ADVERTISING REGULATION AS A KEY POINT OF PHARMACEUTICAL MARKETING IN THE CZECH REPUBLIC

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Abstract

The article is based at the research done at Comenius University in Bratislava as a part of the author´s rigorous thesis [15] and provides insight into several important aspects of advertising regulation from the point of view of pharmaceutical companies in The Czech Republic . It begins with establishing basic principles of advertising regulation in the EU legal order as a fundament of drug advertising regulation and follows with pros and cons of direct-to-consumer prescription drug advertising and social aspect of drug advertising. Authors then explains three modes of advertising of drugs in the EU legal order and the legal order of the Czech Republic and explains the different rules that apply. Following there are explained types of medicinal products and their advertising to cover all possible products in the given category. Justification general advertising ban RX pharmaceuticals to the general public and exceptions to the general prohibition of advertising RX pharmaceuticals to the general public provide reflection in the given matter and as such does provide some important clues which are summarized in the conclusion of the article.

Introduction

Advertising regulation of drugs is reportedly one of the toughest areas of the law that concerns restrictions on the content of marketing communications in the EU. Fundamental limitations of the form and content of communication tools drug manufacturers, of course, limits the possibilities and effectiveness of their marketing and sales. Public controversy and debate still raise questions as to whether certain prohibitions in this area are really effective and sufficiently justified. However the analysis of this issue shows that the legal regulation of advertising of drugs remains perhaps partly misunderstood economic thinking. The second important issue of regulative in the advertising of drugs in the Czech Republic can then mark a fundamental contradictions of EU law and national law. Our legal practice standards of state authorities are in many respects the transposition and implementation of EU regulatory compliant. This condition can be essential in the

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[15] PROCHÁZKA, D. A. *Strategická analýza vnějšího prostředí farmaceutického průmyslu v ČR*. Bratislava, 2012. Rigorózní práce. Univerzita Komenského v Bratislavě,

near future implications for the pharmaceutical industry experts who are very often governed by and just focus according to national practice. However, it is incorrect and in some parts even marginally irrational. Formalism and practical lack of interest other than superficial and pragmatic knowledge of those facts which can be used and mechanically applied in practice, the actual risk of pharmaceutical marketing in the Czech Republic, to which the experts of pharmaceutical industry should pay attention.

Success is a relative term. It often seems to us that certain accomplishments are unnaturally accentuated, others appear to be underestimated.[16] Differences in the evaluation of success are influenced by the subjective views and put forward criteria.[17]

Fundamentals of drug advertising regulation

Advertising regulation in the EU legal order

Regulation of advertising of medicines in the EU legal order is given by directive 2001/83/EC[18]. This directive already represents an area of fully harmonized EU law. This is very important think because variations in legislative and interpretation of the law and its consequences, in the individual Member States themselves should not even occur.

"Directive 2001/83 carried out in the advertising of medicinal products total harmonization, the cases in which Member States are authorized to adopt provisions departing from the rules laid down by this directive, are specifically enumerated."[19]

Scientific literature comparing legal practice in the Member States clearly indicates the status of major differences, which is theoretically unjustifiable.[20] If for example five EU Member States as a result quite differently and variously implemented the same rule implements this directive, then correct and conformist practices of law enforcement carried out either exactly one of them, or none at all. Full harmonization of EU law in the regulation of drug advertising today provides a very solid foundation for direct, factual and reasoned criticism of lawmaking, supervision and interpretation of administrative practice in EU Member States.

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[16] PAPULOVÁ, Z.: Strategické analýzy s podporou strategického myslenia : Aktuálny trend v strategickom manažmente, Bratislava: KARTPRINT, 2012, s. 21

[17] PAPULA, J., PAPULOVÁ, Z.: *Strategické myslenie manažérov. Za tajomstvami strategického myslenia.* Bratislava: Kartprint 2010, s. 13

[18] Directive of the European Parliament and Council Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products (here and hereinafter referred to as "Directive 2001/83/EC").

[19] Judgment of the Court of Justice in Case C-374/05 of 8 November 2007 Gintec International Import-Export GmbH v Sozialer Wettbewerb Verband eV., [2007] ECJ I-09517, paragraph 39th.

[20] The International Comparative Legal Guide to: Pharmaceutical Advertising 2010; Global Legal Group Ltd. London, June 2010, pg. 334, ISBN 978-I-904654-81-0 (dále jen „ICLG PA 2010“).

