ADVERTISING OF MEDICAL DEVICES: FOREIGN EXPERIENCE AND UKRAINIAN PRACTICE

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ABSTRACT

Introduction. Chosen European foreign policy vector for Ukraine establishes its obligation to enforce the process of adaptation of the EU law regulations in the internal legal policy. The approximation of Ukrainian law to the European Union (EU) "acquis communautaire" is not only the instrument for deepening our economic cooperation with the European Union, but also the important measure to enhance further development of Ukraine in general. National legislation, which regulate advertising and promotion of medical devices (MD), is not an exception. Some key points on legal regulation of abovementioned sphere is a base of this study.

Materials and Methods. Ukrainian legislation, European Union`s Law Acts, EU's member-states law, WHO Acts and Recommendations, European Medical Technology Industry Association (EUCOMED) Acts. Article is based on dialectical, comparative, analytic, synthetic and comprehensive research methods.

Discussion. In accordance with Ukrainian legislation, there is no special law that concerns advertising on MD in Ukraine, this sphere is regulated by general law that named «About advertisement», but it doesn't take into account even main characteristics of such a special object as medical devices (MD). Moreover, the law «About advertisement» contain discrepancies in terms that are used, these contradictions, in our opinion, must be eliminated by appropriate law reforms.

Conclusion. The advertising and promotion of MD in EU is regulated by a combination of EU and national legislation of EU Member States, national advertising and promotion of MD are not harmonized with the EU MDD for now, resulting in a fragmented legal landscape that differs from one EU Member State to the other. Practice of adopting different codes and guides that regulate advertising, including advertising of MD, is widespread in EU and EU Member States and thus must be used in Ukraine with appropriate reformation of national law.

KEY WORDS: medical devices, advertising, directive, CE marked, misleading advertising, comparative advertising.

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INTRODUCTION

As is well-known, Ukraine declared European foreign policy vector and it is impossible to avoid the process of adaptation of the EU law regulations in the internal legal policy of Ukraine. The approximation of Ukrainian law to the European Union (EU) "acquis communautaire" is not only the instrument for deepening our economic cooperation with the European Union, but also the important measure to enhance further development of Ukraine in general. National legislation, which regulate advertising and promotion of medical devices (MD), is not an exception. However in fact rules on promotion and advertising MD are not harmonized under the EU legislation for now. Therefore, in this article we'll try to research how this sphere is regulated in EU and in EU-Member States and how in what aspects can we use their experience in Ukrainian national practice.

MATERIALS AND METHODS

Ukrainian legislation, European Union`s Law Acts, EU's member-states law, WHO Acts and Recommendations, European Medical Technology Industry Association (EUCOMED) Acts. Article is based on dialectical, comparative, analytic, synthetic and comprehensive research methods.

DISCUSSION

ADVERTISING OF MD IN EU.

Unlike pharmaceuticals, rules governing the marketing and advertising of MD are unregulated in the EU directives on MD [1]. The general legal European framework for MD includes three Medical Devices Directives (MDD) [2] - Directive 93/42/EEC [3], Directive 90/385/EEC [4] and Directive 98/79/EEC [5], which contains some basic rules regarding the advertising of MD. Thus, Article 2 of the Directive 93/42/EEC (MDD) provides that the manufacturer of a MD may market and promote only MD that are CE marked in accordance with the provision of MDD. Moreover, devices may only be promoted for their intended purpose as defined by Article 1(2) (g) (i.e. `the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials`) [3]. Some problematic on certain aspects of regulation of unusual types of MD is described in our prior researches [17, 18].

That way, if a MD is not CE marked it cannot be promoted in the EU. Most significantly, even if the MD is CE marked in accordance with provision of the MDD (or whichever of the two other basic medical directives [4, 5], any promotion must be limited to the purposes for which

the device has been CE marked. Despite the prohibition of the promotion MD that has not been CE marked, MDD defined special conditions when such promotion is permitted. Article 4 (3) of the MDD permits non CE marked MD to be exhibited at trade fairs, exhibitions and demonstrations. However, devices used for this purpose must be accompanied by a visible sign clearly indicating that they cannot be marketed or put into service until they have been made to comply with the requirements of the MDD as regards to placing on the market [3].

