Regulation of medical gases as pharmaceutical products

The Department of Health (DH) today (June 17) said that the Pharmacy and Poisons Board of Hong Kong (the Board) has endorsed the regulation of medical gases as pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance) with effect from June 14, 2026.

In September 2023, the Board agreed that medical gases should be regulated as pharmaceutical products under the Ordinance after taking into account the regulatory control of medical gases in other jurisdictions and the current situation in Hong Kong. In this connection, a public consultation had been conducted by the DH in November last year for collecting views and comments from the public and relevant stakeholders.

Noting that the overall responses were in support of the regulatory control of medical gases, the Board has decided at its meeting on June 14, 2024, to regulate medical gases as pharmaceutical products under the Ordinance by giving two years' preparatory time (i.e. from June 14, 2024, to June 13, 2026) for the trade to apply for relevant licences and registration of their products. The Board has also promulgated relevant Guidance Notes and details are available at the Board's website (www.ppbhk.org.hk/eng/index.html).

The DH has started issuing letters to inform relevant traders and stakeholders about the aforesaid regulation. When the new regulatory control takes effect, the medical gases, as pharmaceutical products, have to be registered with the Board before they can be legally sold or supplied in Hong Kong. In addition, traders of the pharmaceutical products must obtain relevant licence(s) from the Board before conducting manufacture, wholesale (including import and export) of pharmaceutical products and retail sales of pharmaceutical products containing poisons. According to the Ordinance, illegal possession or sale of unregistered pharmaceutical products or prescription drugs, and manufacture, wholesale of pharmaceutical products and retail sales of pharmaceutical products containing poisons without relevant licences are criminal offences. The maximum penalty for each offence is a fine of \$100,000 and two years' imprisonment upon conviction.

For relevant information on the Regulation of Medical Gases, please visit the website of the Drug Office of the DH (www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/medical_gases_regulation.html).

Transcript of remarks by SEE at media session

Following is the transcript of remarks by the Secretary for Environment and Ecology, Mr Tse Chin-wan, at a media session after attending the launch event for the Strategy of Hydrogen Development in Hong Kong today (June 17):

Reporter: How would the launch of the Hydrogen Strategy help Hong Kong to achieve its goal of carbon neutrality? And what kind of law changes will be proposed to ensure the safe storage and maintenance of the gas? Are there any plans to develop green hydrogen in the future?

Secretary for Environment and Ecology: When we are pursuing carbon neutrality, it is necessary for us to acquire what we call a "zero-carbon energy" in order to support green transition. Hydrogen is a "zero-carbon energy" because when it burns or when it reacts with oxygen, it produces only water. And therefore hydrogen is regarded as a potential new fuel or new energy source for green transition. That is why today we announce the Hydrogen Strategy for Hong Kong. Down the road, the first thing we need to do is to introduce a legislation which governs the production, the storage, the transportation and the use of hydrogen in Hong Kong as well as for those uses, we introduce the safety standards and other standards which govern its application.

We believe that hydrogen has great potential to develop a new green economy in Hong Kong because its production, its storage and also its application in different sectors will enhance the employment of labour and also the setting up of a new industry etc. We would like to work with our neighbouring cities as well as with different sectors, to work hand in hand, to develop the green hydrogen economy in Hong Kong.

(Please also refer to the Chinese portion of the transcript.)

Batch recall of Ferrum Hausmann Drops 50mg/ml (with photo)

The Department of Health (DH) today (June 17) endorsed a licensed drug wholesaler, namely Hong Kong Medical Supplies Ltd (HKMS), to recall eight batches (batch numbers: AAL56301, AAM03804, AAP27103, AAR88304, AAT62402, AAW72104, NAA04302 and NAA14002) of Ferrum Hausmann Drops 50mg/ml (Hong Kong Registration Number: HK-36593) from the market as a precautionary measure due

to a potential quality issue.

The DH received notification from HKMS that the overseas manufacturer of the product is initiating a voluntary recall of the above batches due to the presence of small plastic particles above the cap of the dropper in some samples of the product; the particles may fall out when used. As a precautionary measure, HKMS is voluntarily recalling the affected batches of product from the market. The DH's investigation is continuing.

The above product, containing iron, is an over-the-counter medicine for the treatment of iron deficiency and iron deficiency anaemia. According to HKMS, the concerned batches of product have been imported into Hong Kong for distribution to the Hospital Authority, local private hospitals, private doctors and pharmacies, as well as for re-export to Macao.

HKMS has set up a hotline (2806 3112) to answer related enquiries.

So far, the DH has not received any adverse drug reaction reports related to the affected batches of product. The DH will closely monitor the recall.

Members of the public should consult healthcare professionals if in doubt or feeling unwell after using the affected product.



LegCo to consider Electronic Traffic Enforcement (Miscellaneous Amendments) Bill 2023

The following is issued on behalf of the Legislative Council Secretariat:

The Legislative Council (LegCo) will hold a meeting on Wednesday (June 19) at 11am in the Chamber of the LegCo Complex. During the meeting, the

Second Reading debate on the Electronic Traffic Enforcement (Miscellaneous Amendments) Bill 2023 will resume. If the Bill is supported by Members and receives its Second Reading, it will stand committed to the committee of the whole Council. After the committee of the whole Council has completed consideration of the Bill and its report is adopted by the Council, the Bill will be set down for the Third Reading.

