



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

September 24, 2014

DEPARTMENT ORDER
NO. 2014-0161

SUBJECT: POLICIES, GUIDELINES AND RULES GOVERNING THE IMPLEMENTATION OF THE NATIONAL PROGRAM UTILIZING ACTRX TRIACT® FOR THE TREATMENT OF DENGUE BY THE PHILIPPINE NATIONAL INSTITUTE OF TRADITIONAL AND ALTERNATIVE HEALTH CARE (PITAHC)

I. RATIONALE/BACKGROUND

The 1987 Philippine Constitution mandates the right of every Filipino to health. It enunciates the policy that "the State shall protect and promote the health of the people and instill health consciousness among them" (Article II, Section 15). Furthermore, it provides the adoption by the State of an "integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services accessible to all the people at affordable cost" (Article XII, Section 15).

Consistent with the foregoing policies, the Department of Health (DOH) is mandated, among others, to: (i) direct service provider for specific programs that affect large segments of the population, such as tuberculosis, malaria, schistosomiasis, HIV-AIDS and other emerging infections, and micronutrient deficiencies; (ii) serve as the technical authority in disease control and prevention; (iii) be the innovator of new strategies for responding to emerging and existing health needs/threat; (iv) serve as the lead agency in health and medical research to effectively implement programs, projects and services that will promote the health and well-being of every Filipino; (v) prevent and control diseases among the population at risk; and, (v) treat, manage and rehabilitate individuals affected by diseases.¹

Dengue in the Philippines has in recent years become epidemic. In 2012, there were 187,031 reported cases of dengue with 921 death tolls (Disease Surveillance Report, National Epidemiology Centre). In 2013, the Department of Health recorded 204,906 dengue cases and 660 deaths. Peak incidence occurs during the wet season in the Philippines that the rainy season in the Philippines has become synonymous with "dengue outbreak season." This year, 24,900 cases have resulted in 100 deaths, or a ratio of one fatality for every 249 cases.

¹ Executive Order (E.O.) No. 102, s. 1999, "Redirecting the Functions and Operations of the Department of Health"

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CORAZON S. DELA CRUZ
RECORDS SECTION
Department of Health

Currently, there is no specific treatment for dengue. The standard of care administered to patients afflicted with dengue only involves maintenance of the patient's body fluid volume and relief of symptoms.

On 15 March 2014, Preferred & Proven Theraphies, Inc. (PPTI), together with the PITAHC, the San Lazaro Hospital for Infectious Diseases Medical Research Team, the ActRx Foundation, Inc. and the ActRx Operational Group, Ltd. Presented a report showing the remarkable success of the Clinical Trials conducted at the San Lazaro Hospital of ActRx Triact®, a patented herbal based combination of Artesunate, Berberine and Artemeter as therapy treatment for dengue.

After its independent study, the Philippine Council for Health Research and Development (PCHRD) of the Department of Science and Technology (DOST) likewise noted the remarkable results of ActRx Triact® and fully endorsed the implementation of a national program using said ActRx Triact® treatment. Jaime Montoya, MD, MSc, CESO III wrote "...review of the Protocol shows that it is scientifically valid and sound, to be carried out in Hospitals."

This, the foregoing warrants the integration of the ActRx Triact® treatment in the standard of care in the management of dengue incidents in the Philippines.

Accordingly, in line with its mandate to protect public health and guarantee public access to essential drugs, the DOH, in collaboration with PITAHC and the DOST, shall make available and integrate the ActRx Triact® treatment in the national healthcare program for dengue.

II. OBJECTIVES.

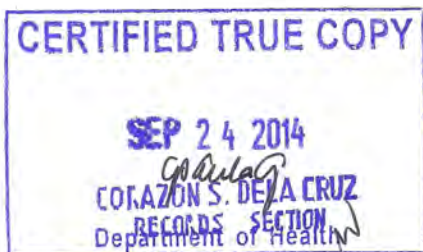
To implement and deliver an updated national program for dengue treatment.

To carry out research and development initiatives in the treatment of dengue, and establish an organizational structure that will ensure the collaboration and timely sharing of information among the bureaus and offices of the DOH as regards dengue treatment.

To determine the efficacy and safety of Artemether + Artesunate in combination with Berberine in the treatment of dengue patients.

III. SCOPE/COVERAGE

These Policies, Guidelines, Rules and Regulations shall apply to the Cooperating Agencies. 15



IV. DEFINITION OF TERMS

1. COOPERATING AGENCY – refers to a medical institution or organization which deals with patients suffering from dengue, and which is authorized by PITAHC or the Secretary of Health as the ex-officio Chairman of PITAHC, to administer ActRx Triact® treatment and document the results thereof. Currently, Cooperating Agencies include, but shall not be limited to, the following:

San Lazaro Hospital
(National Referral Center for Infectious and Tropical Diseases)

East Avenue Medical Center

Dr. Jose N. Rodriguez Memorial Medical Center

Amang Rodriguez Medical Center

Quirino Memorial Medical Center

Jose B. Lingad Memorial Hospital

ACTRX Foundation, Inc. (AFI)

Preferred & Proven Therapies, Inc. (PPTI)

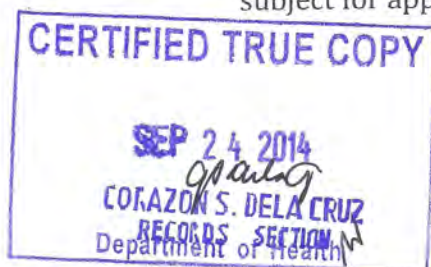
ACTRX Operational Group, Ltd. (AOGL)

2. PROJECT – shall refer to the “Expansive National Application Program Utilizing ACTRX TRIACT®,” a copy of which is attached as Annex “A”.
3. SPECIALISTS – refer to medical doctors or practitioners and health professionals, who have specialized training in treating patients suffering from dengue.

V. GUIDELINES AND PROCEDURE

1. The PITAHC and Cooperating Agencies shall implement the Project by distributing 2,000 ActRx Triact® according to the Duration, Methodology, Work Plan, Schedule, Treatment Protocol and funding provisions stated therein. The Project will commence after this DO is approved and will continue to run for a period of three (3) months or until the 2,000 ActRx Triact has been fully utilized.
2. PITAHC is hereby authorized to issue the Implementing Guidelines of this DO subject for approval of the Secretary of Health.

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3. All expenses for the implementation of the ENAPUActRx, including the training, travel, accommodation expenses and living allowance of the Specialists, shall be for the account of PPTI, AFI or AOGL.
4. The provision for Research Utilization in the Project shall be terminated after the completion of its duration.
5. ActRx Triact® may be provisionally included in the Philippine National Drug Formulary (PNDF) Manual subject to submission and ultimate review by the Formulary Executive Council (FEC) in accordance with existing rules and regulations.
6. Should the rollout become successful, ActRx Triact® may be regularly included in the PNDP Manual subject to existing policies and guidelines.

VI. SEPARABILITY CLAUSE

Should any of the provisions herein be declared invalid or unconstitutional by an appropriate authority or court of law, the same shall not affect the validity of other provisions unless otherwise specified.

VII. EFFECTIVITY

These Department Order shall take effect immediately after signing. All other orders and issuances inconsistent with these Department Order are hereby rescinded, repealed and modified accordingly.



ENRIQUE T. ONA, MD, FPCS, FACS
Secretary

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