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PFSB/SD Notification 0214-9

Call attention to the “Precautions” of anti-influenza virus drugs

From: Safety Division (SD),
Pharmaceutical and Food Safety Bureau (PFSB),
Ministry of Health, Labour and Welfare

To: Pharmaceutical Affairs Division,
Prefectural Public Health Bureaus (Departments)

February 14, 2012

Regarding the potential onset of abnormal behavior after taking anti-influenza virus drugs*, the MHLW issued a notification dated November 22, 2011 and reminded the marketing authorization holders (MAHs) to continue to alert healthcare professionals to the following information which is described in the Important Precautions sections and other sections of package inserts.

Now prescriptions for these medications are anticipated to increase due to the recent spread of influenza infections. In addition, a case has been reported in a teenage patient who plunged to death after taking an anti-influenza virus drug, laninamivir octanoate hydrate, while the situation leading to the death has yet to be revealed as well as the presence or absence of abnormal behavior. In the light of these circumstances, the MHLW required the relevant MAHs to continue to strengthen the alert.

For Healthcare Professionals:

There have been reported of neuropsychiatric symptoms including abnormal behavior after administration of the anti-influenza virus drugs, although the contribution of the drugs to these events has not been established. When the drugs are administered to children and adolescents, healthcare professionals are required to explain to patients or their families that, after initiation of treatment with this drug, (1) abnormal behavior may occur and (2) caregivers should be careful not to leave patients alone at least for 2 days if they are treated at home, as preventative measures to avoid rare accidents including falls due to abnormal behavior. Also, since it has been reported that similar symptoms occur due to influenza encephalopathy, it is required to explain the same as above.

*Notes

Anti-influenza virus drugs include oeltamivir phosphate, zanamivir hydrate, amantadine hydrochloride, laninamivir octanoate hydrate and peramivir hydrate.

References:

MHLW: Influenza Q&A (Q.10, 13, 14)

<http://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou01/qa.html> (Japanese text only)

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<http://www.info.pmda.go.jp/iyaku/file/h240214-001.pdf> (Japanese original text)

Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare (MHLW)
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo
100-8916 Japan

Office of Safety I,
Pharmaceuticals and Medical Devices Agency(PMDA)
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo
100-0013 Japan
E-mail: safety.info@pmda.go.jp
