Dear Healthcare Professionals,

**Prevymis (letermovir) concentrate for solution for infusion - Essential to administer through sterile 0.2 micron or 0.22 micron polyethersulfone (PES) in-line filter**

Your attention is drawn to the European Medicines Agency’s (EMA) announcement that a Direct Healthcare Professional Communication (DHPC) was issued to inform healthcare professional on the following important prescribing information:

- The diluted solution of Prevymis (letermovir concentrate for solution for infusion 20 mg/mL) MUST be infused through a sterile 0.2-micron or 0.22-micron polyethersulfone (PES) inline filter.
- Inspect the vial contents for discoloration and particulate matter. The concentrate is a clear and colorless solution and may contain a few product-related small translucent or white particles. Once diluted, the solution for infusion is clear and ranges from colorless to yellow.
- Do not use if the concentrate or diluted solution is cloudy, discolored, or contains matter other than a few small translucent or white particles.
- Do not use Prevymis concentrate for solution for infusion with IV bags and infusion set materials containing polyurethane or diethylhexyl phthalate (DEHP). Materials that are phthalate-free are also DEHP-free.

Prevymis concentrate for solution for infusion may contain product-related small translucent or white particles. Use of a sterile 0.2-micron or 0.22-micron PES in-line filter prevents possible administration of particles that have been seen in vials of Prevymis injection. Administration through a sterile 0.2-micron or 0.22-micron PES in-line filter has no impact on Prevymis dosage.

.../3

*We build a healthy Hong Kong and aspire to be an internationally renowned public health authority*
Administration of Prevymis diluted solution always requires the use of a sterile 0.2 micron or 0.22 micron PES in-line filter, regardless of whether these product-related particles are visible in the vial or diluted solution.

The healthcare professionals who may be involved in the reconstitution and administration of Prevymis are advised to carefully follow the reconstitution and administration instructions in the summary of product characteristics (SmPC) and the package leaflet (PIL) for Prevymis, as summarized below:

- Prevymis must be diluted prior to intravenous (IV) use according to the instructions in the SmPC.
- Inspect the vial contents for discoloration and particulate matter prior to dilution. Prevymis concentrate for solution for infusion is a clear and colorless solution and may contain a few product-related small translucent or white particles.
- Do not use the vial if the solution is cloudy, discolored, or contains matter other than a few small translucent or white particles.
- Do not use Prevymis concentrate for solution for infusion with IV bags and infusion set materials containing polyurethane or the plasticizer diethylhexyl phthalate (DEHP). Materials that are phthalate-free are also DEHP-free.
- Once diluted, the solution of Prevymis is clear and ranges from colorless to yellow. Variations of color within this range do not affect the quality of the product.
- Discard the diluted solution if the solution is cloudy, discolored, or contains matter other than a few small translucent or white particles.
- The diluted solution must be administered through a sterile 0.2-micron or 0.22-micron PES in-line filter.

Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). Prevymis may be administered orally, with Prevymis 240 mg or 480 mg tablets, or intravenously, using Prevymis concentrate for solution for infusion after suitable dilution.

Please refer to the following website in EMA for details:

We build a healthy Hong Kong and aspire to be an internationally renowned public health authority
In Hong Kong, Prevymis Concentrate For Solution For Infusion 480mg/24ml (HK-66122) and Prevymis Concentrate For Solution For Infusion 240mg/12ml (HK-66125) are pharmaceutical products registered by Merck Sharp & Dohme (Asia) Ltd (MSD), and are prescription-only medicines. As confirmed with the MSD, an application for change of the package insert that encompasses the above precautions has already been submitted to the Department of Health (DH); and the application has been under evaluation. The DH will remain vigilant on any safety update issued by overseas drug regulatory authorities. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Undesirable Medical Advertisements and Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under “ADR Reporting”: http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office’s website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)