Drug News
藥 物 情 報

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This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in January 2023 with relevant information update before publish. For the latest news and information, please refer to public announcements or the website of the Drug Office of the Department of Health (http://www.drugoffice.gov.hk).

Safety Update

European Union: Zolgensma: fatal cases of acute liver failure

On 13 January 2023, the European Medicines Agency (EMA) announced that the Pharmacovigilance Risk Assessment Committee (PRAC) discussed a direct healthcare professional communications (DHPC) containing important information for Zolgensma (onasemnogene abeparvovec).

Fatal cases of acute liver failure were recently reported in patients treated with Zolgensma (onasemnogene abeparvovec), a gene therapy medicine for the treatment of spinal muscular atrophy (SMA), a serious rare condition of the nerves that causes muscle wasting and weakness.

This DHPC informs healthcare professionals of the fatal cases of liver failure and the updated recommendations for monitoring liver function, assessing suspected liver injury after infusion and further advice regarding tapering the corticosteroid treatment.

The PRAC advises that healthcare professionals should promptly assess patients with worsening liver function tests and/or signs or symptoms of acute liver illness. If patients do not respond adequately to treatment with corticosteroids, treating physicians should consult a paediatric gastroenterologist or hepatologist and consider adjustment of the corticosteroid regimen.

The DHPC for Zolgensma will be forwarded to EMA's committee for advanced therapies (CAT) and to EMA's human medicines committee (CHMP). Following the CHMP decision, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holders, according to an agreed communication plan, and published on the 'Direct healthcare professional communications' page and in national registers in European Union (EU) Member States.

In Hong Kong, there is one registered pharmaceutical product containing onasemnogene abeparvovec, namely Zolgensma Solution For Infusion 2 X 10^13 Vector Genomes/ml (HK-67654). The product is registered by Novartis Pharmaceuticals (HK) Limited. It is a prescription-only medicine. As of the end of January 2023, the Department of Health (DH) had not received any case of adverse drug reaction related to onasemnogene abeparvovec. Related news on the risk of acute liver failure associated with the use of onasemnogene abeparvovec was previously issued by Health Canada. The current package insert of the above local onasemnogene abeparvovec-containing product include safety information on the risk of acute liver failure. In light of the above EMA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 16 January 2023, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Canada: Summary Safety Review: Third generation aromatase inhibitors (anastrozole, exemestane, letrozole) - Assessing the potential risk of tendon disorders

On 17 January 2023, Health Canada announced that it reviewed the evidence for the risks of tendonitis, tenosynovitis, and tendon rupture related to the use of third generation aromatase inhibitors to determine whether regulatory actions would be required in Canada. The safety review was triggered by a labelling update for letrozole, to include the risks of tendonitis and tendon rupture, in Europe. While the European Medicines Agency's safety assessment was limited to letrozole, it did not rule

out the possibility that the risk of tendon disorders may be associated with all third generation aromatase inhibitors. At the time of the review, the Canadian product monographs (CPMs) for third generation aromatase inhibitors included information on the risk of tenosynovitis of the hands.

A tendon is a rope-like fibrous tissue that attaches muscle to bone. A thin fibrous sheath surrounds the tendon. Disorders of the tendon include tendon inflammation (tendonitis), tendon tears (tendon rupture) and inflammation of the tendon sheath (tenosynovitis). Tendon disorders can cause serious physical limitations and, in some cases, require surgery.

Health Canada reviewed information from published and unpublished population-based studies and case reports of individual patients. Information was obtained from searches of international databases of published literature, drug manufacturers, as well as searches of the Canada Vigilance database. Health Canada reviewed 5 randomized controlled trials (RCTs) that included a total of 28,873 patients. Reported events of tendonitis and tenosynovitis, which were uncommon in occurrence (less than 1%), were found to be likely linked to the use of third generation aromatase inhibitors. A link with tendon rupture, which was rare in occurrence (less than 0.1%), could not be ruled out. Health Canada also reviewed 25 case reports (2 Canadian and 23 international) of tendon rupture (10 cases) and tendonitis (15 cases). Health Canada did not review case reports of tenosynovitis as there was insufficient information in these reports to separate tenosynovitis from other labelled adverse events involving the muscles and bones. Of the 10 reported cases of tendon rupture, 4 involved the use of anastrozole, 4 letrozole and 2 exemestane (1 Canadian). Of the 15 reported cases of tendonitis, 7 involved the use of anastrozole (1 Canadian), 4 involved letrozole and 4 exemestane. Across the assessed cases, tendonitis and tendon rupture affected both upper and lower limbs. These 25 case reports included other medications and/or conditions that could have contributed to the reported adverse events. From these case reports, a link between the risk of tendon rupture and tendonitis with the use of a third generation aromatase inhibitor could not be ruled out.

