Drug News
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Issue Number 183

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in January 2025 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

The United States: FDA requires Guillain-Barré Syndrome (GBS) warning in the prescribing information for RSV Vaccines Abrysvo and Arexvy

On 7 January 2025, the United States Food and Drug Administration (FDA) announced that it has required and approved safety labeling changes to the Prescribing Information for Abrysvo (Respiratory Syncytial Virus Vaccine) manufactured by Pfizer Inc. and Arexvy (Respiratory Syncytial Virus Vaccine, Adjuvanted) manufactured by GlaxoSmithKline Biologicals. The Prescribing Information for each Respiratory Syncytial Virus (RSV) vaccine has been revised to include the following in the Warnings and Precautions section:

- Abrysvo: The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome (GBS) during the 42 days following vaccination with Abrysvo.
- Arexvy: The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with Arexvy.

GBS is a rare disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis.

Abrysvo was initially approved on 31 May 2023, for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older. Subsequently, FDA has approved the vaccine for the prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV; immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.

Arexvy was initially approved on 3 May 2023, for the prevention of LRTD caused by RSV in individuals 60 years of age and older. Subsequently, FDA has approved the vaccine for use in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

FDA conducted a postmarketing observational study that assessed the risk of GBS following vaccination with Abrysvo and Arexvy. Based on FDA's evaluation of data from clinical trials, reports to the Vaccine Adverse Event Reporting System (VAERS), and the postmarketing study, FDA has determined that the overall body of evidence suggests increased risks of GBS with Abrysvo and Arexvy, but that available evidence is insufficient to establish a causal relationship.

The association between vaccination with Abrysvo and Arexvy and GBS was evaluated among Medicare beneficiaries 65 years of age and older. Using Medicare claims data, between May 2023 through July 2024, vaccinations with Abrysvo and Arexvy were identified through Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) codes and National Drug Codes, and potential cases of hospitalized GBS among recipients of Abrysvo and Arexvy were identified through International Classification of Diseases (ICD) codes. GBS diagnoses in claims data were confirmed by medical record review when available.

The risks of GBS following vaccination with Abrysvo and Arexvy were assessed in self-controlled case series analyses using risk windows of 1 to 42 days post vaccination and control windows of 43 to 90 days post vaccination. The analyses of all GBS cases based on claims data suggest an increased risk of GBS during the 42 days following vaccination, with an estimated 9 excess

cases of GBS per million doses of Abrysvo, and an estimated 7 excess cases of GBS per million doses of Arexvy administered to individuals 65 years of age and older. Background risks of GBS in study populations influence excess GBS case estimates and may differ between studies and analyses within a study, precluding direct comparisons of excess GBS case estimates from other vaccine studies or populations.

While the results from the self-controlled case series analyses of this observational study suggest increased risks of GBS with Abrysvo and Arexvy, available evidence is insufficient to establish a causal relationship.

FDA has required and approved safety labeling changes to the Prescribing Information for Abrysvo and Arexvy based on the totality of data from clinical trials, reports to VAERS, and the results of self-controlled case series analyses in an observational study conducted by FDA that suggest increased risks of GBS with Abrysvo and Arexvy. FDA has further determined that the benefits of vaccination with Abrysvo and Arexvy continue to outweigh their risks.

In Hong Kong, Abrysvo Vaccine Powder And Solvent For Solution For Injection (HK-68213) and Arexvy Vaccine Powder And Suspension For Suspension For Injection (HK-67997) are pharmaceutical products registered by Pfizer Corporation Hong Kong Limited and GlaxoSmithKline Limited respectively. Both are prescription-only medicines. As of the end of January 2025, the Department of Health (DH) had received one case of adverse event following immunisation with Arexvy, but this case was not related to GBS. The DH had not received any case of adverse event following immunisation with Abrysvo. In light of the above FDA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 8 January 2025, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Australia: More prominent safety warnings about the neuropsychiatric effects of montelukast

On 16 January 2025, the Therapeutic Goods Administration (TGA) announced that additional safety information is being added to all montelukast products to strengthen and highlight existing warnings about serious neuropsychiatric events. These include behavioural changes, depression and suicidal thoughts and behaviour. The safety information includes a new boxed warning and additional guidance for prescribers and patients on the management of serious neuropsychiatric events.