Direct-to-consumer prescription drug advertising and overuse of medicines

Central to the main objective is to regulate advertising of pharmaceuticals, as defined in point No. 2 of the Directive 2001/83/EC, effective monitoring of public health. This is an important particularity of this law, because in all other areas of production and services is a central moment regulation of advertising and consumer protection and protection of the economic interests of business the decision-making autonomy of the consumer. In the implementation of effective public health then belongs to the determinant, which is very unusual for the supply and sales of other products and services. It is a rational lifting of drug consumption in the population. It can be formulated as a premise that each population at a given time and place corresponds very specific quantitative and qualitative need for pharmaceuticals, which is directly proportional to the current population morbidity. (The exceptions are preventive therapy drugs.) It is a theoretical need Pmed. Each population in a given time and place is characterized by objective after consuming drugs Smed. Functioning public health systems with their mechanisms must achieve an equitable balance Pmed ≈ Smed. The validity of this equation and principles of effective protection of public health, then we can infer additional system premise: Implementation of advertising of medicinal products must not interfere with the effects of an optimal balance Pmed ≈ Smed. In a properly functioning system of public health practice of advertising of medicinal products may lead to the increased consumption of drugs. Such an outcome would mean achieving the overuse of medicines in the population, which is in direct conflict with effective protection of public health. The rules of advertising regulation and promotional law interpretation must therefore defend such effects. This effect can be found at some point in § 5, paragraph 5 of Law No. 40/1995 Coll., The Act on Regulation of Advertising and amending and supplementing Act No. 468/1991 Coll., On radio and television broadcasting, as amended (the hereinafter referred to as ZoRR) in this version:

§ 5, paragraph 5): Advertising of human medicinal product must support the rational use of objective presentation of this product without exaggerating its properties.[21]

Effect of advertising without "advertising effect" (increased consumption of the product) is from a practical point of view, an irrational assumption. Advertising must in principle achieve an increase in consumption and sales of the promoted product. An there lies the controversy. Maintaining the same drug consumption parameter is global and not product-bound. It has additional legal and social consequences and implications. Advertising of pharmaceuticals in the understanding of EU law is solely a tool of competitive fighting with other pharmaceutical

[21] The Act on Regulation of Advertising and amending and supplementing Act No. 468/1991 Coll.

manufacturers. Increase consumption of a medicinal product to which the result of the advertising of medicines occurs must be compensated by reducing the consumption of other drugs that have not saturated the need for patients in the area. Quantitative increase the consumption of drugs in the population can be only in those cases when a completely new medicine enters the market - medicine for new and therefore still untreated indication.

Social importance of advertising drugs

Advertising of drugs as a tool of exclusively competitive struggle which can not add to the absolute consumption of drugs in the population, is the phenomenon of relatively superfluous. It supports neither economic development nor the quality of the health care system. The economic development can legitimately support much less advertising than in any other industry, and the quality of health care can have a positive impact because of advertising of drugs only when the health system itself fails. The claim that "Without the advertising of medicines, doctors would not know about a new and modern therapy or would not be sufficiently informed," de facto points to a fundamental failure of the continuous education of health professionals, which is politically and professional point of view completely unacceptable proposition, even if it was an objective reality. EU law and regulation of advertising is based on the premise of functioning health systems in the EU Member States, and therefore necessarily pushes advertising of medicinal products to the margins of social importance. In operating systems, public health is not essential element of drug advertising.

This relative social superfluousity of advertising of pharmaceuticals obviously creating huge controversy in relation to the fact of skyrocketing advertising costs of prarmaceuticals these days. Expert sources estimate that in the Czech Republic to CZK 7.3 billion / year from the budget of Public Health and CZK 1.6 billion / year in additional payment of patients.[22]

Three modes of regulation of advertising of drugs

Advertising of medicinal products in the EU legal order and the legal order of the Czech Republic is subject to three different modes of regulation. It is a very common mistake in dayly pharmaceutical marketing practice that schemes to regulate advertising of medicines are only two. This misconception is based, again, like many others, from the formal empirical practice and misunderstanding of the very nature of regulation of drug advertising and its theoretical justification.

