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SPECIFICS OF MEDICAL GOODS AND SERVICES ADVERTISING IN THE LIGHT OF KAZAKHSTAN'S LATEST LEGISLATIVE CHANGES

1. Introduction

It is impossible to imagine modern life without advertising. Public demand for advertising appears where the consumer has a choice and is free to make it. And the wider goes the choice of goods and services, the more intensely the advertising market is developing. Advertising fulfills various functions, ranging from informational to economic, massively circulating the information about goods and services, their nature and point of sale, concurrently promoting their sales.

In any country the market of advertising exists according to its own rules and is pretty much regulated legally. Kazakhstan, as any other civilized state, has a fairly clear-cut and developed system of legal regulation in the advertising field, which generally allows the advertisers attain their objectives to promote goods and services. Advertising in healthcare sector has its specifics and special regulations, which have been permanently changing over the past two years. However, not always and not all advertising legislation amendments attest to its improvement.

In May 2014, in the context of the general reform of Kazakhstan's licensing-and-permitting and notification system[1], amendments were introduced into the Health Code[2] to come into legal force on 21 November 2014. The said amendments significantly change approaches to the advertising of medications, medical products and medical equipment (hereinafter, "medical goods") and medical services, which affects the interests of suppliers and institutional consumers of such goods and services. Such suppliers and consumers include distributors of medical goods, medical and diagnostic centers, SPAs, dental clinics, pharmacies, online medical services, informational services regarding medications availability at pharmacies, etc. The newly introduced restrictions may eventually prejudice the ultimate consumers (who are going to be deprived of free information regarding availability and characteristics of medical goods and services) as well as mass media and educational organizations.

In view of the above, the readers are offered a comparative analysis of the requirements to placement of the medical goods and services advertising, current and those to come into effect in 6 months, and the related legal issues, as well as some of our thoughts as to how to possibly resolve these issues.

[1] RK Law No. 202-V "On Permits and Notifications" dated 16 May 2014; RK Law No. 203-V "On Introduction of Amendments into Certain Legislative Acts of the Republic of Kazakhstan on Permitting System Issues" dated 16 May 2014.
[2] RK Code No. 193-IV "On Public Health and Healthcare System" dated 18 September 2009.

2. *Current Medical Goods and Services Advertising Regulations*

Pursuant to the current legislation, it is necessary to distinguish between the advertising for medical and pharmaceutical professionals (hereinafter, "professionals") and advertising for public.

There exist the following restrictions on the advertising of medical goods and services:

1. In order to disseminate and place the advertising it is necessary to have a permit issued by the RK authorized agency.
2. Medical goods must be registered.
3. It is prohibited to disseminate and place advertising:
   - ✓ if there is no license for the relevant type of activities;
   - ✓ of medical goods in public transport and organizations unrelated to their designation, use and sale;
   - ✓ in the form of posters, stands, light displays, billboards, banners, showbills and other stationary advertising facilities (outdoor advertising);
   - ✓ in the form of dissemination of prescription medication samples;
   - ✓ using in the advertising materials children, their images and voices (except for medications and medical products intended for children);
   - ✓ through medical professionals authorized to prescribe medications and medical products (except for the cases where information on medications and medical products is disseminated for scientific or educational purposes or in order to inform patients).
4. It is allowed to disseminate and place advertising:
   - ✓ of medical goods and services: (i) in specialized medical editions, (ii) in other mass media, and (iii) in healthcare organizations;
   - ✓ of prescription medications: only in specialized print editions intended for professionals.

Moreover, the advertising of medical goods and services falls under the general advertising requirements, including those with respect to:

1. *the language of advertising* (it is allowable to disseminate advertising in the Kazakh and Russian languages, and, at advertiser's discretion, in other languages; translation of the advertising content from one language into another is not to distort its general meaning; trademarks registered in accordance with the established procedure are presented in the original language);

2. *the content of advertising* (for example, advertising cannot be used to propagate or instigate social, racial, national, religious, class or tribal discord; advertising is not to cause panic in public, mislead consumers about the advertised products, discredit, humiliate or ridicule persons not using the advertised goods, contain information violating the generally accepted norms of humanity and morality, etc.)

3. *Amendments to Legislation on Medical Goods and Services Advertising*

Starting 21 November 2014, the following restrictions will be effective with respect to the advertising of medical goods and services:

1. No permit will be any longer required to disseminate and place advertising.

2. Medical goods will have to be registered.
3. It will not be allowed to disseminate and place the advertising:
   - ✓ if there is no license for the relevant type of activities;
   - ✓ in public transport and organizations unrelated to the medical goods' designation, use and sale;
   - ✓ in the form of posters, stands, light displays, billboards, banners, showbills and other stationary advertising facilities (outdoor advertising);
   - ✓ in the form of dissemination of prescription medicine samples;
   - ✓ using in the advertising materials children, their images and voices (except for medications and medical products intended for children);
   - ✓ through medical professionals authorized to prescribe medications and medical products (except for the cases where information on medications and medical products is disseminated for scientific or educational purposes or in order to inform patients).
4. It will be allowed to disseminate and place advertising:
   - ✓ of medical goods and services: (i) in specialized medical editions, and (ii) in healthcare organizations;
   - ✓ of prescription medications: only in specialized print editions intended for professionals.