Health Canada's review of the available RCTs and case reports concluded that there is likely a link between the use of third generation aromatase inhibitors and the risks of tendonitis and tenosynovitis, which were uncommon in occurrence. A link with tendon rupture, which was rare in occurrence, could not be ruled out.

Health Canada is working with the manufacturers of third generation aromatase inhibitors to update the CPMs to include these risks.

In Hong Kong, there are registered pharmaceutical products containing anastrozole (16 products), exemestane (7 products) and letrozole (14 products). All products are prescription-only medicines. As of the end of January 2023, the Department of Health had received adverse drug reaction related to anastrozole (one case), exemestane (7 cases) and letrozole (40 cases), but these cases were not related to tendon disorders. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 18 January 2023, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

The United States: CDC and FDA identify preliminary COVID-19 Vaccine safety signal for persons aged 65 years and older

On 13 January 2023, the US Food and Drug Administration (FDA) announced that, following the availability and use of the updated (bivalent) COVID-19 vaccines, the Centers for Disease Control and Prevention's (CDC) Vaccine Safety Datalink (VSD), a near real-time surveillance system, met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Rapid-response investigation of the signal in the VSD raised a question of whether people 65 and older who have received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent were more likely to have an ischemic stroke in the 21 days following vaccination compared with days 22-44 following vaccination.

This preliminary signal has not been identified with the Moderna COVID-19 Vaccine, Bivalent. There also may be other confounding factors contributing to the signal identified in the VSD that merit further investigation. Furthermore, it is important to note that, to date, no other safety systems have

shown a similar signal and multiple subsequent analyses have not validated this signal:

- A large study of updated (bivalent) vaccines (from Pfizer-BioNTech and Moderna) using the Centers for Medicare and Medicaid Services database revealed no increased risk of ischemic stroke.
- A preliminary study using the Veterans Affairs database did not indicate an increased risk of ischemic stroke following an updated (bivalent) vaccine.
- The Vaccine Adverse Event Reporting System (VAERS) managed by CDC and FDA has not seen an increase in reporting of ischemic strokes following the updated (bivalent) vaccine.
- Pfizer-BioNTech's global safety database has not indicated a signal for ischemic stroke with the updated (bivalent) vaccine.
- Other countries have not observed an increased risk for ischemic stroke with updated (bivalent) vaccines.

Although the totality of the data currently suggests that it is very unlikely that the signal in VSD represents a true clinical risk, FDA believes it is important to share this information with the public when one of its safety monitoring systems detects a signal. CDC and FDA will continue to evaluate additional data from these and other vaccine safety systems.

No change in vaccination practice is recommended.

In Hong Kong, Comirnaty Original/Omicron BA.4-5 Dispersion For Injection COVID-19 MRNA Vaccine (Nucleoside Modified) (15/15 Micrograms)/Dose (HK-67666) is a pharmaceutical product registered by Fosun Industrial Co Limited. The product is a prescription -only medicine. The Department of Health will remain vigilant on any safety update of the product issued by FDA and other overseas drug regulatory authorities.

Canada: Summary Safety Review: Finasteride: Assessing the potential risks of suicide, suicidal thoughts (suicidal ideation) and self-injury

On 19 January 2023, Health Canada announced that it has been monitoring the risk of suicidal ideation with the use of finasteride since 2012. Health Canada completed 2 safety reviews in 2012 and 2015, and the information available at the time was considered too limited to determine whether there was a link between the use of finasteride and suicidal thoughts and behaviours (suicidality).

In 2019, following reports of Canadian and international cases of suicide, suicidal ideation and self-injury with the use of finasteride, Health Canada completed a third safety review that found a possible link between finasteride and the risk of suicidal ideation. The Canadian product monographs (CPMs) of finasteride were updated to include the risk of suicidal ideation.