This safety update follows a TGA safety investigation conducted in 2024 after international regulators strengthened warnings about neuropsychiatric events for montelukast products. The update brings the Australian Product Information (PI) and Consumer Medicine Information (CMI) in line with international regulatory advice.

Montelukast is a prescription medicine used to prevent and treat chronic asthma in adults and children aged 2 years and older, and for symptomatic seasonal allergic rhinitis (hay fever).

The risks of neuropsychiatric events with montelukast are already well documented in both the PI and CMI. In July 2018, the TGA published a review of montelukast and neuropsychiatric adverse events. This evaluated the medical literature and included consultation with international regulators and expert advice from the Advisory Committee on Medicines (ACM).

In 2024, an updated TGA safety investigation was conducted after international regulators strengthened their warnings about neuropsychiatric events. Expert advice from the ACM concluded that up-to-date information did not identify any new neuropsychiatric risks and existing evidence for the association between montelukast and neuropsychiatric risks remained uncertain. The expert group recommended adding a boxed warning in the Australian PI to align with international regulators.

A search of TGA's publicly available Database of Adverse Event Notifications (DAEN) on 18 December 2024 identified 356 cases for montelukast and psychiatric disorders. The most commonly reported symptoms were aggression (100 cases), anxiety (87 cases), suicidal ideation (72 cases), depression (71 cases), insomnia (52 cases) and nightmare (50 cases). There were 91 reports that mentioned suicidal behaviours. Of these, 10 reported a fatal outcome. It is important to note that inclusion in the DAEN does not mean that the details of the reported event have been confirmed, or that the event has been determined to

be related to a medicine.

The following boxed warning will be included in the Australian PIs for montelukast products:

- WARNING:

Serious neuropsychiatric events

Neuropsychiatric events such as behavioural changes, depression and suicidality have been reported in all age groups taking montelukast (see sections 4.4 and 4.8). Events are generally mild and may be coincidental. However, the symptoms may be serious and continue if the treatment is not withdrawn. Therefore, the treatment with montelukast should be discontinued if neuropsychiatric symptoms occur during treatment. Advise patients and/or caregivers to be alert for neuropsychiatric events and instruct them to notify their physician if these changes in behaviour occur.

Additional advice to prescribers will also be included in the existing information on neuropsychiatric events in Section 4.4 Special warnings and precautions of the PI, as follows:

- Neuropsychiatric events

Prescribers should discuss the benefits and risks of montelukast use with patients and caregivers when prescribing montelukast. Patients and/or caregivers should be advised to be alert for changes in behaviour or for new neuropsychiatric symptoms when taking montelukast. If changes in behaviour are observed, or if new neuropsychiatric symptoms or suicidal thoughts and/or behaviour occur, patients should be advised to discontinue montelukast and contact a healthcare provider immediately. In many cases, symptoms resolved after stopping montelukast therapy; however, in some cases symptoms persisted after discontinuation of montelukast. Therefore, patients should be monitored and provided supportive care until symptoms resolve. Prescribers should carefully evaluate the risks and benefits of continuing treatment with montelukast if such events occur.

Health professionals are reminded about the potential neuropsychiatric effects associated with montelukast. These effects have been reported in all age groups taking montelukast, are generally mild and may occur by chance. However, symptoms can be serious and continue if treatment is not stopped. In rare cases, patients taking montelukast have died after experiencing suicidal behaviour.

Health professionals should be vigilant for neuropsychiatric reactions in patients taking montelukast and discontinue treatment if new or worsening symptoms occur. Advise patients and their carers to be alert for changes in behaviour or for new neuropsychiatric symptoms and to seek medical advice immediately should they occur. Consider providing the CMI to remind patients of these effects.

In Hong Kong, there are 58 registered pharmaceutical products containing montelukast. All products are prescription-only medicines. As of the end of January 2025, with regard to montelukast, the Department of Health (DH) had received 7 cases of adverse drug reaction, of which 5 cases were reported as neuropsychiatric events.