[22] *Vavrečka, J., Co nás stojí reklama na léky?, Zdravotnické noviny, Vol. 60, No. 39, page 7*

The first mode is a mode of advertisement regulation of basic control rules. It consists of rules for the regulation of any advertising (industry-unspecific) and the rules that specifically apply in the event of any advertising of medicinal products. Among the non-specific rules include a comprehensive regulation of unfair commercial practices contained in Act No. 634/1992 Coll. Consumer Protection Act, as amended, and the basic rules of advertising regulation as appoint § 1, § 2, § 2, § 2c ZoRR. Specific rules to regulate advertising of medicines that are used whenever after § 5 provides ZoRR. The first mode of regulation we might call the general regime and its meaning is very interesting, controversial and underrated at the same time. Advertising of pharmaceuticals is then further regulated by two special modes of regulation.

The second (the first special) mode is the mode control to regulate advertising of drugs aimed at the so-called experts. This mode describes and implements § 5b ZoRR. Under EU law experts considered and the Czech Republic and only by persons authorized to prescribe medicines or issue. It is therefore only done by doctors and pharmacists. These are people that may have a direct effect on the determination of the use of particular medicinal product by a patient. They are the eyes of professional intermediaries selection and choice of medicine. The main objective of regulation of advertising of drugs targeted at professionals, i.e. to a special mode of regulation is to protect the independence and impartiality of the experts in their decision making.

"Prescribing and dispensing of medicinal products are specialized procedures to be carried out in accordance with the rules of professional ethics." [23]This goal is then correspond to the specific rules and regulatory regime has to be adapted to them and their interpretation of the law in situations formally unclear.

Third (another special) mode is the mode control to regulate advertising of drugs aimed at the general public. This mode describes and implements § 5a ZoRR. Although this fact is not mention anywhere, the rules of the scheme in terms of content regulation are uniquely determined by final consumers of medicines - patients. It contains just elements of protection against manipulation and introducing consumers to make health and business decisions in relation to medicines.

Quite obligately is currently being interpreted that what is not advertising to experts, it is automatically advertising to the general public. Nowhere, however, is not mentioned nor explained

[23] Judgment of the Court of Justice in Case C-62/09 of 22 April 2010, The Queen, on the request of the Association of the British Pharmaceutical Industry v Medicines and Healthcare Products Regulatory Agency, [2010] ECJ, in the 29th paragraph page 7.

the concepts of expert and general public are bound to terms with its importance to the whole population complementary. Principles of regulation of advertising and lawmaking principles are always objective, reasoned, and thus addressed. There's no reason to regulate drug advertising rules "for consumers" when the consumer is not addressed at all. Also, there's no reason to regulate drug advertising rules "for persons authorized to decide on the choice of medicinal product" when it is addressed to someone else. The problem of reasoning is therefore mainly in the fact of imagining who is not an expert in the meaning of this law, nor consumer medicines. This group of people is very broad. They are all employees of state authorities deciding on drug policy, health insurance experts critical part of the payment for medicines and their organizations, for example, then they are all nurses and middle medical staff. These target groups are legitimate recipients of commercial communications of pharmaceutical manufacturers - are addressed advertising of pharmaceuticals. Advertising aimed mainly at those persons is then subject only to the first general regulatory regime, and none of the two specific modes has been used. There is no objective reason to do so.

Types of medicinal products and their advertising

Types of medicines

There are five basic categories of medicinal products, where the medicinal products as defined by the legal definition of a medicinal product as we look to the products subject to the same regulatory regime. From the perspective of their specific regulation (not just advertising) can the EU legal order and the Czech Republic to distinguish these types of medicines:

I. Registered Medicines
a medicinal product subject to prescription dispensing doctors (RX)
b Medicines over the counter (OTC)
i Classical over the counter medicines
ii. Homeopathic Medicines
iii. Traditional Herbal Medicinal Products (THMP)
II. Unlicensed Medicines
a Medicinal Products "by function"
b Medicinal Products "according Presentation"

According to the existing different modes of regulation there are therefore the following groups:

RX, OTC classical homeopathy, THMP, unregistered medicines of any Gross

From the point of view of regulation of advertising of medicinal products there is no five separate modes of regulation. Some of the subcategories of medicinal products for the purposes of the regulation of its advertising are put together and follow the same rules. One could even say that the EU law and Czech law does not distinguish between them and does not create a special regulatory regimes of advertisement by category of medicine. There is not a set of rules to regulate advertising of RX drugs and different set of rules to regulate advertising of OTC drugs. This is in practice often incorrectly perceived by pharmaceutical companies´ experts. They often confuse advertising regulatory regime aimed at professionals for regulating medicines in RX drugs and regulation of advertising aimed at the general public for the regulation of OTC drugs. (Mode of unregistered medicines advertising regulation mode is zero, because the advertising of these products is prohibited). This substitution is only an empirical error. You only need to ask this question:

„To what mode of regulation of advertising has the advertising of OTC medicinal product to be subordinated hen it is primarily intended and aimed at professionals?“

The answer is straightforward.