In 2022, Health Canada completed a review of the risk of suicidal ideation and potential risks of suicide and self-injury with the use of finasteride. This latest safety review was triggered by the publication of a media article that discussed the potential risk of suicide in patients using Propecia (finasteride) for male pattern hair loss. The purpose of the current review was to consider recent information and determine if additional measures were warranted.

Health Canada reviewed the available information from searches of the Canada Vigilance database, the World Health Organization's Adverse Drug Reaction database, and the scientific literature. Health Canada reviewed 401 cases (29 Canadian and 372 international) of suicide, suicidal ideation and/or self-injury in patients using finasteride from the Canada Vigilance database. Of the 401 cases, 25 (10 Canadian) met the criteria for further assessment to determine if there was a link between the use of finasteride and suicide, suicidal ideation and self-injury. Of the 25 cases, 23 (9 Canadian) were found to be possibly linked to the use of finasteride. Two cases (1 Canadian) could not be assessed. Eight of the 14 international cases were fatal (resulted in a completed suicide). In 17 of the 25 cases assessed by Health Canada, patients were 40 years of age or younger and taking finasteride for male pattern hair loss. The number of cases of suicide, suicidal ideation and self-injury reported to Health Canada is considered to be low in individuals treated with finasteride (approximately one Canadian case for every 10.1 million tablets dispensed in Canada). Health Canada also reviewed 16 publications in the scientific literature. There is a growing body of scientific evidence regarding the association between the use of finasteride and the risks of suicide, suicidal ideation and self-injury. Although there were limitations, the publications reviewed supported a possible link between the use of finasteride and suicidal ideation during treatment and following discontinuation of finasteride,

especially in patients treated for male pattern hair loss.

Health Canada's review of the available information found a possible link between the use of finasteride and the risks of suicidal ideation and self-injury. At this time, there is not enough information to establish a link between the use of finasteride and the risk of suicide.

Health Canada is working with the manufacturers to update the CPMs for finasteride-containing products to strengthen the warning statements on the risks of suicidal ideation and self-injury, and to include information about patient screening for psychiatric risk factors prior to starting treatment, as well as continuous patient monitoring during and after stopping treatment.

In Hong Kong, there are 32 registered pharmaceutical products containing finasteride. All products are prescription-only medicines. As of the end of January 2023, the Department of Health (DH) had received 4 cases of adverse drug reaction related to finasteride, but these cases were not related to suicidal ideation, self-injury or suicide.

Related news on the risk of suicidal ideation associated with the use of finasteride was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 91, with the latest update reported in Drug News Issue No. 154. The DH issued letters to inform local healthcare professionals to draw their attention on 25 May 2017. In September 2017, the Registration Committee of the Pharmacy and Poisons Board discussed the matter and decided that the sales pack label and/or package insert of finasteride-containing products should include safety information on suicidal ideation.

In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 20 January 2023, and the matter will be further discussed by the Registration Committee of the Pharmacy and Poisons Board.

Canada: Summary Safety Review: Cephalosporins: Assessing the potential risk of seizures

On 23 January 2023, Health Canada announced that it reviewed the potential risk of seizures with the use of cephalosporins (cephalexin, cefazolin, cefadroxil, cefoxitin, cefuroxime, cefprozil, cefotaxime, ceftazidime, ceftriaxone, cefixime, cefepime, ceftobiprole, and ceftolozane-tazobactam). This safety review was triggered by a United States Food and Drug Administration update to the product safety information for a cefazolin-containing product to include the risk of seizures.

Health Canada reviewed the available information from searches of the Canada Vigilance database, international databases, as well as medical and scientific literature. Health Canada reviewed 84 cases (7 Canadian and 77 international) of seizures in patients taking cephalosporins. Of the 84 cases, 13 were found to be probably linked to the use of cephalosporins. Sixty-two cases (4 Canadian) were found to be possibly linked, and 3 cases were unlikely to be linked to the use of cephalosporins. Six cases (3 Canadian) could not be assessed.

Health Canada's review of the available information concluded that there may be a link between the use of cephalosporins and the risk of seizures. At the time of the safety review, the risk of seizures was already included in the Canadian product monograph (CPM) for some cephalosporins. Health Canada will work with the manufacturers to update the CPM for the cephalosporins that do not already include this risk.