One more provision of MDD that concerns the promotion of MD is Article 4. This provision permits the national authorities of the EU Member States to impose on manufacturers an obligation to provide all information related to a MD in the national language (s) of the territory or in the another EU language [3]. In practice, all of the EU Member States have exercised the power given in this provision and begin from the requirement that all information concerning MD be in their national language (s). However, some (but no means all) Member states provide a derogation from national language requirements for MD that are intended for professional use only [6].

An additional provision that has indirect impact on advertising on MD is Article 17 (3) of the MDD. The provision of this Article prohibits the attachment to MD of marks or inscriptions, which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking [3]. The main goal of this provision is protection EU patients and healthcare professionals from MD that are not marketed in compliance with the MDD.

In addition to the rules established by the MDD, manufactures must also comply with a number of more general provisions provided in other Directives governing the advertising of products in the EU [6].

First of all, they have comply with Directive 2006/114/EC concerning misleading and comparative advertising [7]. This Directive does not include special rules for the advertising MD but it applies directly to their promotion.

Directive 2006/114/EC defines misleading advertising as any advertising:

"...which in any way, including its presentation, deceives or is likely to deceive the persons to whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behavior or which, for those reasons, injures or is likely to injure a competitor." [7]

We should agree that it is worth emphasizing that the advertisement is to be taken as a whole, including all of its features, its context and the intended public. Thus, a claim that a product is similar to an existing product may not be misleading (if justified). [8] However, if the headline of the same advertisement was «well balanced» and prominently used an equally balanced set of scales, it could well be misleading as it implies that the products were identical. [9]

The World Health Organization with this regard establish that advertisement should be factual, fair and capable of substantiation [10]. The same concepts there are in the code of conduct adopted by the European Medical Technology Industry Association (EUCOMED), which contain guidelines for marketing of MD. According to the EUCOMED Code of ethical business practice, "*member companies of EUCOMED are required to ensure that all promotional presentations, including product claims and comparisons are accurate, balanced, fair, objective and unambiguous. Statements should not mislead and intended audience*" [11].

The required substantiation will generally follow from the label (as defined in the MDD), as this determines the scope of the intended purpose of the device concerned.

Furthermore, advertising outside the scope of the intended purpose will normally constitute not only misleading advertising but also off-label advertising, which is usually prohibited and a serious offence [8].

Comparative advertisements are common in the MD arena and, as a result, are also a regular source of dispute in this sector [8].The definition of «comparative advertising» can be found in Article 2 (c) of the Directive 2006/114/EC which defines «comparative advertising» as:

"… any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor" [7].

Article 4 of the Directive 2006/114/EC establish that the comparative advertising shall, as far as the comparison is concerned, be permitted when the following conditions are met:

"(a) it is not misleading within the meaning of Articles 2(b), 3 and 8(1) of this Directive or Articles 6 and 7 of Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market ('Unfair Commercial Practices Directive');

(b) it compares goods or services meeting the same needs or intended for the same purpose;

(c) it objectively compares one or more material, relevant, verifiable and representative features of those goods and services, which may include price;

(d) it does not discredit or denigrate the trademarks, trade names, other distinguishing marks, goods, services, activities or circumstances of a competitor; (e) for products with designation of origin, it relates in each case to products with the same designation;

(f) it does not take unfair advantage of the reputation of a trade mark, trade name or other distinguishing marks of a competitor or of the designation of origin of competing products;

(g) it does not present goods or services as imitations or replicas of goods or services bearing a protected trade mark or trade name;

(h) it does not create confusion among traders, between the advertiser and a competitor or between the advertiser's trademarks, trade names, other distinguishing marks, goods or services and those of a competitor" [7].

As the EU law governing misleading and comparative advertising is in the form of a Directive 2006/114/EC, it is the responsibility of the EU Member States to implement the requirements of the Directive 2006/114/EC in their national law. Although Member States are required to achieve the aims of any Directive 2006/114/EC, the manner in which

these must be achieved can vary from Member State to Member State. As a result, review of the national implemented legislation of individual Member States is important.

