ANNEX

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states

The Member States shall agree the final educational material with the Marketing Authorization Holder (MAH) prior to launch of the product in their territory.

The Member States shall ensure that the MAH provides all physicians who are expected to prescribe or use Vibativ a health care professional educational pack containing the following:

- The Summary of Product Characteristics
- The Patient Information Leaflet
- The Healthcare Professional Guide

The Healthcare Professional Guide should contain the following key messages:

- That Vibativ has a risk of nephrotoxicity including increased risk of mortality in patients with pre existing acute renal failure and is therefore contraindicated in patients with pre-existing acute renal failure and in patients with creatinine clearance < 30ml/min, including patients undergoing haemodialysis. Vibativ should be used with caution with other nephrotoxic drugs.
- That the benefit risk balance for the Complicated Skin and Soft Tissue Infections indication was assessed as negative by the Committee for Medicinal Products for Human Use (CHMP), therefore Vibativ should not be used in this or other indications not approved.
- That patients' renal function should be assessed and monitored and initial dose and dosage adjustments should be calculated based on the creatinine clearance.
- That there is a potential risk of teratogenicity and Vibativ is contraindicated during pregnancy. The pregnancy status of women of childbearing potential must be established prior to dosing with telavancin and women of childbearing potential must use effective contraception during treatment.
- The role and use of the Prescriber Checklist sticker included in the product package to document the established pregnancy status prior to dosing.
- The existence and scope of the pregnancy register and details of how to enter patients into it.
- There is a risk of QTc prolongation and Vibativ should be used with caution in patients taking drugs known to prolong the QT interval.
- That there is a risk of infusion related reactions including red man syndrome-like reactions.

- That there is an identified risk of ototoxicity and patients developing ototoxicity signs or symptoms or patients receiving other drugs with ototoxic potential should be carefully evaluated and monitored.
- Healthcare professionals should be aware that the administration of Vibativ may interfere with some coagulation laboratory tests and qualitative and quantitative urine protein tests.
- The need to counsel patients on important risks associated with Vibativ therapy and appropriate precautions when using the medicine.

The Member States shall ensure that the MAH provides all physicians who are expected to prescribe or use Vibativ a Direct Healthcare Professional Communication letter, the text of which is appended to the CHMP assessment report. The Member States shall agree with the MAH the communication plan for the DHPC letter.