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 April 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

Canada: Health Canada has initiated a safety review on Xeljanz and Xeljanz XR (tofacitinib), used to treat arthritis and ulcerative colitis

On 6 April 2021, Health Canada announced that it is conducting a safety review of Xeljanz and Xeljanz XR (tofacitinib) after a clinical trial identified an increased risk of serious heart-related issues and cancer in trial participants.

The clinical trial investigated the long-term safety of Xeljanz and Xeljanz XR (tofacitinib) at two doses (5 mg twice a day and 10 mg twice a day) in patients with rheumatoid arthritis, who are at least 50 years of age and have at least one cardiovascular risk factor. Pfizer, the manufacturer of the drug, conducted the trial in multiple countries, including Canada.

Previously, Health Canada had conducted a safety review of this drug after increased risks of blood clots in the lungs and death were discovered during a clinical trial. Following this safety review in 2019, Health Canada worked with Pfizer to update the Canadian labelling for Xeljanz and Xeljanz XR (tofacitinib) to include thrombosis as a warning, and informed Canadians and health care professionals of the findings.

Health Canada is working with Pfizer to evaluate the available safety information for Xeljanz and Xeljanz XR (tofacitinib) and will inform the public of any new safety findings, as needed, once the review is completed.

Information for patients taking Xeljanz/Xeljanz XR (tofacitinib):

- Do not stop or change their dose of Xeljanz or Xeljanz XR (tofacitinib) without first talking to their health care professional.

Information for health care professionals:

- Consider the benefits and risks of Xeljanz and Xeljanz XR (tofacitinib) when deciding whether to prescribe or keep patients on the drug.
- Follow the recommendations in the Xeljanz and Xeljanz XR (tofacitinib) product monograph for the specific condition they are treating.
- Report health or safety concerns.

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 May 2021, the Department of Health (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 a letter 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.

Related news on the risk of serious heart-related problems and cancer of tofacitinib was previously issued by the United States Food and Drug Administration (FDA) and Singapore Health Sciences Authority (HSA), and was reported in the Drug News Issue No. 136 and 137. As the review

is ongoing, the DH will remain vigilant on its final conclusions and recommendations, and safety update issued by FDA, HSA, Health Canada and other overseas drug regulatory authorities for consideration of any action deemed necessary.

European Union: AstraZeneca's COVID-19 vaccine: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets

On 7 April 2021, European Medicines Agency (EMA) announced that its safety committee Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria (formerly COVID-19 Vaccine AstraZeneca). In reaching its conclusion, the committee took into consideration all currently available evidence, including the advice from an ad hoc expert group.

EMA is reminding healthcare professionals and people receiving the vaccine to remain aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within 2 weeks of vaccination. So far, most of the cases reported have occurred in women under 60 years of age within 2 weeks of vaccination. Based on the currently available evidence, specific risk factors have not been confirmed. People who have received the vaccine should seek medical assistance immediately if they develop symptoms of this combination of blood clots and low blood platelets.

The PRAC noted that the blood clots occurred in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis) and in arteries, together with low levels of blood platelets and sometimes bleeding. The committee carried out an in-depth review of 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the European Union drug safety database (EudraVigilance) as of 22 Mar 2021, 18 of which were fatal. The cases came mainly from spontaneous reporting systems of the European Economic Area and the United Kingdom, where around 25 million people had received the vaccine.

COVID-19 is associated with a risk of hospitalisation and death. The reported combination of blood clots and low blood platelets is very rare, and the overall benefits of the vaccine in preventing COVID-19 outweigh the risks of side effects.

EMA's scientific assessment underpins the safe and effective use of COVID-19 vaccines. Use of the vaccine during vaccination campaigns at national level will also take into account the pandemic situation and vaccine availability in the individual Member State.

One plausible explanation for the combination of blood clots and low blood platelets is an immune response, leading to a condition similar to one seen sometimes in patients treated with heparin (heparin induced thrombocytopenia, HIT). The PRAC has requested new studies and amendments to ongoing ones to provide more information and will take any further actions necessary.

