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DEPARTMENT OF HEALTH
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8 Oct 2018

(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

**Fluoroquinolone and quinolone antibiotics:**
**PRAC recommends restrictions on use**

Your attention is drawn to the The European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) announcement regarding the recommendation in restricting the use of fluoroquinolone and quinolone antibiotics (used by mouth, injection or inhalation) following a review of disabling and potentially long-lasting side effects reported with these medicines. The review incorporated the views of patients, healthcare professionals and academics presented at EMA's public hearing on fluoroquinolone and quinolone antibiotics in June 2018.

Very rarely, patients treated with fluoroquinolone or quinolone antibiotics have suffered long-lasting and disabling side effects, mainly involving muscles, tendons and bones and the nervous system.

Following its evaluation of these side effects, the PRAC has recommended that some medicines, including all those that contain a quinolone antibiotic, should be removed from the market. This is because they are authorised only for infections that should no longer be treated with this class of antibiotics.

The PRAC recommended that the remaining fluoroquinolone antibiotics should:

• **not** be used
- to treat infections that might get better without treatment or are not severe (such as throat infections);
- for preventing traveller's diarrhoea or recurring lower urinary tract infections (urine infections that do not extend beyond the bladder);
- to treat patients who have previously had serious side effects with a fluoroquinolone or quinolone antibiotic;
- to treat mild or moderately severe infections unless other antibacterial medicines commonly recommended for these infections cannot be used;

• be used **with caution** especially for the elderly, patients with kidney problems, patients who have had an organ transplantation or those who are being treated with a systemic corticosteroid. These patients are at higher risk of tendon injury caused by fluoroquinolone and quinolone antibiotics.

The PRAC also recommended that healthcare professionals should advise patients to stop treatment with a fluoroquinolone antibiotic at the first sign of a side effect involving muscles, tendons or bones (such as inflamed or torn tendon, muscle pain or weakness, and joint pain or swelling) or the nervous system (such as feeling pins and needles, tiredness, depression, confusion, suicidal thoughts, sleep disorders, vision and hearing problems, and altered taste and smell).

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/fluoroquinolone-quinolone-antibiotics-prac-recommends-restrictions-use

Drug safety news related to fluoroquinolones had previously been reported by overseas drug regulatory authorities, and posted on the Drug Office website since 8 Nov 2011, with the last update on 6 July 2017. Letters to inform local healthcare professionals on the above safety news had been issued in 2011, 2013 and 2016. In 2013, the Registration Committee of the Pharmacy and Poisons Board (the Registration Committee) discussed the safety of fluoroquinolones with peripheral neuropathy, and decided that the relevant warnings should be included in the sales packs and/or package inserts of the products. In 2016, the Registration Committee further discussed the safety of fluoroquinolones with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system, and subsequently decided to remain vigilant on further updates by other overseas drug regulatory authorities.

So far, the Department of Health (DH) has received 4 cases of adverse drug reaction related to levofloxacin and 1 case related to moxifloxacin, of these 5 cases one of the levofloxacin case was related to tendinitis and neuropathy, other 4 cases were not related to adverse effects mentioned in EMA's announcement. The DH has not received any case of adverse drug reaction related to other fluoroquinolone and quinolones. In view of the EMA announcement in Feb 2017 and Oct 2018, the matter will be further discussed by the Registration Committee of the Pharmacy and Poisons Board. The DH will maintain vigilant on any further update from these health 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.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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)