4. Implications of Amendments to the Medical Goods and Services Advertising Legislation

Abolition of the permitting procedure for the advertising of medical goods and services generally conforms to the concept of enhancing the efficiency of the permitting and notification procedures applied in Kazakhstan, including via reducing the administrative barriers and the permit-obtaining and notification burden on entrepreneurs.

However, there emerges a stumbling block for both the entrepreneurs and consumers, because the legislator has removed, starting 21 November 2014, all mass media other than specialized medical editions from the list of formats permitted for placement and dissemination of medical goods and services advertising.

Pursuant to legislation[3], a mass media is understood as a periodical print edition, TV or radio channel, documentary film, audiovisual recording or another form of periodic or continuous public dissemination of mass information, including Internet resources. The audiovisual products are understood as cinema, video and photo documents and their combinations, video films, slide films and other forms, regardless of the method of their original or subsequent fixation, created and reproduced on any type of media, consisting of a fixed series of interconnected images (with or without accompanying sound) and intended for visual and auditory (in case there is an accompanying sound) perception with the help of appropriate technical devices[4].

The most obvious inference would be that this is the way to limit access for distributors of the medical goods and services advertising to the TV, radio, photo, video and other means of audiovisual recording, as well as to any Internet resources. Hence, the suppliers of medical goods and services would be able to communicate to the customers, and the customers, accordingly, receive from the suppliers the information on medical goods and services, practically only in case the latter visit healthcare organizations, which adversely affects the

[3] RK Law No. 451-I "On Mass Media" dated 23 July 1999.
[4] Reference Dictionary of the Model Legislation Concepts and Definitions for the CIS Member States, Moscow – Saint Petersburg, 2006.

rights and legitimate interests of all the mentioned participants and limits the possibilities to conduct entrepreneurial activities and promote goods, work and services in the area under consideration.

It is also yet unclear how the own websites of the medical goods and services suppliers (or lectures on the topical issues of these or those medications application) may now be qualified and how one should distinguish between the normal "customer information" and "advertising."

On the other hand, the current legislation does not explain the concept of "specialized medical edition" and does not expressly put it on the list of possible forms of mass media. However, one cannot exclude the possibility that, if broadly interpreting the "mass media" concept, the authorized agency may qualify a specialized medical edition as another form of periodic or continuous public dissemination of mass information.

According to pharmaceutical control officials (who are already orally confirming the prohibition on using any forms of mass media other than print medical editions to advertise medical goods and services), in the nearest future, it is planned to adopt subordinate legislative acts to detail, for the purposes of implementing the statutory amendments, the requirements to medical goods and services advertising. Hence, in fact, the permissibility of this or that form of medical goods and services advertising remains entirely at the discretion of the authorized agency.

5. Possible Ways to Resolve the Current Situation

Practical Way

If one accepts as correct and the only one possible the today's position of pharmaceutical control authorities and all prohibitions stemming therefrom, the medical and pharmaceutical companies have nothing to do but to revise their advertising plans after November 2014 and redistribute the pertinently allocated funds to place the advertising modules in the specialized professional editions and healthcare organizations (including via doctors at hospitals and polyclinics and pharmacists at pharmacies). The format of advertising materials, if distributed in healthcare organizations, may be only in print (on paper in the form of a flyer, leaflet, etc.), since audiovisual information on any media, as well as TV and radio advertising clips and Internet information, fall within the mass media concept and are disallowed.

The following types of print information may be disseminated in order to inform patients and for scientific and educational purposes:

- ✓ information relating to human health or diseases;
- ✓ instructions regarding medical use, trade catalogues, pricelists, reference materials and scientific-and-informational materials containing scientific and analytical data and disseminated in the form of scientific articles, methodological instructions and learning aids of medical nature;
- ✓ information on the individual or legal entity manufacturing or selling the medication.

The possibility to put the logo and the trade name and/or international unpatented name of medical goods on industrial products distributed to professionals (pens, notepads, bags, doctor's overalls, etc.) is still available.

As an additional opportunity, one may consider the option to create one's own mass media – a specialized professional edition, which may be not only in print, but also in electronic format, placed in the Kazakh or foreign segments of the Internet, which is gaining high popularity in the modern world of total electronization. In this case, one should be ready that the process of this idea implementation may involve the issues of edition legalization (record registration of the mass media, etc.), domain name ownership (for instance, when creating the website), provision by individuals of their personal data (for instance, in order to participate in an advertising event),

copyright protection (for instance, in case of placing a scientific article or other similar materials) and other aspects of using electronic informational resources.

Legal Way

It seems to us that the amendments being introduced are not quite legitimate from the point of view of exercising the constitutional right to healthcare and the right to receive full information on the medical goods and services being acquired, as well as the freedom of entrepreneurial activities proclaimed by the civil legislation. This issue requires in-depth analysis.

Still, for all those wishing to take a proactive social position it would make sense to join forces, as early as now, with the public and professional associations of Kazakhstan's medical and pharmaceutical sector (for example, with the Association of International Pharmaceutical Manufacturers of the RK and other public associations in this area) and with human rights organizations specializing in consumer protection, and, having secured support on the part of the legal community, draw the government's attention to the problems created by ban on medical goods and services advertising in mass media.

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