Article 8 of the Directive 2006/114/EC allows EU Member States to retain or adopt provisions to ensure more extensive protection against misleading advertising. However, this is limited only to the protection against misleading advertising and does not apply to the protection against comparative advertising where Member states cannot go beyond the provision of the Directive 2006/114/EC [6].

ADVERTISING MD IN EU-MEMBER STATES.

Despite the absence of a harmonized European legal framework, many countries have already adopted specific rules in relation to the advertising of MD. Belgium, for instance, strictly prohibits the advertisement of MD, which do not bear the CE mark. The CE mark indicates a product's compliance with EU legislation and therefore enables the free movement of products within the European market. Since February 2014, France reiterated the criminal penalties against advertising without prior authorization. Other countries, such as Germany and Italy, have adopted specific rules regarding the advertising of MD to the general public but do not yet foresee specific provisions for the advertising of MD towards HCP. Finally, in countries such as the UK (which will act further as an ex-member of EU), advertising aimed at HCP is governed by the usual laws and Advertising Standards Authority codes.

In Greece, Directive 93/42/CE has been implemented to national legislation via Ministerial Decision ΔΥ8δ/Γ.Π.οικ.130648. According to the Decision, "*any advertisement must reflect the product properties and characteristics. Advertisements, promotional presentations or announcements which may contain any misleading information regarding the use of a medical device or its properties are strictly prohibited*". The Decision also includes an amendment (following the Directive 98/79/CE) that provides guidelines for in-vitro diagnostic MD and stipulates that any advertisement or public sale of an in-vitro diagnostic device that identifies possible HIV contamination is forbidden [2].

The advertising and promotion of medicinal products in the UK is regulated by a combination of European and national legislation. The MHRA publishes a helpful "Blue Guide" on the advertising and promotion of medicines in the UK, which explains the requirements of the relevant legislation, and provides additional clarification on the interpretation of the law and its application.

The control of medicines advertising in the UK is primarily conducted on a self-regulatory basis by a range of industry bodies, supported by the statutory role of the MHRA.

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry (the "ABPI Code") sets the standard for the promotion of prescription medicines to health professionals and appropriate administrative staff in the UK. The ABPI Code reflects the requirements of relevant UK and European laws, and in many cases goes beyond those requirements. All ABPI member companies are required to comply with the ABPI Code as a condition of membership. In addition, approximately 60 companies that are not members of the ABPI have agreed to abide by the ABPI Code in their promotional activities.

The promotion and marketing of pharmaceuticals must also meet the standards set for all advertisements in the UK. The Advertising Standards Authority (ASA) is a self-regulatory body that administers the broadcast (BCAP) and non-broadcast (CAP) advertising codes.

There is a general prohibition on the advertising of prescription-only medicines to the public. It is also prohibited to advertise unlicensed medicines. In limited circumstances, some factual information can be disseminated before a license is granted, such as the provision of pricing information to relevant administrative staff for the purposes of budget planning. In addition, the prohibition on advertising unlicensed medicines does not prevent the provision of a factual answer to an unsolicited question about an unlicensed medicine, provided the response is balanced and non-promotional in nature.

All advertisements for medicines must also comply with quality standards. For example, advertisements must:

- comply with the particulars listed in the summary of product characteristics;
- present the product objectively without exaggerating its properties and encourage the rational use of the product;
- not be misleading; and
- not state or imply that a product is "safe".

Advertisements for medicines directed to persons qualified to prescribe or supply must convey all the key information from the summary of product characteristics including the name and classification of the product, a list of the active ingredients, licensed indications, side-effects and contra-indications, and dosage and method of use.

If the advertisement is directed at treatment of a particular group of patients, for instance children, the advertisement should contain all the relevant information from the summary of product characteristics for that particular group [12].

Kingdom of Sweden. The legislative framework in Sweden does not, however, provide any specific provisions for the advertising of MD and there is limited case law. Unlike many other European countries, the rules in Sweden applicable to advertising of pharmaceuticals are moreover not applicable to advertising of MD.

