



Republic of the Philippines  
Department of Health  
OFFICE OF THE SECRETARY  
Manila



September 30, 2004

ADMINISTRATIVE ORDER  
NO. 170 s. 2004

**SUBJECT: Policies and Guidelines Governing Intellectual Property Rights in relation to Registration of Pharmaceutical Products**

**I. RATIONALE**

It is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them (Section 15, Article II, 1987 Constitution).

To achieve such objective, the State was mandated to (a) adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost (Section 11, Article XIII, 1987 Constitution); and (b) establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems (Section 12, Article XIII, 1987 Constitution).

In view thereof, and to establish an effective drug regulatory system, Section 26(a), in relation to Section 21(b) and 11 (j) of Republic Act No. 3720, as amended by Executive Order No. 175, otherwise known as the "Food, Drugs and Devices and, Cosmetic Act", and consistent with Republic Act No. 6675, otherwise known as the "Generics Act of 1988", Administrative Order No. 67, series of 1989 was promulgated to provide the rules and regulations for the registration of pharmaceutical products.

Nevertheless, in the registration of pharmaceutical products, issues concerning intellectual property rights have been raised that have effectively impeded the achievement of the abovementioned constitutional mandate and objectives. It is clear, however, from the 1987 Constitution

and the aforementioned laws, rules and regulations that the Department, through the Bureau of Food and Drugs (BFAD), is mandated only to ensure the safety, efficacy and good quality of pharmaceutical products applied for registration.

Meanwhile, pursuant to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, issues pertaining to intellectual property rights, particularly patent rights, trademarks, trade names, copyrights, and unfair competition, are properly lodged with either the Intellectual Property Office (IPO) or a court of law with competent jurisdiction on the subject matter.

## **II. PURPOSE AND OBJECTIVE**

The purpose of this Order is to establish policies and guidelines governing intellectual property rights and the registration of pharmaceutical products in recognition of the respective mandate, authority, and jurisdiction of this Department, through BFAD, the IPO, and the court of law with competent jurisdiction over intellectual property rights disputes.

In issuing this Order, this Department, through BFAD, hereby reiterates and consistently adopts its mandate and responsibility to ensure the safety, efficacy and good quality of pharmaceutical products applied for registration.

## **III. GENERAL GUIDELINES**

This Department, through BFAD, therefore adopts the ensuing guidelines for the guidance and compliance of all concerned:

1. The acceptance by BFAD of all new applications for Certificates of Product Registration (CPR) of pharmaceutical products shall not be interpreted or construed as an approval, endorsement or representation that the applicant has the right or privilege to any intellectual property right involving, or attached to, such pharmaceutical product.

2. The applicant shall execute an affidavit of undertaking (a) that there is no existing intellectual property right involving, or attached to, the pharmaceutical product applied for CPR; (b) that should the proper authority decide with finality that the applicant has no intellectual property right involving, or attached to, the pharmaceutical product, then any CPR issued to the product in question shall be automatically cancelled; and (c) to acknowledge and agree to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the registration of the pharmaceutical product with BFAD.

3. All applications for the registration of pharmaceutical products with BFAD shall be submitted and evaluated in accordance with the existing rules for product registration.

4. In the event that any interested party notifies BFAD in writing that there is an existing intellectual property right over the pharmaceutical product under registration, BFAD shall, as a matter of course, *motu proprio* refer the matter to the IPO for appropriate action and disposition. BFAD shall likewise notify all the parties concerned about the referral of the issue to the IPO.

5. Despite such referral, however, BFAD shall nonetheless continue with the processing of such application and the issuance of the CPR, until and unless it is validly and legally restrained or enjoined by the proper authorities from doing so. In this instance, proper authorities shall pertain to the IPO or a court of law with competent jurisdiction on the subject matter.

6. Taking into consideration the aforestated guidelines, the following special remarks previously inserted into the CPR covering pharmaceutical products shall no longer be utilized and printed by BFAD:

"The effectivity of this Certificate of Product Registration (CPR) will be the date after the patent of this product expires."

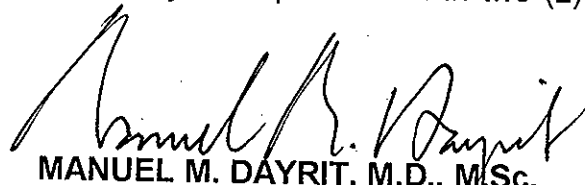
Meanwhile, the abovementioned special remarks contained in the previously-issued CPRs shall be considered superfluous in light of this Order and shall automatically be set aside and rendered ineffective.

#### IV. REPEALING CLAUSE

All other administrative issuances, bureau circulars, and memoranda inconsistent with this Order are hereby withdrawn, repealed and/ revoked accordingly.

#### V. EFFECTIVITY

This Order shall take effect immediately after publication in two (2) newspapers of general circulation.

  
MANUEL M. DAYRIT, M.D., M.Sc.  
Secretary of Health