„It is a regime regulating advertising aimed at professionals. Whether the product is OTC or RX drug does not influence the mode regulation of advertising aimed at the general public or professionals.

Nevertheless it is easy to find significant differences between the rules regulating advertising modes depending only on what type of medicine is given to a particular product. They are regulatory differences between different categories of drugs. We believe that it is efficient and effective in practice to distinguish this point of view there are two different modes of regulation of advertising of medicinal products. It is a mode of regulation of medicines and RX mode control OTC medicines. De facto single but very fundamental difference between these modes is given by the following provision:

§ 5a ZoRR: Advertising of medicinal products aimed at the general public[24]

(1) The subject of advertising to the general public may be medicinal products which, according to their composition, intended use, and designed so that they can be used without a diagnosis, prescription or treatment practitioner, or pharmacist for advice.

(2) The advertising aimed at the general public shall not be

a) medicinal products, prescription only.

[24] The Act on Regulation of Advertising and amending and supplementing Act No. 468/1991 Coll.

This provision implies that advertising of RX drugs must not be aimed at the general public (potential consumers of drugs) and therefore implicitly not to the general public at all. It's a sort of a general ban on all advertising of drugs bound to the doctor's prescription to the general public. From this general prohibition is made several specific exceptions. Previously, it is necessary to pay attention to the causes and the reasons for the ban.

Justification general advertising ban RX pharmaceuticals to the general public

There are very few professional resources that would comprehensively address this issue. Lawmaking legitimate principles presuppose that there must be objective and reasonable grounds to legislator thus significantly limiting the freedom of behavior (advertising) of pharmaceutical manufacturers. According to the preamble to Directive 2001/83/EC of the following reasons must be based on the effective protection of public health. By purely formal logical deduction, we can formulate this as a valid premise:

General advertising ban of RX medicines aimed at the general public in the EU legal order is established precisely because the practice of advertising RX pharmaceuticals to the general public could bring significant elements and moments of danger for public health.

To answer the question then remains, what elements and moments are they? What threatens the consumer? Information? It seems that for non-participating specialists it is truly paradoxical situation that will be explained best by the physicians, creators of advertising and real practice. Through personal consultations with experts of the topic i would like to explain some of the reasons which appear in the literature in a very brief, cautious and inaccurate form.

First reason: Advertising and homo emocionalis

Every copyrighter and advertising account manager now openly admits that the most effective advertising is advertising contextually acting through our emotions. It is an objective, standard and modern advertising expertise to operate an information so that consumers do not make cold rational and fully informed decision, but the decision abbreviated, emotionally driven and often de facto irrational. This natural effect of advertising might seem to be too risky to the European legislator in relation to the use of just RX drugs that differ from OTC drugs by higher biological activity and worse safety profile.

Second reason: Advertising and threats to therapeutic relationship between physician and patient

Basic momentus and a key element in human medicine is a therapeutic physician-patient relationship. It is a socially protected value, which is an important component of the trust and compliance (positive collaboration and patient reflection on the advice and recommendations of a physician). Each physician is obliged to act and vote therapeutic procedures according to the principles of human medicine lege artis. The doctor is not pharmaceuticals salesman who should try to deliver the patient exactly what he wants and what he wants. The doctor is obliged to deliver the patient exactly chat he needs objectively. Advertising of RX drugs would naturally generate subjective needs of the patients. Patients would come to the clinic doctors with a decision and "wishing" a drug which advertising addressed. It is the duty of every doctor in such a situation the patient tells any desire, which is inconsistent with the objektive of medical need lege artis human medicine, or decision, while "legal", but not quite optimal. Advertising RX drugs would undoubtedly complicate the work of a large percentage of physicians who had to "correct" opinions and assumptions of consumers beyond their previous work and it would be their responsibility. Patients in such a situation could more easily conceive distrust of their doctors. (For everything is now perceived as affected by corruption.) They might believe that the choice of doctor is affected by the economic interest and co-operation with pharmaceutical manufacturers. They might not believe the doctors, especially if the impression of the advertisenmnent was emotionally more credible than reasoning of the doctor who is not trained communications professional. However, the question remains why only advertising RX drugs? This principle is exactly the same concerning advertising of OTC drugs. It is necessary to make a more formal conclusion that the pint of view and considering the adequacy of regulation of the European legislator came to the conclusion that especially the RX medicines should be a doctor sovereign and "clean" field of competence and decide on therapy more or less directive manner, without having been asked hurdles and placed under explanatory obligations arising from the effects of advertising RX drugs. For OTC drugs doctor must accept the fact that there may be up against the impact of their advertisenments and the patient must be given accurate information.