The PRAC stresses the importance of prompt specialist medical treatment. By recognising the signs of bloods clots and low blood platelets and treating them early, healthcare professionals can help those affected in their recovery and avoid complications. Patients should seek medical assistance immediately if they have the following symptoms: shortness of breath; chest pain; swelling in the leg; persistent abdominal (belly) pain; neurological symptoms, including severe and persistent headaches or blurred vision; tiny blood spots under the skin beyond the site of injection.

Vaxzevria is one of four vaccines authorised in the European Union for protecting against COVID-19. Studies show that it is effective at preventing the disease. It also reduces the risk of hospitalisation and deaths from COVID-19. As for all vaccines, EMA will continue to monitor the vaccine's safety and effectiveness and provide the public with the latest information.

Information for the general public:

- Cases of unusual blood clots with low platelets have occurred in people who received Vaxzevria (formerly COVID-19 Vaccine AstraZeneca).
- The chance of having this occur is very low, but they should still be aware of symptoms so they can get prompt medical treatment to help recovery and avoid complications.
- They must seek urgent medical attention immediately if they have any of the following symptoms in the weeks after their injection: shortness of breath; chest pain; leg swelling; persistent abdominal (belly) pain; neurological

symptoms, such as severe and persistent headaches or blurred vision; tiny blood spots under the skin beyond the site of the injection.
- Speak to their healthcare professional or contact their relevant national health authorities if they have any questions about the roll out of the vaccine in their country.

Information for healthcare professionals:
- EMA has reviewed cases of thrombosis in combination with thrombocytopenia, and in some cases bleeding, in people who received Vaxzevria (formerly COVID-19 Vaccine AstraZeneca).
- These very rare types of thrombosis (with thrombocytopenia) included venous thrombosis in unusual sites such as cerebral venous sinus thrombosis and splanchnic vein thrombosis as well as arterial thrombosis. Most of the cases reported so far have occurred in women under the age of 60 years. Most cases occurred within 2 weeks of the person receiving their first dose. There is limited experience with the second dose.
- As for the mechanism, it is thought that the vaccine may trigger an immune response leading to an atypical heparin-induced-thrombocytopenia like disorder. At this time, it is not possible to identify specific risk factors.
- Healthcare professionals should be alert to the signs and symptoms of thromboembolism and thrombocytopenia so that they can promptly treat people affected in line with available guidelines.
- Healthcare professionals should tell people receiving the vaccine that they must seek medical attention if they develop: symptoms of blood clots such as shortness of breath, chest pain, leg swelling, persistent abdominal pain; neurological symptoms such as severe and persistent headaches and blurred vision; petechiae beyond the site of vaccination after a few days.
- The benefits of the vaccine continue to outweigh the risks for people who receive it. The vaccine is effective at preventing COVID-19 and reducing hospitalisations and deaths.
- National authorities may provide additional guidance on the roll out of the vaccine based on the situation in their country.

In Hong Kong, the above product is not a registered pharmaceutical product. Related news was previously issued by the EMA, and was reported in the Drug News Issue No. 137.

Australia: Wider storage and transportation conditions for the Pfizer COVID-19 vaccine now approved

On 8 April 2021, the Therapeutic Goods Administration (TGA) announced that it has recently approved wider storage and transportation conditions for the Pfizer COVID-19 vaccine in Australia (COMIRNATY - BNT162b2). These changes will enable greater flexibility in storage, transport and deployment of the Pfizer COVID-19 vaccine across Australia.

While longer term storage at dry ice or ultra-cold temperatures (-90C to -60°C) is still required, for unopened vials, storage and transportation at domestic freezer temperatures (-25°C to -15°C) is now permitted for up to 2 weeks. Vials stored or transported in this manner can also be returned to ultra-cold longer term storage within the original shelf life of the product.

In addition, unopened vials can now be stored for up to 5 days at domestic refrigerator temperatures (2°C to 8°C). Within this 5 day period, up to 12 hours may be used for transportation, but the time used for transport of unopened vials at refrigerator temperatures counts against the 5 day limit for storage at 2°C to 8°C. Once thawed, COMIRNATY should not be re-frozen.