In Hong Kong, there are registered pharmaceutical products containing cephalexin (54 products), cefazolin (4 products), cefadroxil (6 products), cefuroxime (31 products), cefotaxime (11 products), ceftazidime (13 products), ceftriaxone (31 products), cefepime (11 products) and ceftolozane-tazobactam (one product). All products are prescription-only medicines. There is no registered pharmaceutical product containing cefoxitin, cefprozil, cefixime or ceftobiprole. As of the end of January 2023, the Department of Health (DH) had received adverse drug reaction related to cefazolin (one case), cefuroxime (4 cases), cefotaxime (7 cases), ceftazidime (one case), ceftriaxone (7 cases) and cefepime (3 cases), but these cases were not related to seizures. The DH had not received any case of adverse drug reaction related to cephalexin, cefadroxil or ceftolozane-tazobactam. The risk of seizures associated with the use of cephalosporins is documented in overseas reputable drug references, such as the "AHFS Drug Information". The DH will remain vigilant on any safety update of the

drugs issued by other overseas drug regulatory authorities.

The United Kingdom: Topical testosterone (Testogel): risk of harm to children following accidental exposure

On 25 January 2023, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that premature puberty and genital enlargement have been reported in children who were in close physical contact with an adult using topical testosterone and who were repeatedly accidentally exposed to this medicine.

Topical testosterone products are gels or creams applied directly to the skin. They are authorised to replace testosterone in men who do not produce sufficient natural testosterone; a condition known as hypogonadism. These products are also used outside of the licence for a range of conditions, including for peri/post-menopausal symptoms in women. If this product is repeatedly accidentally transferred to another person through physical contact, it can increase their blood testosterone levels. This may result in possible side effects (for example, growth of facial and/or body hair, deepening of the voice, irregular menstrual cycles in women, and premature puberty and genital enlargement in children).

The MHRA received a report of a child who was repeatedly accidentally exposed to the topical testosterone product that their parent was using, resulting in increased growth and genital enlargement. It was confirmed through clinical investigations that the child had increased testosterone in their blood and that the topical testosterone product was the source of the testosterone. There are also literature reports and non-United Kingdom reports of premature puberty and genital enlargement in children who were repeatedly accidentally exposed to a topical testosterone product via transfer from an adult with whom they were in close contact.

The risk was reviewed by the Paediatric Medicines Expert Advisory Group of the Commission on Human Medicines, which recommended that a specific paediatric warning be added to the product information for topical testosterone products. MHRA has requested that the manufacturers of topical testosterone products update the Summary of Product Characteristics and the Patient Information Leaflet. These updates will provide warnings about accidental exposure to children and set out the precautions concerning washing the application site before physical contact with another person (adult or child). A specific warning will be included about the risk of accidental testosterone transfer to children.

Advice for healthcare professionals:

- When prescribing topical testosterone, inform patients of the potential consequences if it is accidentally transferred to other people.
- Inform patients that accidental transfer can lead to increased blood testosterone levels in the other person.
- Advise patients of the possible effects should accidental exposure occur in adult women (facial and/or body hair growth, deepening of voice, changes in menstrual cycle) or children (genital enlargement and premature puberty, including development of pubic hair).
- Counsel patients on methods to reduce the risks of accidental exposure, including washing their hands with soap and water after application, covering the application site with clean clothing once the gel has dried, and washing the application area with soap and water before physical contact with another person.
- Encourage patients to be vigilant about implementing measures to minimise risk, to be alert for signs of accidental exposure, and to seek medical advice if accidental exposure is suspected.

In Hong Kong, there are 3 registered pharmaceutical products which are topical testosterone. All products are prescription-only medicines. As of the end of January 2023, the Department of Health (DH) had received one case of adverse drug reaction related to topical testosterone, but this case was not related to premature puberty or genital enlargement in children due to accidental exposure to the drug. In light of the above MHRA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 26 January 2023, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

European Union: EMA confirms measures to minimise risk of serious side effects with Janus kinase inhibitors for chronic inflammatory disorders

On 27 January 2023, the European Medicines Agency (EMA) announced that its Committee for Medicinal Products for Human Use (CHMP) has endorsed the measures recommended by the Pharmacovigilance Risk Assessment Committee (PRAC) to minimise the risk of serious side effects with Janus kinase (JAK) inhibitors used to treat several chronic inflammatory disorders and the updates to further align dosing recommendations for the medicines. These side effects include cardiovascular conditions, blood clots, cancer and serious infections.

