Drug News
藥 物 情 報

Issue Number 136

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in February 2021 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

Australia: Investigation reveals no specific risk of COVID-19 vaccinations in elderly patients

On 2 February 2021, the Therapeutic Goods Administration (TGA) announced that it received reports of about 30 deaths in over 40,000 elderly individuals in Norway vaccinated with the Pfizer BioNTech vaccine on 14 Jan 2021. The deaths were recorded among very frail patients, including some who were anticipated to only have weeks or months to live. The TGA was advised promptly of the Norwegian deaths and has worked closely with the European Medicines Agency (EMA) and Pfizer on further investigations. The case reports were discussed at a recent meeting of the EMA Pharmacovigilance Risk Assessment Committee, which concluded that there was not a specific safety concern, and no causal link between vaccination and deaths could be established. In addition, wider discussions with regulators in North America, United Kingdom and Europe reached a similar conclusion.

The TGA therefore has concluded that there is no specific risk of vaccination with the Pfizer BioNTech COVID-19 vaccine in elderly patients.

On 24 January 2021, the TGA provided provisional approval to the Pfizer BioNTech vaccine, COMIRNATY "to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older". Elderly patients can receive this vaccine and there is no cap on the upper age limit. The Product Information for health care professionals contains the following advice: "The data for use in the frail elderly (>85 years) is limited...the potential benefits of vaccination versus the potential risk and clinical impact of even relatively mild systemic adverse events in the frail elderly should be carefully assessed on a case-by-case basis".

The TGA will continue to monitor the safety of COVID-19 vaccines as they are rolled out in Australia and internationally. Australia co-chairs the global regulatory (International Coalition of Medicines Regulatory Agencies) network for safety monitoring of COVID-19 vaccines and therefore has very timely access to international vaccine safety reports.

In Hong Kong, the above product is not a registered pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap. 138), but is authorised for emergency use in Hong Kong in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). The Department of Health (DH) will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

Canada: Summary Safety Review: Tecentriq (atezolizumab): Assessing the potential risk of autoimmune hemolytic anemia

On 3 February 2021, Health Canada announced that it reviewed the potential risk of autoimmune hemolytic anemia (AIHA) in patients treated with Tecentriq. This review was triggered by safety information from clinical trials and from published scientific literature that support a possible link between the use of Tecentriq and the risk of AIHA. AIHA is a condition where the body's immune system attacks and destroys its own red blood cells.

Health Canada reviewed information received from the manufacturer, as well as information from searches of the Canada Vigilance Dabatase, international databases, and published literature. Health Canada's review focused on 36 case reports (one Canadian, 35 foreign) in order to assess the

link between the use of Tecentriq and the risk of AIHA. Of the 36 case reports, 5 reports (none Canadian) met the criteria for further assessment. A link between Tecentriq use and AIHA could not be ruled out for these 5 reports; 3 reports were found to be probably linked to the use of Tecentriq and 2 reports were possibly linked. The remaining 31 reports could not be assessed further due to factors such as limited information in the reports, or patients taking other medications at the same time that could also cause AIHA. Health Canada also looked at additional information available from 56 studies in published scientific literature. Health Canada's review of these published studies supported a possible link between the use of Tecentriq and the risk of AIHA.

Health Canada's review of the available information concluded that there may be a link between the use of Tecentriq and the risk of AIHA. Health Canada is working with the manufacturer to update the Canadian product safety information for Tecentriq to include the risk of AIHA.

In Hong Kong, Tecentriq Concentrate For Solution For Infusion 1200mg/20ml (HK-65567), Tecentriq Concentrate For Solution For Infusion 1200mg/20ml (HK-66341) and Tecentriq Concentrate For Solution For Infusion 840mg/14ml (HK-66613) are registered pharmaceutical products containing atezolizumab. All products are registered by Roche Hong Kong Limited, and are prescription-only medicines. As on 5 March 2021, the DH has received 87 cases of adverse drug reaction related to atezolizumab, but these cases are not related to autoimmune hemolytic anemia. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 4 February 2021, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Singapore: Important information on Gliolan® (5-aminolevulinic acid): What to do in case of delayed surgery and information on fluorescence in non high-grade glioma

On 2 February 2021, Health Sciences Authority (HSA) announces that a Dear Healthcare Professional Letter has been issued by Link Healthcare Singapore Pte Ltd to inform healthcare professionals on the use of Gliolan® (5-aminolevulinic acid, 5-ALA) in case of delayed surgery and information on fluorescence in non high-grade glioma.