COMIRNATY is diluted with saline prior to administration. The diluted vaccine, in either vials or syringes can be stored or transported at room temperatures of up to 30°C for up to 6 hours. The preparer of the reconstituted vaccine must be careful to manage microbiological risks and package integrity, particularly for prepared dosing syringes.

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). Related news was previously issued by various overseas drug regulatory authorities, and was reported in the Drug News Issue No. 136 and 137. The DH will remain vigilant on safety update of the product issued by other overseas drug

regulatory authorities.

Canada: Summary Safety Review: Veklury (remdesivir) - Assessing the Potential Risks of Acute Kidney Injury (AKI) and Acute Renal Failure (ARF)

On 9 April 2021, Health Canada announced that it reviewed the potential risks of acute kidney injury (AKI) and acute renal failure (ARF) with Veklury (remdesivir) to analyse the emerging information and determine if further measures were needed in Canada. This safety review was initiated following the submission of international case reports of AKI/ARF from the manufacturer.

Veklury (remdesivir) is authorized for sale in Canada to treat coronavirus disease 2019 (COVID-19) in adults and adolescents with pneumonia (a lung infection) and requiring oxygen. This authorization includes conditions on the manufacturer to provide additional information to Health Canada on the drug's performance, along with active safety monitoring.

At the time of the review, the Canadian product safety information (Canadian Product Monograph) for Veklury included information on potential kidney toxicity and recommended measuring kidney function before starting Veklury and during treatment. It also advised against using Veklury with drugs that reduce kidney function, or in patients with severe kidney problems. The purpose of this review was to assess if additional actions were required in Canada.

Health Canada reviewed the available information from searches of the Canada Vigilance database, international databases, published literature, and information received from the manufacturer. At the time of the review, Health Canada had not received any Canadian reports of AKI/ARF related to Veklury use. Health Canada reviewed 88 international case reports of AKI/ARF in patients receiving Veklury. 60 of these foreign cases were from the Canada Vigilance database. Of the 88 case reports, 64 cases were found to be possibly linked with the use of Veklury, 14 cases were unlikely to be linked, and 10 cases did not have enough information to be further assessed. In all 64 cases assessed as possibly linked, the role of Veklury in causing AKI/ARF could not be established due to several contributing factors such as, other medications taken by the patients, existing medical conditions and/or COVID-19 illness that may have contributed to AKI/ARF.

Health Canada also looked at additional information available from 10 articles in published scientific literature and 4 studies provided by the manufacturer on the risk of AKI/ARF with Veklury use. Overall, there is limited information suggesting that treatment with Veklury in COVID-19 patients can lead to AKI/ARF.

Based on Health Canada's review of the available information, a direct link between the use of Veklury and the risk of AKI/ARF could not be established. The available information does not suggest a change in the overall safety profile for Veklury. Presently, the Canadian Product Monograph (CPM) for Veklury provides appropriate information on kidney toxicity and recommendations on usage, therefore, no updates are required at this time.

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 May 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 and 136. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 12 April 2021, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Singapore: Nitrosamine impurity 1-methyl-4-nitrosopiperazine (MNP) found in rifampicin products

On 23 April 2021, the Health Sciences Authority

(HSA) announced that it had informed healthcare professionals about the recent findings of a newly discovered nitrosamine impurity, 1-methyl-4-nitrosopiperazine (MNP), in rifampicin products. HSA has tested and found that all the rifampicin products in the Singapore market contain trace amounts of MNP. However, in consultation with local infectious diseases experts, HSA has assessed that the benefit of rifampicin, being an essential medicine for active and latent tuberculosis and its role in curtailing the spread of tuberculosis, far outweighs the theoretical long-term risk posed by MNP. In consideration of this, HSA will temporarily allow the supply of rifampicin products with trace amounts of MNP so that patients can have continued access to this essential medicine.

In Hong Kong, there are 28 registered pharmaceutical products containing rifampicin (also known as rifampin). All products are prescription-only medicines.

Related news was previously issued by the US Food and Drug Administration, and was reported in the Drug News Issue No. 130. As on 5 May 2021, the DH has received 22 cases of adverse drug reaction related to rifampicin. None of them is concluded to be related to the presence of 1-methyl-4-nitrosopiperazine (MNP).

