

(e) [The Department shall distribute the formulary and its revisions to:

- (1) All of the pharmacies in this State;
- (2) All authorized prescribers in this State; and
- (3) Any other person whom it considers appropriate.]

THE DEPARTMENT MAY DISQUALIFY A DRUG PRODUCT ON THE UNITED STATES FOOD AND DRUG ADMINISTRATION'S CURRENT LIST FROM BEING USED IN MARYLAND AS A GENERIC SUBSTITUTE IF THE DEPARTMENT DETERMINES THAT THE DRUG IS THERAPEUTICALLY NONEQUIVALENT OR HAS A NEGATIVE PHYSICAL OR BIOLOGICAL EFFECT ON THE CONSUMER OF THAT DRUG PRODUCT:

(1) AFTER PROVIDING AN OPPORTUNITY FOR PUBLIC COMMENT AS PROVIDED IN TITLE 10, SUBTITLE 1 OF THE STATE GOVERNMENT ARTICLE; OR

(2) PRIOR TO PROVIDING AN OPPORTUNITY FOR PUBLIC COMMENT, IF THE DEPARTMENT BELIEVES THAT A PARTICULAR GENERIC DRUG PRODUCT CONSTITUTES AN IMMINENT DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE, AND THE DEPARTMENT:

(I) PROVIDES AN OPPORTUNITY FOR PUBLIC COMMENT AS PROVIDED IN TITLE 10, SUBTITLE 1 OF THE STATE GOVERNMENT ARTICLE WITHIN 30 DAYS OF DISQUALIFYING THE PRODUCT; AND

(II) AFTER PROVIDING AN OPPORTUNITY FOR PUBLIC COMMENT, DETERMINES WHETHER THE PRODUCT SHOULD REMAIN DISQUALIFIED.

(F) FOR A DRUG PRODUCT THAT THE DEPARTMENT HAS DISQUALIFIED FROM BEING USED IN MARYLAND AS A GENERIC SUBSTITUTE UNDER SUBSECTION (E) OF THIS SECTION, THE DEPARTMENT SHALL PROVIDE AN OPPORTUNITY FOR PUBLIC COMMENT AS PROVIDED IN TITLE 10, SUBTITLE 1 OF THE STATE GOVERNMENT ARTICLE BEFORE REINSTATING THE DRUG PRODUCT FOR USE IN MARYLAND AS A GENERIC SUBSTITUTE.

(\*) (G) [The Department shall:

- (1) Assess the need for public education regarding the provisions of this section;
- (2) Provide whatever public education regarding the provisions of this section that it considers appropriate; and
- (3) Monitor periodically the effects of this section.