Dear Healthcare Professionals,

**FDA updates vinca alkaloid labeling for preparation in intravenous infusion bags only**

Your attention is drawn to the U.S. Food and Drug Administration (FDA) announcement that is alerting health care professionals to labeling updates for the preparation of vinca alkaloids, a group of chemotherapy agents that includes vincristine sulfate injection, vinblastine sulfate (for) injection, and vinorelbine tartrate injection. To reduce the potential for unintended intrathecal (spinal) administration, which causes death or severe neurological injury, FDA is working with drug application holders to remove instructions for preparation of these drugs by syringe and to recommend preparation in intravenous infusion bags only.

In 2007, the World Health Organization issued an alert about medication errors related to accidental intrathecal injection of vinca alkaloids. The Institute for Safe Medication Practices has published multiple reports about these wrong route-of-administration medication errors that resulted in adverse outcomes. In response, FDA has twice strengthened safety warnings in labeling for vinca alkaloids to warn against intrathecal administration and emphasize the products are for intravenous administration only. As published data suggests that dispensing vinca alkaloids prepared in intravenous bags reduces the risk of medication errors due to erroneous intrathecal administration, FDA is taking action to remove instructions for preparing vinca alkaloids in a syringe from the prescribing information for vinca alkaloids. The updated prescribing information for vinca alkaloids will only contain instructions for health care professionals to prepare these drugs in intravenous infusion bags.

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On January 24, 2020, FDA approved labeling changes for the brand name Navelbine (vinorelbine tartrate injection) that removed instructions for preparing it in a syringe, and drug companies are required to update generic vinorelbine product labeling to match the brand name labeling. Vinorelbine tartrate injection is indicated to treat patients with metastatic non-small cell lung cancer (NSCLC) and, in combination with cisplatin, for patients with locally advanced or metastatic NSCLC.

On January 14, 2021, the agency removed instructions for preparing vincristine sulfate injection in a syringe. Vincristine sulfate injection is indicated to treat acute lymphocytic leukemia in children and adults, and as part of combination chemotherapy for patients with Hodgkin’s disease, non-Hodgkin’s malignant lymphomas (including Burkitt’s lymphoma), rhabdomyosarcoma, neuroblastoma, and Wilms’ tumor.

FDA also requested more extensive labeling changes for the preparation of vinblastine sulfate (for) injection products. These labeling changes will remove instructions for preparation in a syringe and add instructions for preparation in an intravenous infusion bag. The changes should be completed during 2021.

Vinblastine sulfate injection is indicated to treat numerous malignancies including: generalized Hodgkin’s disease (Stages III and IV), lymphocytic lymphoma, histiocytic lymphoma, mycosis fungoides (advanced stages), and advanced testicular carcinoma.

Please refer to the following website in FDA for details:

In Hong Kong, there are 4 registered pharmaceutical products containing vincristine sulfate, 2 registered pharmaceutical products containing vinblastine sulfate, and 7 registered pharmaceutical products containing vinorelbine tartrate for parenteral use. All products are prescription-only medicines. So far, the Department of Health (DH) has received 58 cases of adverse drug reaction related to vincristine, 2 cases of adverse drug reaction related to vinblastine, and 2 cases of adverse drug reaction related to vinorelbine, but these cases are not related to medication errors in relation to accidental intrathecal injection. In light of the above US FDA’s announcement, the DH will remain vigilant on safety update of the drugs issued by other overseas drug regulatory authorities for consideration of any action deemed necessary. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

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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)