.

(Source: Amended at 24 Ill. Reg. 18711, effective December 8, 2000)