The DH has contacted the certificate holders of all registered rifampicin products for follow up on the local impact of the issue and to provide evidence that MNP in the products are below acceptance limit. When any health risks are posed to the public, a press statement will be issued as soon as possible. The DH will remain vigilant on the development of the issue and any safety update of the drug issued by overseas drug regulatory authorities for consideration of any action deemed necessary.

The United Kingdom: Polyethylene glycol (PEG) laxatives and starch-based thickeners: potential interactive effect when mixed, leading to an increased risk of aspiration

On 27 April 2021, Medicines and Healthcare products Regulatory Agency (MHRA) announced that addition of a polyethylene glycol (PEG)-based laxative to a liquid that has been thickened with a starch-based thickener may counteract the thickening action, placing patients with dysphagia at a greater risk of aspiration.

Polyethylene glycol (PEG) laxative products treat constipation through an osmotic effect. They are indicated mostly for adults with some formulations also indicated for use in children. Some PEG laxative products such as Movicol, Macrogol 3350, and Moviprep are available in the form of a powder, which must be dissolved in liquid before administration.

Thickened liquids are usually taken by patients with dysphagia, including people who are elderly or have disabilities that affect swallowing. Thickening the liquid before swallowing improves bolus control and reduces the risk of aspiration, which can be life-threatening. There are two main types of thickening agents – a starch-based (for example, corn-starch) or a gum-based (xanthan gum). Most thickeners are classified as foods for special medicinal purposes and are used to thicken both liquids and foods to various consistencies. There are many different brands of thickeners available and they can be in the form of powder or a liquid. The recommendation to use a thickener should be based on the patient's degree of dysphagia (and potential risk of aspiration), the desired consistency required, the texture required, palatability, and other clinical considerations.

The Institute for Safe Medication Practices (ISMP) Canada issued a Safety Bulletin discussing the possible potential harmful interaction between PEG laxative and starch-based thickeners. One case report was identified where a patient was switched to a thickened diet for dysphagia. PEG-3350 was mixed with a starch-based pre-thickened juice. On day 2 of administration the patient showed possible signs of aspiration after swallowing the dose. The patient died a few hours later. Although the cause of death was difficult to establish due to the patients underlying medical conditions, aspiration was thought to have been a contributing factor.

Addition of a PEG laxative to a liquid that has been thickened with a starch-based thickener can produce a mixture that is thin and watery – undoing the intended act of thickening. Patients with dysphagia who swallow the thinner liquid are potentially at greater risk of aspiration.

Constipation and dysphagia coexist more commonly in the elderly and in people with disabilities that affect swallowing. Therefore these populations may be of particular risk if a PEG laxative is added to liquid thickened with starch. The MHRA is currently not aware of any case

reports of this potential interaction in the United Kingdom. MHRA has requested that the manufacturers of United Kingdom PEG laxative products add information about the potential interactive effect to the Summary of Product Characteristics and the Patient Information Leaflet.

Advice for healthcare professionals:

- There have been reports of a possible potential harmful interaction between polyethylene glycol (PEG) laxatives and starch-based thickeners when they are mixed together.
- Combining the two compounds can counteract the thickening action and result in a thin watery liquid – patients with swallowing difficulties (dysphagia) are potentially at greater risk of aspiration of the thinner liquid.
- Avoid directly mixing together PEG laxatives and starch-based thickeners, especially in patients with dysphagia who are considered at risk of aspiration such as elderly people and people with disabilities that affect swallowing.

In Hong Kong, there are 5 registered pharmaceutical products containing polyethylene glycol (PEG) laxatives (including macrogol 3350 and macrogol 4000). All products are over-the-counter medicines. As on 5 May 2021, the DH has not received any case of adverse drug reaction related to the macrogols. In light of the above MHRA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 28 April 2021, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Drug Recall

Batch recall of Aimafix 500IU/10 ML Powder and Solvent for Solution for Infusion (Factor IX)

On 13 April 2021, the DH endorsed a licensed drug wholesaler, namely Trenton-Boma Limited (T-Boma) to recall one batch (batch number: 612021) of Aimafix 500IU/10 ML Powder and Solvent for Solution for Infusion (Factor IX) from the market due to a potential quality issue of the infusion needle supplied together with the product.