Occasionally, delays and postponement of surgery may occur despite 5-ALA having been administered. As it is unknown how long useful fluorescence persists in tumour cells beyond the defined window of lucid contrast, healthcare professionals are advised to reschedule surgery that is delayed by > 12 hours for the next day or later, in which case another dose of 5-ALA can be administered two to four hours before anaesthesia. Re-administration of 5-ALA on the same day should not be considered as there is no available information on the safety of early repeated dosing or on the specificity of fluorescence.

Healthcare professionals are also reminded that false negative and false positive results may occur with the use of 5-ALA for intraoperative visualisation of malignant glioma. Non-fluorescing tissue in the surgical field does not rule out the presence of tumour in patients with glioma. On the other hand, fluorescence may be seen in areas of abnormal brain tissue, necrotic tissue, inflammation, infections, CNS lymphoma or metastases from other tumour types. The package insert for Gilolan® will be updated accordingly to reflect the above information.

In Hong Kong, Gliolan Powder For Oral Solution 30mg/ml (HK-62756) is a registered pharmaceutical product containing 5-aminolevulinic acid. The product is registered by Biopro Pharmaceutical (HK) Ltd, and is a prescription-only medicine. As on 5 March 2021, the DH has not received any case of adverse drug reaction related to 5-aminolevulinic acid. In light of the above HSA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 11 February 2021, and the DH will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

The United States: Initial safety trial results find increased risk of serious heart-related problems and cancer with arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR (tofacitinib)

On 4 February 2021, the US Food and Drug Administration (FDA) announced that it is alerting the public that preliminary results from a safety clinical trial show an increased risk of serious heart -related problems and cancer with the arthritis and ulcerative colitis medicine Xeljanz, Xeljanz XR

(tofacitinib) compared to another type of medicine called tumor necrosis factor (TNF) inhibitors. FDA required the safety trial, which also investigated other potential risks including blood clots in the lungs and death. Those final results are not yet available. FDA will evaluate the clinical trial results it has received to date and will work with the drug manufacturer to obtain further information as soon as possible. FDA will communicate its final conclusions and recommendations when it has completed its review or has more information to share.

Patients should not stop taking tofacitinib without first consulting with their health care professionals, as doing so may worsen their condition. Talk to their health care professionals if they have any questions or concerns.

Health care professionals should consider the benefits and risks of tofacitinib when deciding whether to prescribe or continue patients on the medicine. Continue to follow the recommendations in the tofacitinib prescribing information.

When FDA first approved tofacitinib, it required the manufacturer, Pfizer, to conduct a safety clinical trial in patients with rheumatoid arthritis (RA) who were taking methotrexate to evaluate the risk of serious heart-related events, cancer, and infections. The trial studied two doses of tofacitinib (5 mg twice daily, which is the approved dosage for RA, and a higher 10 mg twice daily dosage) in comparison to another type of RA medicine called a TNF inhibitor. Patients in the trial were required to be at least 50 years old and have at least one cardiovascular risk factor. In Feb 2019 and Jul 2019, FDA warned that interim trial results showed an increased risk of blood clots and death with the higher 10 mg twice daily dosage, and as a result, approved a Boxed Warning to the tofacitinib prescribing information. The clinical trial is now complete and initial results show a higher occurrence of serious heart-related events and cancer in RA patients treated with both doses of tofacitinib compared to patients treated with a TNF inhibitor. FDA is awaiting additional results from the trial.

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). All products are registered by Pfizer Corporation Hong Kong Limited, and are prescription-only medicines. As on 5 March 2021, the DH has received 8 cases of adverse drug reaction related to tofacitinib, of which one case is related to lung cancer.

Related news on the risk of blood clots of tofacitinib was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 112, 115, 117, 120, 121, 125 and 128. The DH issued letters to inform local healthcare professionals to draw their attention on 29 July 2019 and 19 June 2020. In December 2019, the Registration Committee discussed the matter, and decided that the sales pack or package insert of tofacitinib should include the relevant safety information. As the FDA's review is ongoing, the DH will remain vigilant on its final conclusions and recommendations, and safety update issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

The United Kingdom: Latest monitoring data confirms safety of COVID-19 vaccines

On 5 February 2021, Medicines and Healthcare products Regulatory Agency (MHRA) announced that data published from the United Kingdom's independent medicines regulator confirms approved vaccines meet strict regulatory standards for safety. Vast majority of reported side effects are mild and short lasting, reflecting a normal immune response to vaccines – including a sore arm and fatigue. The benefits of the COVID-19 vaccines outweigh the risks.

