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VIETNAM: Granting of Retail Licenses Suspended due to “Administrative Reforms”

Foreign retailers intending to enter the Ho Chi Minh City retail market will face tough times because the Ho Chi Minh City government has issued an official dispatch under which the grant of new retail licenses to foreign investors is temporarily suspended.

However, this authority could not confirm when exactly the draft will be submitted to the People’s Committee. This means that foreign retailers may possibly suffer from loss of business opportunities for the next few months while waiting for the issuance of such a new guidance.

As an attempt to reform the administrative procedures in accordance with Project 30¹ of the Vietnamese Government, Ho Chi Minh City plans to promulgate a specific guidance concerning the grant of business licenses and retail licenses for foreign investors as provided under Decree No. 23/2007/ND-CP² of the Government. For this purpose, the People’s Committee of Ho Chi Minh City (the “**HCMC P’sC**”) on 21 January 2010 issued Official Dispatch No. 45/TB-VP under which the Ho Chi Minh City Department of Planning and investment (the “**HCMC P’sC**”) is delegated to draft the guidance in order for the People’s Committee to approve and issue.

For the purpose of comparison between the two largest cities of the country, we also contacted the Hanoi Department of Planning and Investment on the same issue. So far Hanoi does not plan any additional guidance as enabled by Decree No. 23/2007/ND-CP so the status for retail license applications in Hanoi remains unchanged.

As a conclusion, new coming investors should take this as an unexpected situation and wait for further feedback from the Ho Chi Minh City government. Otherwise, they may consider Hanoi as an alternative destination.

Besides the positive objective to facilitate administrative procedures, such a policy brings a negative effect to foreign retailers who wish to enter the Ho Chi Minh City retail market. While waiting for the guidance, the HCMC P’sC only grants amended licenses to the existing retail companies (if requested). This implies that in the meantime, a newly registered retail outlet will temporarily not be granted.

The concern is that the HCMC P’sC did not inform about the time limit for such suspension, leaving foreign retailers vulnerable to start their businesses. When we inquired with HCMC DPI regarding the above issue, it was only confirmed that the HCMC DPI is under the process of collecting opinions from relevant authorities for the draft guidance.

¹ A national program of Vietnam to reform its administrative procedures in order to improve its business environment and its competition capability.

² Decree No. 23/2007/ND – CP detailing the Commercial Law regarding goods purchase and sale activities or goods purchase and sale related activities of foreign-invested enterprises in Vietnam issued by the Government on 12 February 2007.

Dear Reader,

This issue is dedicated to Vietnam and summarizes various rather recent legal developments in Vietnam relating to retail licenses and to health care issues.

You might also like to know that our **Guide to the Legal Aspects of Healthcare in Vietnam (73 pages)** has just been published. For further details please email Rusy (Rusy@rflegal.com).

As usual, if you have any comments, remarks or questions, we’d love to hear from you.

Please contact me at +65-6324-0060 or by email to respondek@rflegal.com.

Kind regards,
RESPONDEK & FAN
Andreas Respondek
Managing Director

SINGAPORE Office

1 North Bridge Road
#16-03 High Street Centre
Singapore 179094

Tel: +65-6324-0060 Fax: +65-6324-0223

THAILAND Office

23 Silom Road, United Centre,
39th Floor, Suite 3904 B
Bangkok 10500

Tel: +66-2-635-5498 Fax: +66-2-635-5499

VIETNAM Office

5th Fl., Suite 5.03,
58 Dong Khoi Street, District 1
Ho Chi Minh City

Tel: +84-8-3824-8887 Fax: +84-8-3824-8885



VIETNAM: New Law on Medical Examination and Treatment

In the process of harmonization of the legal system, and to speed up the socialization of the healthcare services, the National Assembly of Vietnam adopted the Law on Medical Examination and Treatment (the "LMET") in its latest session in November 2009. The LMET will take effect on 1 January 2011 and replace the Ordinance on Private Medical Pharmaceutical Practice.