Third reason: Advertising and professional incompetence of patients

A very important and entirely rational also appears to be an objective reason of professional inkompetence of patiens to make the right decision even when Theky have sufficient information. It is simply not possible to achieve in a reasonable time such information to consumers so that they were able to make correct and optimal decisions. Three weeks of surfing the Internet did not help anyone to become a good airplain pilot. Likewise, reading 40 articles and information resources did not help anyone to become a good physician. Background of pharmacotherapy with the whole

physiology and pathophysiology of the human organism and the empirical experience of patients is not able to acquire in a reasonably short time, even if tried hard. It is therefore a very high risk that even completely correct and truthful information on medicinal products would result in the incorrect assumptions and consumer decisions. This assumption is then seem much more severe in RX pharmaceuticals, where there is worse safety profile of these products vigorously defended - preferably just general ban targeted advertising RX pharmaceuticals to the general public.

Exceptions to the general prohibition of advertising RX pharmaceuticals to the general public

The first exception is an exception of advertisenment of vaccines. The vaccine, which always belongs to RX drugs, are possible to advertise to consumers, dissemination of information to the general public to promote their sale. However, this is only possible if the relevant national authority (Ministry of Health) approved a vaccine event, and therefore it is technically justified and in the time and place of urgent interest to the specific protection of public health.

The second exception is a set of specific information, the usefulness to consumers and minimal opportunity to introduce it in thought sufficiently justifies their provision. It is a well-defined reduced advertising content, which can then be carried out.

§ 5, paragraph 2 ZoRR: The provisions of this Act shall not apply to

a) the labeling of medicinal products and the package leaflet pursuant to special regulations,

b) correspondence necessary to answer specific questions about specific human medicinal product and any accompanying materials non-promotional,

c) sales catalogs and price lists, unless they contain a description of the characteristics of medicinal products, as well as the notification, alerts, and provide information on, for example, to pack changes, adverse-reaction warnings medicinal product for human

d) information relating to human health or diseases, provided no reference, even indirect, to humane medicine.

Legal regulations say that in this case i tis not a commercial drug. Such a conclusion would also be inconsistent, because it is a specific information. Dissemination of such information may still be advertising purpose and can promote the sale and distribution of drugs. However, other circumstances or the content of such information leads us to find that certain inadequacies, if the content of the information should be applied to the rules regulating advertising. Even when the disclosure of such information is therefore a commercial drug it is still posible, but some information for an exhaustive list of such advertising should not be subordinated to the scope of the rules of regulation.

Conclusion

The concept of advertising in the EU legal order expresses the specific type of behavior traders - entrepreneurs. Regulation of advertising is basically synonymous with the regulation of commercial communications. The aim of EU law is to substantively reduce utility road to professionals who pursue the business for his own benefit or other merchants without the same rules should limit normal daily communication of ordinary people, that would be entirely unreasonable "for life." For example, tell your friends to the event scientifically unproven information that a cosmetic cream cure psoriasis, would constitute a misdemeanor speaker's responsibility for illegal advertising, although it is a violinist who has absolutely nothing to do with selling these creams, just heard it somewhere and said it.

The decisive moment - the moment of watching advertising purpose - must always be filled with communication, this communication we could legally qualify as advertising.

For the purpose of protecting public health, therefore, European policymakers appeared to be useful to extend the scope of the rules and regulation of advertising on somewhat different types of behavior than is necessary and for the protection of consumers' economic interests sufficient in other industries. Therefore it substantively expanded the definition of advertising of medicinal products.

It is concluded by this article that without rigorous implementation of the EU law there would be hard consequences especially in the social meaning of the use of pharmaceutical drugs and the relationship between physician and the patient could be severely influenced to the disadvantage of the patient and the general health of the population.

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