Routine safety monitoring and analysis of the approved COVID-19 vaccines by the United Kingdom's medicines regulator, the MHRA, shows that the safety of these vaccines remains as high as expected from the clinical trial data that supported the approvals. The safety profile of the vaccines remains positive and the benefits continue to far outweigh any known side-effects.

Over 10 million doses of the Pfizer/BioNTech and the Oxford University/AstraZeneca vaccines have been given across the United Kingdom and the MHRA has gathered a large amount of safety data. Data published today shows 22,820 reports of suspected side effects, or an overall reporting rate of 3 in 1,000 doses of vaccine administered from 9 Dec 2020 to 24 Jan 2021. This reassuring data has shown that the vast majority of reported side effects are mild and all are in line with most types

of vaccine, including the seasonal flu vaccine. These include sore arms and mild 'flu-like' symptoms, which reflect a normal immune response to vaccines and are short-lasting.

In Hong Kong, the above products are not registered pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). The COVID-19 vaccine by Fosun Pharma/BioNTech (i.e. Comirnaty) is authorised for emergency use in Hong Kong in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). The DH will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

Canada: Pfizer-BioNTech COVID-19 Vaccine: Updated dosage and administration and post-market adverse reaction information

On 9 February 2021, Health Canada announced that, at the time of authorization, the Pfizer-BioNTech COVID-19 Vaccine Product Monograph (PM) and vial and carton labels indicated that, after dilution, each vial contained 5 doses of 0.3 ml of vaccine. Based on updated information, it is possible to extract a 6th dose of 0.3 ml using low dead-volume syringes and/or needles.

In addition, post-market adverse reaction information has been identified during pharmacovigilance activities. Severe allergic reactions, including anaphylaxis, have been reported during mass vaccination outside of clinical trials. This new information does not change the benefit-risk profile of this product.

Health Canada has authorized updates to the Pfizer-BioNTech COVID-19 Vaccine PM, the terms and conditions of authorization imposed by Health Canada and vial and carton labels to reflect the new information.

Healthcare professionals are advised that (regardless of the type of syringe and/or needle used):

- Each dose must contain 0.3 ml of the vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 m., to discard the vial and any excess volume.
- Excess vaccine from multiple vials should not be pooled to create extra doses.

Healthcare professionals should also be aware that severe allergic reactions, including anaphylaxis, have been reported during mass vaccination outside of clinical trials. This new information does not change the benefit-risk profile of this product.

Healthcare professionals are also advised that:

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of this vaccine.
- People who receive the vaccine should be kept under observation for at least 15 minutes after immunization.
- 30 minutes is a preferred interval when there is a specific concern about a possible vaccine reaction.
- A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer-BioNTech COVID-19 Vaccine.

In Hong Kong, the above product is not a registered pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap. 138). The COVID-19 vaccine by Fosun Pharma/BioNTech (i.e. Comirnaty) is authorised for emergency use in Hong Kong in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). The DH will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

European Union: PRAC concludes that use of Veklury is not associated with kidney problems. PRAC starts new safety signal procedure with Veklury

On 12 February 2021, European Medicines Agency (EMA) announced that the Pharmacovigilance Risk Assessment Committee (PRAC) has concluded its review of a safety signal to assess reports of acute kidney injury (AKI) in patients with COVID-19 treated with Veklury (remdesivir). The PRAC assessed all available information, including data provided by the marketing authorisation holder, analysis of reported adverse reactions, data from clinical trials and published scientific literature. After taking all the data into consideration, the PRAC concluded that currently there is no evidence indicating that the reported kidney problems are associated with the use of Veklury. The risk of kidney injury will continue to be carefully monitored in the context of the periodic safety update reports (PSURs) and of the pandemic

summary safety reports submitted by the marketing authorisation holder.