On Members' motions, Mr Lam Chun-sing will move a motion on promoting the popularisation of flexible working system. The motion is set out in Appendix 1. Ms Nixie Lam, Professor William Wong, Mr Luk Chung-hung, Mr Lee Chun-keung and Mr Yim Kong will move separate amendments to Mr Lam's motion.

Ms Nixie Lam will move a motion on policies on supporting assisted reproduction. The motion is set out in Appendix 2. Ms Judy Chan, Mr Kenneth Leung and Mr Lee Chun-keung will move separate amendments to Ms Lam's motion.

Mr Chan Yung will move a proposed resolution under section 34(4) of the Interpretation and General Clauses Ordinance to extend the period for amending a subsidiary legislation. The proposed resolution is set out in Appendix 3.

During the meeting, Mr Chan Chun-ying will present the "Finance Committee Report on the examination of the Estimates of Expenditure 2024-2025" and address the Council.

Members will also ask the Government 22 questions on various policy areas, six of which require oral replies.

The agenda of the above meeting can be obtained via the LegCo Website (www.legco.gov.hk). Members of the public can watch or listen to the meeting via the "Webcast" system on the LegCo Website. To observe the proceedings of the meeting at the LegCo Complex, members of the public may call 3919 3399 during office hours to reserve seats.

Government announces Strategy of Hydrogen Development in Hong Kong

The Government today (June 17) announced the Strategy of Hydrogen Development in Hong Kong (the Hydrogen Strategy).

Announcing the Hydrogen Strategy today, the Secretary for Environment and Ecology, Mr Tse Chin-wan, said, "To tackle the challenge of climate change, the world is striving to phase out fossil fuels and accelerate energy transition. Hydrogen energy is regarded as a low-carbon energy with development potential, and countries around the world are actively promoting

the development of the hydrogen energy industry. With a solid foundation for developing the hydrogen energy industry, our country has stated clearly that hydrogen would be an important component of the national energy system in the future. Seizing the opportunities brought about by the development of hydrogen energy can help Hong Kong strive towards carbon neutrality, develop a new quality productive force and maintain international competitiveness."

To prepare for opportunities presented by the development of hydrogen energy, the Government has set up an Inter-departmental Working Group on Using Hydrogen as Fuel (the Working Group) in 2022, comprising more than 10 bureaux and professional departments, to remove barriers and facilitate commencement of local hydrogen applications. The Working Group has assisted in formulating interim standards for hydrogen applications in Hong Kong and has given agreement-in-principle to 14 projects. These projects, which include cross-boundary hydrogen transportation, supply facilities, as well as applications in transport, construction sites and remote areas, etc, have commenced progressively.

Having reviewed various considerations, the Government has formulated the Hydrogen Strategy to address the technical challenges in the six major areas of safety, suitable technologies, infrastructure, cost effectiveness, capacity building and public acceptance, as well as the unique situation of Hong Kong. The Strategy sets out the four major strategies of improving legislations, establishing standards, aligning with the market, and advancing with prudence to create an environment conducive to the development of hydrogen energy in Hong Kong in a prudent and orderly manner, so that Hong Kong would be able to capitalise on the environmental and economic opportunities brought about by the recent developments of hydrogen energy in different parts of the world, the country in particular. It can also help Hong Kong broaden co-operation with the Guangdong-Hong Kong-Macao Greater Bay Area and even the world, integrate into the country's overall development, and develop a new quality productive force.

According to the Hydrogen Strategy, the Government will introduce legislative amendments in the first half of 2025 to provide a legal basis for regulating the manufacture, storage, transport, supply and use of hydrogen used or intended to be used as fuel, and formulate the approach for certifying a hydrogen standard that aligns with international practices by 2027. The Government will also promote regional co-operation, investment outside Hong Kong, development or importation of hydrogen through joint ventures; leverage on Hong Kong's distinctive advantages of enjoying strong support of the motherland and being closely connected to the world to promote Hong Kong as a demonstration base for the development of hydrogen energy in the country; facilitate the development of the hydrogen industry in the Belt and Road region; and, in collaboration with Invest Hong Kong and relevant bureaux and departments, capitalise on Hong Kong's roles as a "super connector" and "super value-adder" to reach out to overseas and Mainland potential enterprises and talent to promote Hong Kong's business opportunities arising from hydrogen energy development.

Regarding the implementation of the Hydrogen Strategy, the Government will expand the roles and functions of the Working Group. In addition to

examining and approving future trial projects, the Working Group will also co-ordinate the development and continuous enhancement of the relevant technical standards and guidelines for hydrogen applications; advise on the pathway for wider application and commercialisation of various hydrogen projects; provide support for local infrastructure developments and capacity building for hydrogen applications; assist in the promotion of the popularisation of hydrogen applications; and regularly review the implementation progress and update the Hydrogen Strategy.

The full text of the Strategy has been uploaded to the Carbon Neutrality and Sustainable Development website of the Environment and Ecology Bureau (cnsd.gov.hk/strategy-of-hydrogen-development-in-hong-kong booklet en.pdf).