Related news on the risk of neuropsychiatric events associated with the use of montelukast was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News since Issue No. 119, with the latest update reported in Drug News Issue No. 174. The DH issued letters to inform local healthcare professionals to draw their attention on 20 September 2019 and 5 March 2020.

In April 2021, the Registration Committee of the Pharmacy and Poisons Board discussed the matter and decided that the sales pack label and/or package insert of montelukast-containing products should include the relevant safety information, including the strengthened warnings in the above TGA's announcement. The DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

European Union: Medicines containing semaglutide: PRAC investigating risk of rare eye condition (NAION)

On 17 January 2025, the European Medicines Agency (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC), has started a review of medicines containing semaglutide following concerns regarding an increased risk of developing non-arteritic anterior ischemic optic neuropathy (NAION), a rare eye condition, as suggested in two recent observational studies, while two other recent observational studies do not suggest an increased risk.

Semaglutide, a GLP-1 receptor agonist, is the active substance in certain medicines used in the

treatment of diabetes and obesity (namely Ozempic, Rybelsus and Wegovy).

PRAC is assessing whether patients treated with semaglutide may have an elevated risk of developing NAION. This is a disorder caused by reduced blood flow to the optic nerve in the eye with potential damage to the nerve, which can lead to loss of vision in the affected eye. Patients with type 2 diabetes might already have an inherently higher risk of developing this condition.

PRAC will now review all available data on NAION with semaglutide including data from clinical trials, post-marketing surveillance, studies on the mechanism of action and the medical literature (including the results of the observational studies).

EMA will communicate further when appropriate

In Hong Kong, there are 11 registered pharmaceutical products containing semaglutide. All products are prescription-only medicines. As of the end of January 2025, the Department of Health (DH) had received 10 cases of adverse drug reaction related to semaglutide, but these cases were not related to NAION. In light of the above EMA's announcement, the DH will remain vigilant on the conclusion of the review and any safety update issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

United Kingdom: GLP-1 and dual GIP/GLP-1 receptor agonists: potential risk of pulmonary aspiration during general anaesthesia or deep sedation

On 28 January 2025, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that Healthcare professionals should be aware of the potential risk of pulmonary aspiration in patients using GLP-1 or dual GIP/GLP-1 receptor agonists who undergo surgery or procedures with general anaesthesia or deep sedation.

GLP-1 and dual GIP/GLP-1 receptor agonists are a class of medications that are used to treat type II diabetes mellitus and/or obesity. The GLP-1 and dual GIP/GLP-1 receptor agonists available in the UK include dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide. Tirzepatide is a GLP-1 receptor agonist combined with glucose-dependent insulinotropic polypeptide (GIP) receptor agonist. Semaglutide is also approved to reduce the risk of cardiovascular events in patients with established cardiovascular disease.

Residual gastric content is a risk factor for aspiration in patients who undergo surgery or procedures with general anaesthesia or deep sedation. All GLP-1 and dual GIP/GLP-1 receptor agonists slow down gastric emptying, therefore patients taking these medicines may have a higher risk of pulmonary aspiration due to retained gastric contents. This can potentially lead to severe complications, such as aspiration pneumonia. Cases have been reported in the literature as well as through Yellow Card reports.

A recent European review of the available evidence for all GLP-1 and dual GIP/GLP-1 receptor agonists concluded that the data supports an association between GLP-1 or dual GIP/GLP-1 receptor agonists and the potential risk of pulmonary aspiration during anaesthesia or deep sedation because of the delayed gastric emptying associated with these medicines. The findings of this review were considered by the Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM), which agreed with the recommendations. The product information of all GLP-1 and dual GIP/GLP-1 receptor agonists has been updated to include the potential risk of pulmonary aspiration under general anaesthesia or deep sedation.

The PEAG recommended that the MHRA inform healthcare professionals and patients of the possibility of aspiration in patients using GLP-1 or dual GIP/GLP-1 receptor agonists who undergo surgery or procedures requiring general anaesthesia or deep sedation.