As part of the review of the pandemic summary safety reports for Veklury, the PRAC already looked at cardiac adverse events (cases of arrythmia(s), hypotension and shock). Additionally AIFA, the Italian Medicines Agency raised a signal regarding 11 cases of sinus bradycardia (slow heartbeat with a resting heart rate of 60 beats per minute or less) in patients who had received Veklury. After reviewing the available evidence provided in these cases, the PRAC decided to request an in-depth evaluation of all available data, including reports from Eudravigilance, clinical trials and the published literature. At this stage, it is not yet clear whether there is a causal association between Veklury and the reports of sinus bradycardia. These reports form a 'safety signal' - information on new or changed adverse events that may potentially be associated with a medicine and that warrants further investigation.

In Hong Kong, there is one registered pharmaceutical product containing remdesivir, namely Veklury Powder for Concentrate for Solution for Infusion 100mg (HK-66766). The product is registered by Gilead Sciences Hong Kong Limited, and is a prescription-only medicine. The product is indicated for SARS-CoV-2 Infection and is conditionally approved with very limited safety, efficacy, and quality data for public health emergency to satisfy local unmet medical need and the registration status is subjected to be reviewed by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee. As on 5 March 2021, the DH has received one case of adverse drug reaction related to remdesivir, and this case is related to hypotension.

Related news on the safety signal of acute kidney injury in patients taking remdesivir was previously issued by EMA, and was reported in the Drug News Issue No.132. In light of the above EMA's announcement, the DH will remain vigilant on safety update of the drug issued by EMA and other overseas drug regulatory authorities.

The United Kingdom: Ulipristal acetate 5mg (Esmya): further restrictions due to risk of serious liver injury

On 18 February 2021, MHRA announced that the indication of ulipristal acetate 5mg for uterine fibroids has been further restricted due to the risk of serious liver injury and liver failure, with some cases requiring liver transplantation. Although the temporary suspension has been lifted, this medicine should only be used for intermittent treatment of moderate to severe symptoms of uterine fibroids before menopause and when surgical procedures (including uterine fibroid embolisation) are not suitable or have failed.

In 2018, a European safety review was conducted due to 4 cases reported worldwide of severe liver injury resulting in liver transplantation. Several measures were introduced in 2018 to minimise the risk of severe liver injury.

In 2020, a fifth case of severe liver injury resulting in liver transplantation was reported, prompting a further European review. While this further review was conducted, the licences for all ulipristal acetate 5mg medicines were temporarily suspended. Esmya 5mg tablets were recalled from patients, pharmacies and wholesalers in the United Kingdom on 18 March 2020.

The temporary suspension has now been lifted, but the indication for ulipristal acetate 5mg has been further restricted. The review recommended that the risk of severe liver injury does not justify its use for the pre-operative treatment of uterine fibroids. However, the review considered that the benefits of ulipristal acetate 5mg in controlling fibroids may outweigh this risk in women who have no other treatment options. As such, Esmya can be used for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause and when surgical procedures (including uterine fibroid embolisation) are not suitable or have failed.

The Commission on Human Medicines' Medicines in Women's Health Expert Advisory Group (MWHEAG) has considered the safety data and advised that physicians should carefully consider if ulipristal acetate 5mg is an appropriate option for their patient, and accurately and thoroughly discuss the benefits and risks of ulipristal acetate 5mg with them before prescribing. This conversation should include the risk of liver injury and liver failure, including rare cases requiring liver transplantation associated with ulipristal acetate 5mg.

The product information for medicines containing

ulipristal acetate 5mg has been amended and a letter sent to healthcare professionals to inform them of the latest safety advice. The prescribing guide for physicians and the patient card will also be updated.

The frequency of occurrence of liver failure with ulipristal acetate 5mg is unknown and no patient risk factors could be identified from the available data. Since authorisation and to date, MHRA has received 20 suspected adverse drug reaction reports of liver disorders with the use of Esmya in the United Kingdom. None report liver transplant or death. In the United Kingdom, Esmya has been suspended since March 2020.

The emergency contraceptive ellaOne also contains ulipristal acetate in a single dose of 30mg. No concern has been raised about serious liver injury with ellaOne and there are no changes to its use.