These medicines should be used in the following patients only if no suitable treatment alternatives are available: those aged 65 years or above, those at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past and those at increased risk of cancer.

JAK inhibitors should be used with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism, VTE) other than those listed above. Further, the doses should be reduced in patient groups who are at risk of VTE, cancer or major cardiovascular problems, where possible.

The recommendations follow a review of available data, including the final results from a clinical trial1 of the JAK inhibitor Xeljanz (tofacitinib) and preliminary findings from an observational study involving Olumiant (baricitinib). The review also included advice from an expert group of rheumatologists, dermatologists, gastroenterologists and patient representatives.

The review confirmed Xeljanz increases the risk of major cardiovascular problems, cancer, VTE, serious infections and death due to any cause when compared with medicines belonging to the class of TNF-alpha inhibitors. EMA has now concluded that these safety findings apply to all approved uses of JAK inhibitors in chronic inflammatory disorders (rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, ulcerative colitis, atopic dermatitis and alopecia areata).

The product information for JAK inhibitors used to treat chronic inflammatory disorders will be updated with the new recommendations and warnings. In addition, the educational material for patients and healthcare professionals will be revised accordingly.

Information for healthcare professionals:

- An EMA review has found that, compared with TNF-alpha inhibitors, Janus kinase (JAK) inhibitors used to treat chronic inflammatory disorders (rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, ulcerative colitis, atopic dermatitis and alopecia areata) are linked to a higher risk of major adverse cardiovascular events (MACE), venous thromboembolism (VTE), malignancy, serious infections and all-cause mortality.
- The review included the final results from an open-label clinical trial (ORAL Surveillance study)1 of the JAK inhibitor Xeljanz (tofacitinib) in patients with rheumatoid arthritis and cardiovascular risk factors which found a higher risk of these events with Xeljanz than with TNF-alpha inhibitors.
- Preliminary findings from an observational study (B023) involving another JAK inhibitor, Olumiant (baricitinib), also suggest an increased risk of MACE and VTE in patients with rheumatoid arthritis treated with Olumiant compared with those treated with TNF-alpha inhibitors.
- EMA concluded that the identified risks apply to all JAK inhibitors approved for the treatment of chronic inflammatory disorders.
- These medicines (Xeljanz, Cibinqo, Olumaint, Rinvoq and Jyseleca) should only be used in the following patients if no suitable treatment alternatives are available: those aged 65 years or above, those who are current or past long-time smokers, those with a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors, or those with other malignancy risk factors. Cautious use is also recommended in patients with known risk factors for VTE other than those listed above.
- If JAK inhibitors are needed in patients with these risk factors, a lower dose may be recommended, depending on the medicine, the indication and the specific risk factor.
- Healthcare professionals should discuss the risks associated with JAK inhibitors with their patients.
- It is recommended that healthcare

Safety Update

professionals carry out periodic examinations of their patients' skin to check for skin cancer, particularly for patients at risk for skin cancer.

In Hong Kong, there are 3 registered pharmaceutical products containing tofacitinib, namely Xeljanz Tablets 5mg (HK-63303), Xeljanz XR Extended Release Tablets 11mg (HK-66141) and Xeljanz Tablets 10mg (HK-66833), which are registered by Pfizer Corporation Hong Kong Limited; 2 products containing baricitinib, namely Olumiant Tablets 2mg (HK-65663) and Olumiant Tablets 4mg (HK-65664), which are registered by Eli Lilly Asia, Inc.; 2 products containing upadacitinib, namely Rinvoq Prolonged-Release Tablets 15mg (HK-66872) and Rinvoq Prolonged-Release Tablets 30mg (HK-67512), which are registered by Abbvie Limited; and 3 products containing abrocitinib, namely Cibinqo Tablets 100mg (HK-67658), Cibinqo Tablets 200mg (HK-67659) and Cibinqo Tablets 50mg (HK-67660), which are registered by Pfizer Corporation Hong Kong Limited. All products are prescription-only medicines. There is no registered pharmaceutical product containing filgotinib.