This does not however mean that no rules apply to the marketing of MD. General provisions regarding advertising and sales promotions of medical devises can be found in the Swedish Marketing Practices Act (2008:486) (the "Marketing Practices Act") and the ICC Code of Advertising and Marketing Communication. In some cases, marketing of medical devices can fall within the legislation of pharmaceuticals. That is the case, e.g., when the MD contains an active medical ingredient and therefore is considered as a pharmaceutical or when the medical device is marketed together with a pharmaceutical. In such cases, the marketing must comply with the Medicinal Products Act

(1992:859), the Code of Statues of the Medicinal Product Agency and the ethical rules for the pharmaceutical industry (the LIF Rules).

Marketing of medical devices is permitted under Swedish law both in relation to consumers and health care professionals. According to the Marketing Practices Act, all marketing must comply with good marketing practice, which must be evaluated on a case-by-case basis. For MD, it is particularly important that the marketing is correct and trustworthy. Statements should not mislead the recipients and must be justified by appropriate evidence. This is particularly important for claims, which are of a medicinal character, which must always be able to be verified with scientific proofs. According to the case law of the Marketing Court it is also important to bear in mind that marketing claims, which state that MD can cure diseases or the symptoms of diseases (e.g. use of expressions such as "medicinal", "diagnosis", or "ordination"), which indicate that the product in fact is a medicinal product or has medicinal effects, are misleading and forbidden and may only be permitted for advertising of pharmaceuticals. Testimonials or statements from doctors, patients and other "satisfied customers" should be used with great caution and only be used on the condition that the conclusions of the statement are in line with the overall prevailing perception or can be verified by scientific acceptable research results. A few positive results in some cases are generally not sufficient acceptable proof [1].

The Netherlands. In the Netherlands, one may bring a direct suit against a competitor for unlawful comparative advertising constitutes a tort under article 6:194a of the Civil Code. In practice, many cases are brought alleging unlawful comparative advertising, including in the MD industry. A claimant can obtain an enforceable judgment from a Dutch court in injunction proceedings normally within approximately three weeks from service of a writ of summons until receipt of the judgment [8].

Complaints can also be brought before the self-regulatory body KOAG/KAG, whose code includes specific provisions on comparative advertising [13]. Furthermore, a compliant can be brought before the Advertising Code Commission (Reclame Code Commissie), which is not specialized in MD but will hear comparative advertising complaints in the sector [14].

Germany. In Germany, competitors, in practice, take action directly through the civil courts and seek to obtain injunctive relief against unlawful advertisements. They generally seek injunctive relief to stop advertisements violating their rights on the basis of the Act Against Unfair Competition (Gesets gegn unlauteren Wettbewerb). In addition, competitors can request a corrective statement or the communication or publication of the judgment to third parties. Apart from this, a claimant can also sue for damages and compensation, and can request an account of any profit made. However, it is not only direct competitors that may take direct action through the civil courts but also associations promoting commercial interests (Wettbewerbsvereine), and consumer associations. Industry and chambers of commerce are also entitled to such claims.

In practice, the competent authorities would rarely take action against an advertisement that it considers to be unlawful. While they do have the power to stop further publication of such an advertisement, they have no legal power to force a MD company to publish a corrective statement. Competent authorities take action only in very serious cases [8].

Advertising of MD in Ukraine. In Ukraine, there is no special law that concerns advertising on MD. General law that named «About advertisement» regulates this sphere. It consist of general rules on advertising of all products and not only MD (definitions, principals of advertising, language, general requirement, comparative advertising etc.). Although this document include Article 21 that provides special rules on advertising medical product and MD [15]. First of all, we can see discrepancies in terms that are used in this article. Thus, in the name of the article legislator use the term «medical equipment» but than in the text of this article we meet term «medical device» that is much wider term than «medical equipment» and include it as a part. For our opinion, rules on advertising have to cover all MD that are in stream of commerce. That is why the Article 21 have to be renamed and used term «medical device» instead of «medical equipment».

In addition, one more thing that attract attention in this article. Part 4 of the article 21 provides necessary condition with which advertising on medical product and MD have to comply. Among others, there is the requirement that advertisement have to contain recommendation on the mandatory introduction with instructions before using. However, this requirement covers exclusively medical product and does not cover MD. Our position is that such rule have to cover both: medical product and MD because using MD without prior reviewing the instruction can be very dangerous for customers.