The DH received notification from T-Boma that the overseas manufacturer informed the wholesaler on a potential risk due to incorrect sterilization of the infusion needle supplied in the package of the above batch of product. As a precautionary measure, the wholesaler voluntarily recall the affected batch of the product.

The aforementioned product, containing Human Plasma Coagulation Factor IX, is a prescription medicine for treatment of hemophilia. The product is not registered in Hong Kong but was imported for the treatment of particular patients by registered medical practitioners. According to the wholesaler, the affected batch has been only supplied to the Hospital Authority hospitals.

As on 5 May 2021, the DH has not received any adverse reaction reports in connection with the affected product. A notice was posted the Drug Office website on 13 April 2021 to alert the public of the product recall.

Batch recall of Apo-Amitriptyline Tablets 10 mg

On 15 April 2021, the DH endorsed a licensed drug wholesaler, Hind Wing Co Ltd (Hind Wing), to recall one batch (batch number: RF0410) of Apo-Amitriptyline Tablets 10 mg (Hong Kong registration number: HK-09273) from the market as a precautionary measure due to the presence of an impurity in the product.

The DH received notification from Hind Wing today that the overseas manufacturer of the product is initiating a voluntary recall of the batch concerned due to the presence of a higher than accepted level of an impurity, N-nitrosodimethylamine (NDMA), in the affected batch. NDMA is classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, Hind Wing is voluntarily recalling the affected product from the market.

The above product is a prescription medicine used for the treatment of depression. According to Hind Wing, the product has been supplied to DH clinics, private hospitals, local doctors and pharmacies as well as exported to Macao.

As on 5 May 2021, the DH has not received any adverse reaction reports in connection with the product. Press release was posted the Drug Office website on 15 April 2021 to alert the public of the product recall.

Government announces investigation results regarding packaging defects of BioNTech vaccine and arrangements for resumption of vaccination service

On 1 April 2021, the Government announced that it has received from German drug manufacturer BioNTech the investigation results regarding packaging defects of the vial caps of the BioNTech vaccine (batch 210102) and the follow-up proposal. The Government took note of the investigation results and announced the arrangements for resumption of vaccination service of the BioNTech vaccine starting from 5 April 2021 under the Government vaccination programme.

According to the information provided by Fosun Industrial Co., Limited (Fosun) and German drug manufacturer BioNTech, BioNTech has completed the relevant investigation and analysis regarding defects found in a small number of vial caps in a batch of vaccines supplied to the Hong Kong and Macao regions. It is confirmed that the occurrence of the said problem is only associated with vaccine packaging under transport conditions. The production process and quality of the vaccine are found to be intact.

Results of further investigation including repeated tests and comparisons revealed that the occurrence of defects in the vial caps of the BioNTech vaccine was resulted from the crimping process during fill and finish in which the container integrity could not be effectively ensured for the said batch of vaccines (batch 210102). If the metal cap of the said batch of vials was not optimally crimped, there might be ingress of ambient gas into the vials under the ultra-cold storage and transport environment (i.e. -70 degrees Celsius). The subsequent thawing procedures conducted might lead to increased air pressure in the vials and thus over-pressure in some vials and leakages from the vials, etc. Having conducted further tests, the relevant problem was also observed in other batches (including batch 210104) which were filled and finished at the same plant (including the crimping process). In contrast, for batches not filled and finished at the same plant (including the crimping process), the problem was not observed after conducting the same tests repeatedly.

After conducting detailed analysis of the testing statistics and results of random sampling, the German drug manufacturer BioNTech considered that there was no evidence that pointed to any safety risks for batches 210102 and 210104 of the BioNTech vaccine. The drug manufacturer indicated that in view the vaccine was stored under ultra-cold conditions, the risk of microbial contamination was very low. Also, as of now, no relevant adverse event had been discovered under the continuous monitoring mechanism. The German drug manufacturer BioNTech also indicated that, even if the vials had the above problems, the integrity of the messenger RNA and lipid nanoparticles was not affected. Having regard to the above results, the drug manufacturer confirmed that the safety and efficacy of the vaccine were not affected by the aforesaid issue, hence members of the public who had received the BioNTech vaccine did not need to worry. That said, for the sake of prudence, batches 210102 and 210104 will continue to be put on hold at the request of the drug manufacturer until completion of the final investigation report. The Government is also prepared to follow the recommendation of the drug manufacturer to suitably handle the relevant batches at a later time, including no longer administering the relevant batches of the BioNTech vaccine.