The LMET is aimed at protecting the rights and interests of patients and improving the quality of medical examination and treatment. It has 9 chapters and 91 articles and provides a level playing field for both private and public health facilities. Under the LMET, the government will give budget priority to public need for medical examination and treatment. It prohibits any refusal or delays in giving emergency aid to patients by any health facility. It also prohibits health workers practicing without proper certificate. Public health workers are not allowed to set up or manage private hospitals or health facilities. However they are entitled to set up private health consultation rooms and to sign work contracts with private health establishments to earn "moonlight" money. Furthermore, The Ministry of Health (the "MOH") will continue efforts to upgrade provincial, district and general hospitals and offer more training for doctors and assistant doctors to work in mountainous and remote areas.

Specifically, the MOH will grant a practicing certificate to people who satisfy the following conditions: ¹

- i) Having one of the following certificates which is compatible with the form and scope of professional practice: (1) a professional diplomas to be granted or recognized in Vietnam; (2) a herb doctor certificate, or (3) a certificate of having a home remedy.
- ii) Having documents proving that he/she has passed the probation period, except for herb doctors and persons who have a home remedy;
- iii) Having certificate of good health for professional practice; and
- iv) Not subject to the prohibitions of practicing in health care sector as regulated by the law.

In addition to the above conditions, a foreign medical practitioner must fully meet the following requirements:²

- i) A person directly giving medical examination or treatment to Vietnamese must be fluent in the Vietnamese language or have interpreters in case he/she is not fluent in Vietnamese;

- ii) Having legal records certified by competent bodies of the host country; and
- iii) Having work permits granted by Vietnamese agencies performing the State management over labor.

The Minister of the MOH will promulgate the criteria for certifying a foreign practitioner to be fluent in Vietnamese in the health care sector. ³

Also under the LMET, Vietnam recognizes practicing certificates granted by other countries in accordance with the international treaties or agreements to which Vietnam is a member. ⁴

With regard to a medical practicing organization, a medical establishment can be organized under one of the following forms, depending on its scope of professional practice: ⁵

- Hospital;
- General consulting-room, specific consulting-room, and family doctor;
- Traditional medical treatment establishment;
- Maternity hospital;
- Health care services provider;
- Commune-level medical station; and
- Other forms of medical establishment.

¹ The LMET, Article 18.

² The LMET, Articles 19 and 23.1.

³ The LMET, Article 23.3.

⁴ The LMET, Article 22.

⁵ The LMET, Article 41.



A medical establishment can commence its operation once it is granted (1) an establishment decision, business certificate or investment certificate (depending on the form of the medical establishment) by the competent State body and (2) an operation permit by the MOH or other competent authorities.⁶

The MOH grants an operation permit once a medical establishment has fulfilled the following requirements:⁷

- i) Having the premises, facilities, medical equipment, IT equipment and other necessary conditions as required under the national construction standard for medical establishment;
- ii) Having necessary conditions for medical waster disposal and radiation safety by the law;

- iii) Having enough professional practitioners compatible with its scope of professional activities;
- iv) The person responsible for the professional management of the medical establishment has been practicing in medical sector for at least 36 months.

Finally, as the biggest concern of the Vietnamese government is to make healthcare universal and affordable to its populace, the Government will undertake all efforts to provide the necessary methods to ensure that until 1 January 2016, all medical establishment are granted operation permits.⁸

⁶ The LMET, Article 42.

⁷ The LMET, Article 43.

⁸ The LMET, Article 44.6.

Advertisement of Pharmaceutical Products in Vietnam

The drug information provisions and advertisements are governed by the Pharmacy Law 2005 and Ordinance on Advertisement 2001. In order to unify the regulations on advertisement of pharmaceutical products, on 01 September 2009, the Ministry of Health issued Circular No. 13/2009/TT-BYT guiding drug information provision and advertising (“**Circular No.13**”).