The European assessment evaluated whether a specific time to pause the use of a GLP-1 or dual GIP/GLP-1 receptor agonist prior to anaesthesia could be recommended, as well recommending new fasting guidelines or an appropriate medical procedure to confirm an empty stomach. The evidence to support further recommendations was limited and it was concluded that anaesthetists should retain the flexibility to provide individualised assessment.

New warnings have been added to the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets. The new advice aims to raise

awareness of the risk of pulmonary aspiration amongst healthcare professionals and patients. Anaesthetists are warned that residual gastric contents may remain despite routine recommended fasting in patients taking a GLP-1 or dual GIP/GLP-1 receptor agonists. This should be considered within the preoperative risk assessment, with subsequent management in preventing or minimising the risk.

In Hong Kong, there are registered pharmaceutical products containing dulaglutide (4 products), exenatide (1 product), liraglutide (5 products), lixisenatide (2 products), semaglutide (11 products), and tirzepatide (6 products). All products are prescription-only medicines. As of the end of January 2025, the Department of Health (DH) had received adverse drug reactions with semaglutide (10 cases; of which 4 were related to aspiration pneumonia). The DH had also received adverse drug reactions with dulaglutide (5 cases), exenatide (2 cases), liraglutide (1 case) and lixisenatide (1 case), but these cases were not related to aspiration and pneumonia aspiration. The DH had not received any case of adverse drug reaction related to tirzepatide. Related news was previously issued by the European Medicines Agency (EMA), and was reported in Drug News Issue No. 177. The DH issued letters to inform local healthcare professionals to draw their attention on 15 July 2024. As previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Canada: Summary Safety Review - HMG-CoA Reductase Inhibitors (atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin and simvastatin) - Statins - Assessing the Potential Risk of Myasthenia Gravis, Including Ocular Myasthenia

On 31 January 2025, Health Canada announced that it reviewed the potential risk of myasthenia gravis, including ocular myasthenia, with the use of statins. The safety review was triggered by a labelling update for all statin products by the European Medicines Agency.

Statins are prescription drugs authorized for sale in Canada, to be used along with diet, to lower cholesterol and triglyceride (fat) levels in the blood, and to reduce the risk of heart attack or stroke in patients with risk factors for heart problems.

At the time of this review, the manufacturers of 2 Canadian statin products, Crestor (rosuvastatin) and Zocor (simvastatin), initiated a labelling update to include the risk of myasthenia gravis, including ocular myasthenia, in their respective CPMs. The purpose of this review was to determine whether this risk is associated with all statin products, warranting labelling updates across the drug class.

Health Canada reviewed the available information provided by manufacturers, and from searches of the Canada Vigilance database, international databases and the scientific literature. Health Canada reviewed 31 cases (2 Canadian and 29 international) of myasthenia gravis and/or ocular myasthenia in patients taking statins. Of the 31 cases, 27 (1 Canadian) were found to be possibly linked to the use of statins, 1 was unlikely to be linked and 3 (1 Canadian) could not be assessed due to missing information. Of the possible cases, 3 had recurrence of symptoms of myasthenia gravis and/or ocular myasthenia when treated with different statins, which suggests a drug class-effect for this risk.

Health Canada also reviewed 4 studies published in the scientific literature. Despite limitations, the studies provided evidence supporting a link between statins and worsening myasthenia gravis and/or ocular myasthenia. Evidence of a link between statins and new occurrence of myasthenia gravis and/or ocular myasthenia in published studies was limited; however, published case reports supported a possible link.

Health Canada's review found a possible link between statins and the risk of myasthenia gravis, including ocular myasthenia, and that this is a class-effect. Health Canada will work with the manufacturers to include the risk of myasthenia gravis, including ocular myasthenia, in the CPM for statin products that do not currently include this risk.

In Hong Kong, there are registered pharmaceutical products containing atorvastatin (94 products), lovastatin (3 products), pravastatin (8 products), rosuvastatin (71 products) and simvastatin (81 products). All products are prescription-only medicines. There is no registered pharmaceutical product containing fluvastatin or pitavastatin.

