Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

OCT 2 8 2016

DEPARTMENT MEMORANDUM
No. 2016- 0383

TO: **REGIONAL DIRECTOR ARIEL I. VALENCIA AND CHIEFS OF HOSPITAL WITH PROGRAMMATIC MANAGEMENT OF DRUG-RESISTANT TUBERCULOSIS (PMDT) TREATMENT FACILITIES IN THE NATIONAL CAPITAL REGION**

ATTENTION: **DR. ALFONSO VICTORINO H. FAMARAN JR.**
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SUBJECT: **Use of Bedaquiline in the Treatment of Drug-resistant Tuberculosis under Program Condition**

As part of the on-going efforts to address high drug-resistant TB (DR-TB) burden in the country, the National TB Control Program of the Disease Prevention and Control Bureau will introduce new treatment regimens and novel anti-TB drugs for the treatment of DR-TB under program condition. One of these is Bedaquiline (BDQ), a bactericidal anti-TB drug belonging to the diarylquinoline family that has a completely novel mechanism of action against Mycobacterium tuberculosis by inhibiting the ATP synthesis. BDQ is indicated to be added to a World Health Organization (WHO)-recommended regimen in adult patients with pulmonary multi drug-resistant tuberculosis (MDR-TB). BDQ has already been registered with the Philippine Food and Drug Administration (FDA) since October 2014 and has been approved for use under the NTP.

The NTP has adopted the use of BDQ in accordance with the WHO's recommendations. (Refer to attached Annex). Also, the following guidelines shall be implemented with the use of Bedaquiline under Program setting:

(1) The PMDT treatment facility staff who will provide BDQ to their patients shall be oriented on the proper use of this drug.
(2) All DR-TB patients who will be treated with a BDQ-based regimen shall be asked to sign an informed consent form (ICF);
(3) All DR-TB patients who are started with a BDQ-based regimen shall undergo monthly clinical evaluation and laboratory/diagnostic test monitoring with

ECG, liver enzymes (SGPT, SGOT) and electrolytes (K, Ca, Mg) on top of the recommended monitoring for other second-line anti-TB drugs.

(4) Monitoring of the implementation of Bedaquiline under program condition shall be integrated with the regular monitoring for PMDT treatment facilities, and;

(5) All serious adverse events (SAE) shall be reported to FDA and Global Drug Facility (GDF) through the Lung Center of the Philippines-National Center for Pulmonary Research within 24 hours upon awareness of the event. SAE form, as well as the ICF, shall be provided to the PMDT treatment facilities.

This memorandum hereby directs the NCRO TB Team to advise all PMDT treatment facilities to implement the use of Bedaquiline in the treatment of DR-TB and to coordinate with **Dr. Mary Rosary T. Santiago**, PMDT Specialist, NTP Management Office, through (02) 2309626, 09175128710 or maryrosarytaguinod0@gmail.com, the NTP pointperson for clarification and inquiry.

Attached is the Bedaquiline Prescribing Information Sheets for reference.

For information and compliance.

By Authority of the Secretary of Health

GERARDO V. BAYUGO MD, MPH, CESO III
Undersecreatary of Health
Office for Technical Services

ANNEX:

Based on the WHO's recommendation, BDQ can be given to patients in any of the following four (4) scenarios: 1) **MDR-TB plus resistance to fluoroquinolones with no second-line injectable resistance,** 2) **MDR-TB plus resistance to both classes of second-line injectable agents (aminoglycosides and polypeptides) or severe intolerance to second-line injectable agents and no resistance to fluoroquinolones,** 3) **MDR-TB plus two or more oral second-line anti-TB drugs compromised or severe toxicity with no resistance to fluoroquinolones and second-line injectable agents, and** 4) **extensively drug-resistant TB (XDR-TB).**

Bedaquiline is generally used for 6 months from the start of treatment regardless of missed doses or extension of intensive phase. It is added to the DR-TB regimen and the overall length of the treatment does not change. The six-month dosing schedule of the medication is as follows:

- Week 0-2: Bedaquiline 400 mg (4 tablets of 100 mg) daily (six days per week)
- Week 3-24: Bedaquiline 200 mg (2 tablets of 100 mg) 3 times per week (with at least 48 hours between doses) for a total dose of 600 mg per week
- Week 25 (start of month 7) to end of treatment: Continue other second-line anti-TB drugs only