Circular No. 13 took effect from 16 October 2009, and replaced Decision No. 2557/2002/QD-BYT dated 4 July 2002 issuing Rules on advertising and providing information on pharmaceuticals for human and on cosmetic products having direct influence on human health, and Circular 12/2002/TT-BYT dated 23 August 2002 guiding the advertisement of vaccines and immunizes chemicals used for people.

Who is eligible to give information and advertise pharmaceutical products?

Under Circular No.13, only entities which have already registered drugs are entitled to register the file of drug information and advertising for such registered drugs. If these entities prefer to authorize other entity to register the file of drug information and advertising, the authorization must be made in writing, and the authorized entity must has its legal entity status.¹

Entities which give information and advertise drugs must bear full responsibility for the content and legality of the information stated in their drug information and advertising.²

What pharmaceutical products are permitted to be advertised?

Only drugs, which have been already granted their registration visa numbers for free-circulation in Vietnam, will be permitted to be informed and advertised. Drugs that have not been granted their registration visa numbers for free-circulation in Vietnam, but have been permitted to be freely circulated in other countries, will only be permitted to be informed to health officers via drug introduction conferences.³

Specifically, drugs on the list of non-prescription drugs promulgated by the Ministry of Health with valid registration numbers may be advertised on books, newspapers, magazines, leaflets, online newspapers, websites of enterprises and advertising service providers, panels, posters, banners, illuminative objects, aerial or underwater objects, means of transport, other movable objects and other advertising media.⁴

¹ Circular No.13, Article 3.1.

² Circular No.13, Article 3.6.

³ Circular No.13, Article 3.2.

⁴ Circular No.13, Article 19.1.

SINGAPORE Office

1 North Bridge Road
#16-03 High Street Centre
Singapore 179094

Tel: +65-6324-0060 Fax: +65-6324-0223

THAILAND Office

323 Silom Road, United Center,
39th Floor, Suite 3904 B
Bangkok 10500

Tel: +66-2-635-5498 Fax: +66-2-635-5499

VIETNAM Office

5th Fl., Suite 5.03,
58 Dong Khoi Street, District 1
Ho Chi Minh City

Tel: +84-8-3824-8887 Fax: +84-8-3824-8885



Drugs with registration numbers for circulation in Vietnam granted by the Ministry of Health and having main active ingredients on the Ministry of Health's list of active ingredients permitted for registration of advertising on radio and television may be advertised on radio and television.⁵

Contents of drug advertising

The content of drug information and advertising must ensure must be scientific, objective, accurate, truthful and clear, and must not lead to misunderstanding.⁶

The language and script used in informing and advertising are in Vietnamese, except for the cases of the words have been internationalized or the trade name and words that could not be replaced by Vietnamese.⁷

The minimum size of the letters used in information and advertising must be clear enough for reading in the normal condition, but it must not be smaller than the 11-font VnTime size.⁸

Dossier and procedure for registration of drug information and advertising

Entities which prefer to give information and advertise drugs must submit their application dossiers for drug information and advertising to the Drug Administration of Vietnam (under the Ministry of Health) before its drug information and advertising.⁹

An application dossier includes:¹⁰

- A Request for registration of drug information and advertising (a standard form);
- A Proposed form and content of drug information and advertisement;
- The references verifying the content of drug information and advertisement;
- A copy of the instructions for use of drug approved by the Drug Administration of Vietnam;
- A copy of the certificate of satisfaction of all the conditions for drug business or the license of operation of the foreign enterprise in Vietnam;
- Screenplays, videos, tapes in case the advertising is made through radio broadcasting or television broadcasting (screenplays must describe clearly the images, words and music).

Such entities will be entitled to give information and advertise drugs in accordance with the content registered with the Drug Administration of Vietnam after 10 working days upon receipt of the valid and proper dossier.¹¹

⁵ Circular No.13, Article 19.2.

⁶ Circular No.13, Article 3.3.

⁷ Circular No.13, Article 3.4.

⁸ Circular No.13, Article 3.5.

⁹ Circular No.13, Article 30.1.

¹⁰ Circular No.13, Article 30.2.

¹¹ Circular No.13, Article 30.6.