On the other hand, according to information provided by Fosun, a batch of around 300 000 doses of the BioNTech vaccine which were produced in Germany and filled and finished at another plant in Germany was expected to arrive Hong Kong from Germany on 2 April 2021. To ensure that problems similar to those mentioned above which might have led to packaging defects will not happen to the relevant batch of vials, German drug manufacturer BioNTech has conducted a series of stringent tests and assessment, including pressure tests conducted on more than 15 000 vials which had been stored in ultra-cold conditions. It was confirmed that the aforesaid problems were not found. German drug manufacturer BioNTech and Fosun will also enhance sampling and monitoring to ensure the integrity of the vials. The Government will also continue to provide relevant information to all healthcare professionals responsible for handling vaccines at Community Vaccination Centres (CVCs), with a view to effectively detecting the occurrence of similar problems. It was pointed out that the relevant problem was discovered under the stringent checking procedures at the Government's CVCs. This demonstrates that the relevant procedures are working well and can effectively prevent similar problems from occurring to the vaccines.

Related news was previously issued by the Macao Health Bureau on 2 April 2021.

Scientific Committees under CHP update interim recommendations on COVID-19 vaccination

On 22 April 021, the Scientific Committee on Vaccine Preventable Diseases and the Scientific Committee on Emerging and Zoonotic Diseases under the Centre for Health Protection (CHP) of the Department of Health (JSC) convened a meeting today (April 22), joined by the Chief Executive's expert advisory panel (EAP), to discuss and update recommendations on the use of mRNA COVID-19 vaccines in pregnant and lactating women and the use of AstraZeneca COVID-19 vaccine.

The JSC-EAP acknowledged there is emerging data on the use of mRNA COVID-19 vaccines in pregnant and lactating women. Given there are no known risks associated with administering mRNA COVID-19 vaccines to lactating women, they are recommended to receive the mRNA vaccines as for the rest of the population. Pregnant women who consider mRNA COVID-19 vaccines should consult their obstetricians on the risks and benefits of vaccination.

During the meeting, the JSC-EAP discussed the use of AstraZeneca COVID-19 vaccine. Reports of extremely rare adverse events of thrombosis with thrombocytopenia syndrome (TTS) following vaccination with AstraZeneca COVID-19 vaccine was noted. Causal relationship between the vaccine and TTS is possible but still under investigation. Currently, evidence and data on the occurrence of TTS following vaccination of AstraZeneca COVID -19 vaccine is still emerging. In view of the local epidemiological situation and the availability of alternative COVID-19 vaccines in Hong Kong, there is no need for the introduction of AstraZeneca COVID-19 vaccine in Hong Kong.

Two batches of Comirnaty COVID-19 vaccine with packaging defects to be returned to manufacturer in Germany

On 29 April 2021, the Government announced that two batches of the Comirnaty COVID-19 vaccine, put on hold earlier due to packaging defects, will be returned to the manufacturer, BioNTech, in Germany for disposal.

On March 24, the Government suspended the use of two batches of the vaccine (Batch Nos. 210102 and 210104) for the sake of prudence and as a precautionary measure after being notified of packaging defects including loose vial caps and leakage from the vials. The Government received the latest notification from BioNTech that the two batches concerned should be returned to the manufacturer in Germany.

BioNTech has also finished the investigation on the cause of the packaging defects and confirmed that the root cause of the incident was the imperfect crimping process at one packaging plant in Germany, and that there is no safety issue related to the defects. Fosun has arranged for the affected batches to be replaced by new batches that were packaged in another packaging plant (Baxter) in Germany. Since the resumption of the vaccination service of the BioNTech vaccine in Hong Kong, similar complaints related to crimping defects have not been received.

Related news was previously issued by the Macao Health Bureau on 29 April 2021.

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.

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.