As of the end of January 2023, the Department of Health (DH) had received adverse drug reaction related to tofacitinib (9 cases; of which 2 cases were related to cancer, 3 cases were related to deep vein thrombosis, one case was related to disseminated tuberculosis, one case was related to cellulitis, one case was related to pneumonia and one case was related to herpes zoster disseminated), baricitinib (3 cases; of which one case was related to deep vein thrombosis, one case was related to pneumocystis jirovecii pneumonia and one case was related to hypotension) and upadacitinib (6 cases; of which 4 cases were related to herpes zoster, one case was related to cytomegalovirus colitis and one case was related to lung inflammation); and no case was related to abrocitinib.

Related news on the risk of blood clots, serious heart-related problems, cancer and serious infections of JAK inhibitors was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 112, with the latest update reported in Drug News Issue No. 158. The DH issued letters to inform local healthcare professionals to draw their attention on 29 July 2019, 19 June 2020, 15 June 2021, 2 September 2021 and 31 October 2022.

In December 2019, the Registration Committee of the Pharmacy and Poisons Board (the Committee) discussed the matter on the risk of blood clots and death associated with the use of tofacitinib, and decided that the sales pack or package insert of tofacitinib products should include safety information about increased risk of blood clots and death with higher dose (10 mg twice daily).

In December 2021, the Committee discussed the matter on the risk of venous thromboembolic events (including deep vein thrombosis and pulmonary embolism) associated with the use of JAK inhibitors (tofacitinib, baricitinib and ruxolitinib), and decided that the sales pack or package insert of these products should include the relevant safety information.

As previously reported, the matter will be further discussed by the Committee.

Drug Recall

Recall 4 batches of Diprospan Injection (1ml ampoule)

On 27 January 2023, the Department of Health (DH) endorsed a licensed drug wholesaler, Organon Hong Kong Limited (Organon), to recall 4 batches (batch number: U037539, W001030, W026080 & W032423) of Diprospan Injection (1ml ampoule) (Hong Kong Registration Number: HK-18689) from the market due to potential quality issue.

The DH received notification from Organon that the overseas manufacturer of the product is initiating a recall of the above batches due to detection of stainless steel particles in the product. As a precautionary measure, Organon is voluntarily recalling the affected batches from the market. DH investigation is continuing.

The above product, containing betamethasone dipropionate and betamethasone sodium phosphate, is a prescription medicine. Betamethasone is a steroid substance for treating inflammation. According to Organon, the affected batches of product have been imported into Hong Kong and supplied to the Hospital Authority, Department of Health clinics, private hospitals, private medical

Drug Recall

practitioners, pharmacies, and re-exported to Macau.

As of the end of January 2023, the DH had not received any adverse reaction reports in connection with the above batches of product. A notice was posted in the Drug Office website on 27 January 2023 to alert the public of the product recall. The DH will closely monitor the recall.

A product containing any western drug ingredient must be registered under the Pharmacy and Poisons Ordinance before it can be sold in Hong Kong. Part 1 poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part 1 poisons and unregistered pharmaceutical products are offences under the Pharmacy and Poisons Ordinance (Cap. 138). The maximum penalty is a fine of $100,000 and two years' imprisonment for each offence. Antibiotics can only be supplied at registered pharmacies by registered pharmacists or under their supervision and upon a doctor's prescription. They should only be used under the advice of a doctor. Illegal sale or possession of antibiotics are offences under the Antibiotics Ordinance (Cap. 137) and the maximum penalty is a $50,000 fine and one year's imprisonment for each offence.

Under the Import and Export Ordinance (Cap. 60), pharmaceutical products must be imported or exported under and in accordance with an import or export licence issued under the Import and Export Ordinance. Illegal import or export of pharmaceutical products are offences under the Import and Export Ordinance (Cap. 60) and the maximum penalty is a fine of $500,000 and 2 years' imprisonment.

Update on Drug Office's website: You can now search the newly registered medicines in the past year at http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare_providers?pageNoRequested=1.
Details of ALL registered pharmaceutical products can still be found in the Drug Office website at http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/news_informations/reListRPP_index.html.

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The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.