As of the end of January 2025, the Department of Health (DH) had received adverse drug reaction related to atorvastatin (22 cases), rosuvastatin (20 cases) and simvastatin (8 cases), but these cases

were not related to myasthenia gravis. The DH had not received any case of adverse drug reaction related to lovastatin and pravastatin. The DH issued letters to inform local healthcare professionals to draw their attention on 27 September 2023.

In February 2024, the Registration Committee of the Pharmacy and Poisons Board discussed the matter and the Committee decided that the sales pack label and/or package insert of statins-containing products should include the relevant safety information. The DH will remain vigilant on any safety update of the drugs issued by other overseas drug regulatory authorities.

Canada: Summary Safety Review - Breyanzi (lisocabtagene maraleucel), Carvykti (ciltacabtagene autoleucel), Kymriah (tisagenlecleucel), Tecartus (brexucabtagene autoleucel) and Yescarta (axicabtagene ciloleucel) - Chimeric Antigen Receptor T-cell (CAR-T) Therapies - Assessing the Potential Risk of Secondary T-cell Malignancy

On 31 January 2025, Health Canada announced that it reviewed the potential risk of secondary T-cell malignancy associated with the use of CAR-T therapies. The safety review was triggered by a labelling update in the United States for all CAR-T therapies.

Chimeric antigen receptor T-cell therapies are a type of gene therapy authorized for sale in Canada for the treatment of various blood cancers, including certain types of leukemia (cancer in the blood and bone marrow), lymphoma (cancer that forms in the immune cells of the lymphatic system) and multiple myeloma (cancer that forms in a type of white blood cell called a plasma cell) in patients whose cancer has relapsed (come back) or is refractory (has stopped responding to previous treatment). These treatments use a patient's own T-cell to find and attack cancer cells throughout their body.

In 2024, the manufacturers of some CAR-T therapies (Yescarta, Tecartus, Carvykti and Kymriah) updated the CPM for those products to include the risk of secondary T-cell malignancy.

Health Canada reviewed the available information provided by manufacturers and foreign regulatory agencies, as well as from searches of the Canada Vigilance database and the scientific literature. Health Canada reviewed 30 cases (1 Canadian and 29 international) of secondary T-cell malignancy in patients undergoing CAR-T therapies. Of those 30 cases, 6 were found to be probably linked to the CAR-T therapies, 9 were found to be possibly linked, 9 were found unlikely to be linked and 6 (1 Canadian) could not be assessed due to missing information.

Of the probable or possible cases, the diagnosis of secondary T-cell malignancy ranged from 29 days to over 3 years following administration of CAR-T therapy. Ten deaths were reported among the 30 cases reviewed by Health Canada, with 5 occurring in cases found to be probably or possibly linked to the CAR-T therapies. However, it was not possible to determine whether the deaths were related to the CAR-T therapies due to insufficient information about the cause of death.

Patients who receive CAR-T therapies generally have advanced B-cell lymphoma or multiple myeloma and have failed other cancer therapies, including chemotherapy. Both the underlying diseases and prior therapies are important risk factors in developing T-cell malignancy. However, the role of the CAR-T therapy in the development of a secondary cancer could not be excluded.

Health Canada's review of the available information concluded that there is a possible link between CAR-T therapies and the risk of secondary T-cell malignancy. Health Canada is working with the manufacturers to align the CPM for all CAR-T therapies to include information about the risk of secondary T-cell malignancy.

Manufacturers will be required to update their product's educational materials to include information about this risk and a recommendation for life-long monitoring of patients for secondary T-cell malignancies. They will also be required to update testing procedures for patients with secondary T-cell malignancies, monitor data for this risk in Canada and other jurisdictions, and provide updates to Health Canada for the next 3 years.

Health Canada will inform healthcare professionals about these updates through a Health Product InfoWatch communication.

In Hong Kong, Kymriah (tisagenlecleucel) Dispersion for Infusion (HK-66588) is a pharmaceutical product registered by Novartis Pharmaceuticals (HK) Limited. It is a

Safety Update

prescription-only medicine. As of the end of January 2025, with regard to tisagenlecleucel, the Department of Health (DH) had received 18 cases of adverse drug reaction, of which 8 cases were reported as malignancies. The other products mentioned in the above Health Canada's announcement are not registered pharmaceutical products in Hong Kong.

