I. GOALS

The goals of the VIBATIV REMS are:

A. To inform healthcare professionals (HCP) about the increased risk of mortality associated with VIBATIV in patients with pre-existing creatinine clearance of ≤50 mL/min being treated for hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP)

B. To avoid unintended exposure of pregnant women to VIBATIV through:
   • Educating healthcare professionals and patients on the potential risk of fetal developmental toxicity if women are exposed to VIBATIV while pregnant
   • Informing HCPs that a serum pregnancy test should be performed before initiating therapy with VIBATIV in Females of Reproductive Potential (FRP)
   • Informing HCPs that FRP, including those being treated in the outpatient setting, should be counseled about pregnancy prevention and use of effective contraception during VIBATIV use

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each VIBATIV prescription in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS and is appended.

B. Communication Plan

Theravance Biopharma Antibiotics, Inc. will implement the following elements of a communication plan:

1. **A Dear Healthcare Provider (DHCP) Letter** will be sent within 60 days, and again at 6 months, 1 and 2 years of approval, of the most recent REMS modification. The letter will be sent through either hardcopy mailings by U.S. mail or email to healthcare professionals likely to prescribe or dispense VIBATIV. This includes, but is not limited to healthcare professionals who practice in: hospitals, infectious disease,
emergency medicine, critical care, general surgery, obstetrics and
gynecology, family practice and outpatient infusion centers. Subsequent
letters will be sent to any new health care provider that was not initially
sent the appended DHCP letter. The DHCP Letter will be distributed with
the VIBATIV Package Insert and Medication Guide.

a. The letter will be available via a link from the VIBATIV website at
www.vibativ.com and as well as from the medical information
department for a period of one year after the approval of the most
recent modification of the REMS. The letter will include Pregnancy
Registry Information.

b. The Dear HCP Letter will be sent to the leadership of the following
professional organizations with a request that these organizations
disseminate the content of the letter to their professional
membership:

    Infectious Disease Society of America
    American College of Emergency Physicians
    Society of Critical Care Medicine
    Society of Hospital Medicine
    Surgical Infection Society
    American Thoracic Society
    American College of Chest Physicians
    American College of Obstetrics and Gynecology
    Outpatient Parenteral Antimicrobial Therapy
    American Medical Association
    American Hospital Association
    Federation of American Hospitals
    American Society of Health-System Pharmacists
    American College of Clinical Pharmacists
    Society of Infectious Disease Pharmacists
    American College of Clinical Pharmacists
    American Pharmacists Association
    Premier

2. The email will target physicians based on the American Medical
Association database. The email distribution list for other healthcare
providers will be based on other databases and secured through a private
contractor.

3. Providers that have an email address on file will receive the DHCP Letter
via email. If the intended recipient does not open the DHCP Letter within
10 days, the materials will be distributed hardcopy via U.S. mail. The
healthcare providers on the target audience list who do not have an email
on file will receive a hardcopy via U.S. mail.

4. The DHCP letter will be provided to MedWatch at the same time it is
provided to the professional organizations.
The DHCP Letter is part of the REMS and is appended.

C. **Timetable for Submission of Assessments**

Theravance Biopharma Antibiotics, Inc. will submit REMS Assessments to FDA at 18 months, 3 years, and 7 years following the approval date of the most recent modification of the REMS (6/2013).

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Theravance Biopharma Antibiotics, Inc. will submit each assessment so that it will be received by FDA on or before the due date.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
11/12/2014