Advice for healthcare professionals:

- Ulipristal acetate 5mg for uterine fibroids has been associated with cases of serious liver injury and liver failure (requiring transplantation in some cases); the licence was temporarily suspended in March 2020 to allow a further review of these risks.
- Although the temporary suspension has been lifted, the indication for ulipristal acetate 5mg has been further restricted – it should be used only for intermittent therapy of moderate to severe uterine fibroid symptoms before menopause and when surgical procedures (including uterine fibroid embolisation) are not suitable or failed.
- Ulipristal acetate 5mg should no longer be prescribed for controlling symptoms of uterine fibroids while waiting for surgical treatment.
- If ulipristal acetate 5mg is felt to be an appropriate therapy, talk about the risks and benefits with patients before prescribing so they can make an informed decision about treatment options; this conversation should include discussion of: all available treatment options for moderate to severe symptoms of uterine fibroids, and the advantages and risks of these depending on personal situation; the potential risk of liver injury and liver failure with ulipristal acetate 5mg, which in rare cases has led to liver transplantation; signs and symptoms of liver injury and what to do if they occur.
- Do not use ulipristal acetate 5mg in patients with an underlying liver disorder.
- Continue to follow advice to monitor liver function according to the recommended schedule of liver function tests before, during, and after treatment courses.

In Hong Kong, Esmya (ulipristal acetate) Tablets 5mg (HK-62553) is a pharmaceutical product registered by Orient Europharma Co. Ltd, and is a prescription-only medicine. As on 5 March 2021, the DH has not received any case of adverse drug reaction related to Esmya.

Related news on the previous review of Esmya was previously issued by various overseas drug regulatory authorities, and was reported in Drug News Issue No. 98, 100, 103, 106 and 114. The DH issued letters to inform local healthcare professionals to draw their attention on the risk of serious liver injury on 12 February 2018. In December 2018, the Registration Committee of the Pharmacy and Poisons Board discussed the matter, and decided that the sales pack or package insert of the product should include the relevant safety information.

Related news on the further review of Esmya was previously issued by various overseas drug regulatory authorities, and was reported in Drug News Issue No.125, 131, 132 and 133. The DH issued letters to inform local healthcare professionals to draw their attention on the European Medicines Agency's recommendation to suspend ulipristal acetate for uterine fibroids were issued by the DH on 16 March 2020.

On 20 March 2020, the DH endorsed Orient Europharma Co. Ltd to voluntarily recall Esmya Tablets 5mg (HK-62553) from patients due to the potential risk of liver injury. The recall was reported in the Drug News Issue No. 125 and was completed. As previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

The United States: FDA allows more flexible storage, transportation conditions for Pfizer-BioNTech COVID-19 Vaccine

On 25 February 2021, the FDA announced that it is allowing undiluted frozen vials of the Pfizer-BioNTech COVID-19 Vaccine to be transported and stored at conventional temperatures commonly found in pharmaceutical freezers for a period of up to two weeks. This reflects an alternative to the preferred storage of the undiluted

Safety Update

vials in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF). The change is being reflected in updates to the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

Pfizer submitted data to the FDA to support this alternative temperature for transportation and storage. This alternative temperature for transportation and storage of the undiluted vials is significant and allows the vials to be transported and stored under more flexible conditions. The alternative temperature for transportation and storage will help ease the burden of procuring ultra-low cold storage equipment for vaccination sites and should help to get vaccine to more sites.

Pfizer submitted data to the FDA to demonstrate that its COVID-19 vaccine remains stable after storage of the undiluted vials for up to two weeks at standard freezer temperature. The alternative temperature for storage of frozen vials is not applicable to the storage of thawed vials before dilution (which can be held in the refrigerator for up to 5 days), or on the storage of thawed vials after dilution (which can be held at refrigerator temperature or room temperature for use within 6 hours).

In Hong Kong, the above product is not a registered pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap. 138). The COVID-19 vaccine by Fosun Pharma/BioNTech (i.e. Comirnaty) is authorised for emergency use in Hong Kong in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). The DH will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

Drug Incident

Public urged not to buy or consume unlabelled slimming products with controlled ingredients

On 25 February 2021, the DH appealed to the public not to buy or consume unlabelled slimming products that may contain controlled medicine ingredients and might be dangerous to health.

Acting upon intelligence, it was found that someone was offering for sale via a social media platform various unlabelled slimming products claiming to be imported from overseas. Samples of the above products were purchased for analysis and the test results from the Government Laboratory revealed that the samples contained ephedrine, fluoxetine, hydrochlorothiazide and topiramate, which are Part 1 poisons under the Pharmacy and Poisons Ordinance (Cap. 138).