The current product insert of the locally registered Kymriah product already includes safety information about secondary malignancies.

Related news was previously issued by the United States Food and Drug Administration (US FDA) and the European Medicines Agency (EMA), and was reported in Drug News Issue No. 169, 171, 174 and 176. On 17 June 2024, the DH issued letters to inform local healthcare professionals to draw their attention on the potential risk of secondary malignancies of T-cell origin associated with the use of CAR-T therapies. As previously reported, the matters will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Drug Recall

Batch recall of Acrason Cream

On 24 January 2025, the Department of Health (DH) endorsed a licensed drug wholesaler, namely SB Pharma Limited (SB Pharma), to recall one batch (batch number: 2408) of Acrason Cream (Hong Kong Registration number: HK-64023) from the market due to mislabeling of the product.

The DH received notification from SB Pharma regarding a report indicating that the label on a tube of Acrason Cream was inconsistent with the actual product. Further investigations by the overseas manufacturer showed that the issue was due to mislabeling of small amount of empty cream tubes for Acrason Cream supplied by material supplier.

The above product is a prescription only medicine which contains betamethasone, clotrimazole and gentamicin. It is a topical corticosteroid and antimicrobial preparation used in the treatment of various skin disorders. According to SB Pharma, the above batch of product has been supplied to local private doctors and local pharmacies after import.

As of the end of January 2025, the DH had not received any adverse reaction reports in connection with the above batch of product. A notice was posted in the Drug Office website on 24 January 2025 to alert the public of the product recall. The DH will closely monitor the recall.

Drug Incident

Public urged not to buy or use two topical products labelled "Eczevandia Cream" and "Eczevandia Baby Cream"

On 9 January 2025, the Department of Health (DH) urged the public not to buy or use two topical products labelled "Eczevandia Cream" and "Eczevandia Baby Cream", as they are suspected of containing undeclared controlled drug ingredients.

The DH received intelligence that the premises of a Listed Seller of Poisons (commonly known as medicine store) in Ho Man Tin was suspected of selling the above products and immediately took follow-up action by purchasing product samples from the premises concerned for analysis. The laboratory test results revealed that the samples of both products contained mometasone furoate, while the sample of "Eczevandia Cream" also contained miconazole.

Miconazole and mometasone furoate are Part 1 poisons under the Pharmacy and Poisons Ordinance (Cap. 138) (PPO). The products are also suspected of being unregistered pharmaceutical products. The DH, in collaboration with the Police, took enforcement action at the premises on 9 January 2025. During the operation, a 50-year-old man and a 54-year-old woman were arrested for suspected illegal sale and/or possession of Part 1 poisons and unregistered pharmaceutical products.

The DH will continue to follow up and investigate the incident.

Mometasone furoate is a steroid substance for treating skin inflammation. Inappropriate or excessive application of steroids could cause skin problems and body-wide side effects such as moon face, high blood pressure, high blood sugar, muscle atrophy, adrenal insufficiency and osteoporosis. Miconazole is used for the treatment of fungal

infection with side effects that include local irritation and sensitivity reactions. Products containing miconazole should be supplied in the premises of an Authorized Seller of Poisons (i.e. pharmacy) under the supervision of a registered pharmacist, while products containing mometasone furoate should be used under a doctor's directions and be supplied in a pharmacy under the supervision of a registered pharmacist upon a doctor's prescription.

A press release was posted in the Drug Office website on 9 January 2025 to alert the public of the drug incident.

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.

All registered pharmaceutical products should carry a Hong Kong registration number on the package in the format of "HK-XXXXX". The products mentioned in the above incidents were not registered pharmaceutical products under the Ordinance in Hong Kong. Their safety, quality and efficacy cannot be guaranteed. Members of the public were exhorted not to use products of unknown or doubtful composition. They should stop using the aforementioned products immediately if they had them in their possession and to consult healthcare professionals if they felt unwell after taking the products. The products should be destroyed or disposed properly, or submitted to the Department's Drug Office during office hours.

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.

Useful Contact

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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.