Important to say that in Ukraine there are a lot of similar with EU law provisions regarding advertising on MD. For example, part 1 of the Article 21 permitted advertising only MD that are certified for use in Ukraine by authorized national body. Moreover, Ukrainian legislation contains the same exclusion of this rule. In according with part 15 of the Article 21 the provision of this article does not cover advertising of MD that is situated in specialized publications intended for medical institutions and doctors, and is distributed at seminars, conferences, symposia on medical topics.

It is worth to remark that in contrast with EU Directive 2006/114/EC, which establish that the comparative advertising shall be permitted when the special conditions are met, the Ukrainian law prohibit comparison of MD in advertisement with other MD for increasing advertisement effect. In fact this provision prohibits comparative advertising at all because it is difficult to prove that comparison with other MD in advertisement are used with other goal than increasing advertisement effect. In our view, EU rules that concerns comparative advertising, are more flexible and fair than Ukrainian one. That is why in this part it can be useful to use experience of EU and EU's member states.

It is of high importance to note that Article 21 in sufficient detail regulates advertising on MD that corresponds with specific of this kind of products. For instance, it requires that advertisement of MD have include:

1) *objective information about the MD, and carried out so that it is clear that there are indications advertising and the advertised product is a MD;*
2) *requirement to consult with a doctor before the use of MD;*
3) *recommendation on the mandatory introduction with instructions on medical product (this point we've commented above);*
4) *disclaimer as follows: "Self-medication can be harmful to your health", which takes at least 15 percent area (length) of all advertising* [15].

In addition, there are a number of strict prohibitions regarding advertising of MD, including such concerning ethical problems and IP law principles [Such situation is morally unjust and unethical from any point of view. [16, p. 588]. Thus, the advertisement of medical devices forbidden if it contains:

1) *information that may give the impression that for use of MD the specialist's consultation is not necessary;*
2) *information that the therapeutic effect of the use MD is guaranteed;*
3) *image with changes of the human body or its parts as a result of disease, injury;*
4) *statements that can lead to the emergence or development of fear for illness or affect their health through advertised MD;*
5) *statements that promote self-diagnosis of human diseases and pathological conditions and self-treatment with medical products advertised;*
6) *references to MD as the most effective, safest, exceptional in terms of absence of side effects;*
7) *comparisons with other MD to strengthen the advertising effect;*
8) *references to specific cases of successful use of MD;*
9) *recommendations or references to medical recommendations of medical stuff, researchers, medical institutions and organizations in terms of advertised goods or services;*
10) *specific manifestations of gratitude, appreciation, letters, its parts with recommendations, stories about the use and results of the advertised goods or services from individuals;*
11) *images and mentions of the names of popular people, heroes of movies, TV and animated films, reputable organizations;*
12) *information that can confuse consumer about the composition, origin, efficiency, patent protection of product that advertised* [15].

Despite enough level of details in regulation placed in the law of Ukraine «About advertisement», in our view, it is necessary to adopt special guide that specifically concerns advertising on MD in Ukraine. It can be developed on self-regulation basis by a range of industry bodies and organizations, such as Medical Devices Subcommittee of European Business Association, Association of operators of the market of medical devices and others.

CONCLUSIONS

- The advertising and promotion of MD in EU is regulated by a combination of EU and national legislation of EU Member States, which seems to be an effective and flexible practice.
- Advertising and promotion of MD are not harmonized under the EU MDD, resulting in a fragmented legal landscape that differs from one EU Member State to the other. Such situation needs clarification and appropriate reform on EU level.
- Practice of adopting different codes and guides that regulate advertising, including advertising MD, is widespread in EU and EU Member States and such law specialization experience may be helpful for national law reform.
- There is no special law that concerns advertising on MD in Ukraine, this sphere is regulated by general law that named «About advertisement». Despite it including of some special MD's advertisement provisions, the law «About advertisement» contains some discrepancies in terms that are used. And these contradictions, on our opinion, ultimately must be eliminated.
- Ukrainian legislation has a lot of same provision with EU directives, although EU rules, that concerns comparative advertising, are more flexible and fair than Ukrainian one. That is why in this part it can be useful to use experience of EU in national practice.
- The law «About advertisement» in sufficient detail regulate advertising on MD, but despite enough level of specific regulations in our view it is necessary to adopt special guide concerning advertising on MD in Ukraine.

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