**SOME BASIC NOTES WHEN REGISTERING TO ADVERTISE DRUGS**

 With the rapid spread of information on the media and social networks, advertising plays an important role in businesses. Thanks to advertising, consumers can effortlessly approach and research the products. At the same time, companies have the opportunity to find potential customers to promote shopping demand. Nevertheless, in advertising activities in general and for some specific products such as cosmetics, chemicals, medical equipment and especially drugs  advertisement, legal regulations require conditions to be viewed as "quite stringent" to ensure the safety of consumers. Accordingly, this article will analyze some essential issues relevant to the registration of drug advertisement content to help the operations have a general overview of the subject during their implementation.

Previously, drugs advertisement content would be stipulated by (i) the Law on Advertising 2012 and guiding regulations of the Law on Advertising and (ii) the Pharmacy Law 2016 and related guiding regulations. However, from July 1st, 2017, specialized regulations related to drug advertisement registration will be uniformly implemented in accordance with the Law on Pharmacy and guiding regulations, specifically Decree No. 54/2017/ND-CP guiding the implementation of the law on pharmacy (hereinafter referred to as **“Decree 54/2017”**).

For the application for registration of drug advertisement content, the applicants should pay attention to 03 main contents, which are:

(1) Requirements for the drug advertisement content.

(2) What content should not be provided in the drug advertisement?

(3) Effect of the certificate of drug advertisement contents.

Specifically:

**(1) Requirements for drug advertisement content**

**1.1. Drug advertisement contents shall conform to the following documents:**

a) The label and instructions for use approved by the Ministry of Health;

b) The disquisition on the drug in the National Pharmacopoeia of Vietnam;

c) Documents and professional instructions related to the drug issued or admitted by the Ministry of Health.

Note: Normally, the label used for advertising must be approved by the Drug Administration of Vietnam. In some specific cases, the applicants can still use the old label. However, the old label used to apply for registration must be enclosed with the instruction sheet (for patients and medical staffs), which the Drug Administration of Vietnam has stamped.

**1.2. The drug advertising contents have the following compulsory information:**

**1.2.1. General provisions**

1. Drug name;
2. Active ingredients or herbal ingredients in the approved package insert. Names of herbal ingredients must be written in Vietnamese. Names of untranslatable foreign herbal ingredients may be written in the Latin language;
3. Indications;
4. Uses;
5. Dosage;
6. Contraindications and warnings for special users (pregnant women, breastfeeding women, children, old people, people having chronic diseases);
7. Cautions and what to avoid when using the drug;
8. Side effects and adverse effects;
9. Name and address of the manufacturer;
10. The text “Đọc kỹ hướng dẫn sử dụng trước khi dùng" (“Read the instructions carefully before use”);
11. The text “Số Giấy xác nhận nội dung quảng cáo thuốc của Bộ Y tế: .../XNQC..., ngày ... tháng ... năm...;” (“Number and date of the certification of drug advertisement contents issued by the Ministry of Health: …”) at the end of the first page;
12. Pages of a multi-page document must be numbered. The first page must specify the number of pages and contain the table of content;
13. Reference documents and extracts therefrom are specified. The extracts must be accurate without addition or removal of information which leads to misunderstanding of the safety and efficacy of the drug.

**1.2.2. Other regulations**

1. Voice and text in a drug advertisement shall comply with the Law on Advertising;
2. The font size in drug advertisement contents must be clear, easy to read and recognize, but must not be smaller than the font size 12 of VnTime or Times New Roman font on A4 paper;
3. The advertising script must clearly describe the image, the text, the text, and the music;
4. Drug advertisement content must only provide information about the drug, not provide information unrelated to the drug;
5. For each specific form of advertising, such as advertising on online newspapers, advertising screens or the advertisement is an audio or video track that has multiple pages or footages, in addition to meeting the above general regulations, the applicants need to meet and comply with a number of regulations corresponding to each form of advertising.

**(2) What content should not be provided in drug advertising?**

The information and images that are not allowed to be used in the advertising content are specified in Article 126 of Decree 54/2017.

A common cause of the rejection of an advertising registration dossier is the use of adjectives, such as quick pain relief.  With the word “fast” in the dossier, the Drug Administration may require the provision of using results of the drug to verify that the treatment time is faster than that of other identical products. The other cases make a use of a comparative word that is typically the best product; or contain additional phrases such as “root treatment”, “high quality”, “trusted for generations”, etc.

**(3) Effect of the certificate of drug advertising contents**

The certification of drug advertisement contents does not have a specific expiration date and shall be invalidated in the following cases:

1. The certificate of drug registration expires;
2. The certificate of drug registration is revoked;
3. A change to drug information is made that requires issuance of another certification of drug advertising contents. Specifically, the certification of drug information was issued but the applicant for drug registration, drug name, ingredients, concentration, dosage form, indications, contraindications, dosage, uses for special cases, warnings or drug safety information is changed;
4. There is a recommendation from the State management agency in charge of pharmacy on limiting use or using under the supervision of medical examination and treatment practitioners;
5. The drug contains an active ingredient or herbal ingredient that has been removed from the list of Over-The-Counter (OTC) drugs promulgated by the Minister of Health.

Particularly, in case the certificate of drug registration is renewed, the certification of drug advertising contents will be automatically renewed with the same duration as that of the certificate of drug registration.

Perhaps the applicants facing with the restrictions of legal regulations will feel flinch from administrative procedures. On the one hand, from the manufacturer's perspective, when the manufacturer ensures the compliance with the provisions of the law and the product quality is highly appreciated by the consumers, the manufacturer will have a competitive advantage over competitors in the domestic market. On the other hand, satisfying and complying with statutory conditions are also basis for manufacturers to protect themselves when facing with some side effects of the products. However, it cannot be denied that, from consumers' perspective, they need to be protected because the drug will have a direct impact on health, especially when the drug is indicated use for the elderly and children.