During a joint operation conducted with the Police today, a 27-year-old man was arrested by the Police for illegal possession of Part 1 poisons and unregistered pharmaceutical products. The DH's investigation is continuing.

Ephedrine is usually used for the treatment of nasal congestion and its side effects include anxiety, headache, insomnia and nausea. Hydrochlorothiazide is used for the treatment of hypertension and its side effects include low blood pressure and electrolyte imbalance. Fluoxetine is used for treatment of mood disorder and may cause hallucination and insomnia. Topiramate is used for treatment of seizures and prophylaxis of migraines and may cause cognitive-related dysfunction, and neuropsychiatric abnormalities.

A notice was posted on the Drug Office website on 25 February 2021 to alert the public of the drug incident.

New in Brief

Safety monitoring of COVID-19 vaccines

On 26 February 2021, DH announced that, with the implementation of the COVID-19 Vaccination Programme, it is closely monitoring the potential adverse events after COVID-19 vaccinations by enhancing the existing passive surveillance and conducting active surveillance.

The Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation) stipulates that it is necessary to put in place a mechanism for the monitoring of any adverse event occurring to the recipients associated with the administration of COVID-19 vaccines authorised for emergency use under the Government Vaccination Programme in Hong Kong.

Currently, the DH has established a pharmacovigilance system to receive and assess reports of adverse events following immunisations (AEFIs) submitted by healthcare professionals (for example, registered medical practitioners, nurses and pharmacists) and the pharmaceutical industry, in particular serious AEFIs, and conduct causality assessments to ascertain whether the adverse events were associated with the vaccinations.

For the COVID-19 Vaccination Programme, apart from requiring the authorisation applicant to report local AEFIs, the DH will keep in view and refer to the safety and efficacy assessment of the vaccines promulgated by the drug regulatory authorities of various countries and regions and the World Health Organization (WHO).

Besides publication of Vaccination Fact Sheets which list the expected side effects after vaccination and when it is necessary to seek the advice of healthcare professionals, the DH has made reference to the COVID-19 vaccines safety surveillance strategies recommended by the WHO to enhance the existing passive surveillance and conduct active surveillance. The surveillance measures include:

(i) A dedicated COVID-19 Vaccine Adverse Event Online Reporting system has been set up to receive AEFI reports of COVID-19 vaccines from healthcare professionals and the pharmaceutical industry;

(ii) Letters to healthcare professionals and relevant organisations have been issued to encourage them to report suspected serious or unexpected AEFIs; and

(iii) For active surveillance, the DH has partnered with the Department of Pharmacology and Pharmacy of the University of Hong Kong to actively collect data of potential adverse events of authorised vaccines, in particular rare or serious adverse events of special interest (AESI) (e.g. Guillain Barre syndrome, acute disseminated encephalomyelitis) from public and private healthcare facilities and conduct causality assessments. At the same time, comprehensive monitoring of all potential adverse events amongst the different authorised COVID-19 vaccines from selected target groups will also be conducted.

To tie in with the aforementioned surveillance measures, the DH has established the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation (Expert Committee) for continuous monitoring of potential clinical events (including AEFIs and AESIs) associated with COVID-19 vaccinations and provide expert opinions and advice on the safety monitoring of authorised vaccines. The Expert Committee has formulated the risk communication plan, which covers the monitoring, notification and follow up of reported clinical events. Follow up actions include safety alerts on the concerned vaccine to healthcare professionals, updates of product labels and product information, and instructing the vaccine supplier to conduct recalls, etc. If the risks of the authorised vaccine outweigh the benefits, the DH will take appropriate actions, which include providing the relevant information to the Advisory Panel established under the Regulation to review and consider whether to recommend the Secretary of Food and Health to revoke the authorisation of the concerned vaccine.

The DH issued a letter to inform local healthcare professionals to draw their attention on 22 February 2021 and Press release was posted on the Drug Office website on 26 February 2021 to alert the public of the safety monitoring.

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 $30,000 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

Drug Complaint:

Tel: 2572 2068

Fax: 3904 1224

E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:

Tel: 2319 2920

Fax: 2319 6319

E-mail: adr@dh.gov.hk

Link: http://www.drugoffice.gov.hk/adr.html

Post: ***Undesirable Medical Advertisements and Adverse Drug Reaction Unit,***
Drug Office, Department of Health,
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon

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.