Mendel University in Brno
Faculty of Business and Economics

Unfair practices in the marketing of pharmaceuticals

Diploma Thesis

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Abstrakt

Cílem diplomové práce je poskytnout doporučení výrobcům a distributorům humánních léčivých prostředků, aby se vyhnuli při tvorbě reklamy porušení zákona. Pro dosažení stanoveného cíle, práce bude rozdělena na 2 části: teoretickou a praktickou část. Teoretická část pokryje definice humánních léčivých prostředků a reklamy a poskytne souhrn regulace reklamy na humánní léčivé prostředky z pohledu veřejného a soukromého práva v rámci Evropské Unie a České Republiky. Praktická část je rozdělena na analýzu soudních rozhodnutí, rozhodnutí kontrolních orgánů a výsledku dotazníku zabývající se citlivostí na reklamu na humánní léčivé prostředky a její regulaci.

Klíčová slova

Humánní léčivé přípravky, Reklama, Regulace, Senzitivita, Nekalé praktiky, Státní ústav pro kontrolu léčiv

Abstract

The aim of the diploma thesis is to provide a set of recommendations for the manufacturers and distributors of the human pharmaceuticals to avoid a creation of an advertisement that violates the law. To achieve this goal the thesis will be divided into 2 parts: theoretical and practical part. The theoretical overview will cover definitions of human pharmaceuticals, the advertising and it will provide a summary of the legal regulations of the advertising on the human pharmaceuticals from the point of view of the public and private law in the European Union and in the Czech Republic. The practical part is divided into analysis of case laws, decisions of the supervision institutions and on the results of a questionnaire, which focuses on the sensitivity on the advertising on the human pharmaceutical and its regulation.

Keywords

Human pharmaceuticals, Advertising, Regulation, Sensitivity, Unfair practises, State Institute for Drug Control

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1 Introduction

In general, the advertising has become nowadays more and more powerful tool of the manufacturers and distributors to promote their products or services. As a communication medium, the advertising evolved into an economically important element of the competitiveness. Every day, we are a target of the numerous sophisticated attempts to influence our consumption behaviour via various medias and some of us succumb to this pressure. So, the necessity to regulate the advertising in any form has become more important, especially in case of the pharmaceuticals, because they could be potentially dangerous, Institute of Medicine (2007). Every year, we can witness multiple cases of the unfair practices in the marketing of pharmaceuticals. Since 2008, The State Institute for Drug Control (SÚKL) has detected and set a fine upon companies in 144 cases for the violations of the law on advertising regulation, SÚKL (2017). Since 2011, The Council for Radio and Television Broadcasting (RRTV) has detected 39 violations of this law, RRTV (2017). So, the regulation of this type of the advertising belongs into the most important and the most regulated area of the European and Czech legislation.

According to Winter (1999, p.7), the advertising on the human pharmaceuticals is divided into two segments, based on the target audience: the advertising targeting public and the advertising targeting healthcare professionals. The content and the research of the thesis focuses on the advertisement targeting the general public, not on the advertisement aimed at the medical professionals. The diploma thesis focuses on the most problematic and the most common violations of the legal regulations, which are presented on 20 actual cases, which deal with the formal and contentual aspects of the advertising, such as the use of questionable elements, like the motive of fear, the pictures with the explicit content, imputing the food supplements with prevention and treatment effects.

2 Objectives

The primary objective of the diploma thesis is to provide a set of recommendations for the manufacturers and distributors of the human pharmaceuticals to avoid a creation of an advertisement that violates the law or would not be perceived as suitable. As indicated previously the subject of the research is only the advertisement targeting the general public, so the recommendations target this type of the advertising. The set of the recommendations is based on the fulfilment of the secondary objectives which are described more in the details below:

1. To provide a detailed review of the legal framework, containing European and Czech laws and regulations concerning unfair practices in the marketing, which would be a part of the literature overview. The core of the review is a deep analysis of the general provisions and subsect ion concerning the advertising for human pharmaceuticals of the Act No. Act No. 40/1995 Coll., on Advertising Regulation and on Amendments to Act No. 468/1991 Coll., on the Operation of Radio and Television Broadcasting, as amended.
2. Using qualitative research method, the thesis provides primary data, through the analyses of the judicial decisions and the decision of the State Institute for Drug Control and The Council for Radio and Television Broadcasting.
3. Using quantitative research method, the thesis will provide an overview on sensitivity of the respondents to pharmaceutical advertising and to the most common offences against the law on advertising regulation.
4. Last secondary objective of the thesis is to evaluate the effectivity of the current regulations and suggest the improvements if necessary.

3 Methodology

The diploma thesis is divided into a theoretical and a practical part. Theoretical part of the thesis focusses on the essence of the advertising of the human pharmaceuticals and it provides an analysis of the legal enactments, which regulate this particular issue, including the correlation between European and Czech legislation. The sources of information for the thesis are European and Czech legal norms and regulations, specialised literature and other articles from scientific magazines as well as the Court of Justice case-laws and other decisions of supervision institutions, which are subjects of descriptive method. The theoretical part provides legal and logical framework for whole thesis. The practical part is divided into two interconnected parts. The first part provides primary data for further quantitative research and is a subject of an analytical method. It focusses on analysis of the decision of supervisory bodies including the appellate reviews of the courts. The primary data consists of the most common mistakes and offences against the law on advertising regulation. Afterwards, the thesis provides a review of sensitivity of the target group on the current regulations and on the most common mistakes in the advertising of human pharmaceuticals, using the quantitative method of the questionnaire.

3.1 The questionnaire

The questionnaire consists of 17 closed questions, of which 3 questions serve as target group identification and 14 specialized questions, focusing on the advertising of human pharmaceuticals. The diversification of respondents is based on gender, age and the level of achieved education:

1. Gender:
   - *Male*
   - *Female*
2. Age group:
   - *≤ 20 years*
   - *21 – 35 years*
   - *36 – 55 years*

- *≥ 56 years*

3. Level of achieved education:

- *primary education*
- *secondary education*
- *higher professional education*

The quantitative research emphasises the diversification of respondents based on their age. The goal of the quantitative research is to achieve 4 target groups divided by age, which contain at least 100 respondents in each age group. The 14 specialized questions of the questionnaire are divided into 4 main blocks of questions:

- The general questions about the advertising on the pharmaceuticals
- The formal aspects of the advertising on the pharmaceuticals
- The contentual aspects of the advertising on the pharmaceuticals
- The advertising on the pharmaceuticals on prescription

It also contains 2 visual replications of the advertisings, which were found as illegal by the State Institute for Drug Control, to determine the effectivity of the current regulations.

The questionnaire was distributed in both online and paper form. The online form of the questionnaire was created using the Google Forms and it was distributed mainly through the social medias such as Facebook, Google+. The paper form was distributed to the students of Gymnázium Brno, Vídeňská, příspěvková organizace and to people with no direct access to social media.

The results of the quantitative research are a subject of a descriptive method, because the questionnaire was only a supplement to a qualitative analysis of the case laws, to determine the sensitivity and awareness of the respondents, which would be used as secondary source for a creation of the recommendations. The data are presented on graphs and tables using a Microsoft Excel software.

The conclusion and discussion provides a summary of information, obtained during the writing of the thesis, and the evaluation of the current legal regulations, with regards to the results of the questionnaire, including the suggestions to its improvement, if necessary.

4 Theoretical part

The theoretical part provides an overview on the pharmaceutical industry as a whole, on the fundamental differences between the pharmaceuticals on prescription, over-the-counter pharmaceuticals and the food supplements. An introduction to the marketing and advertising as well as to ethics of advertising, but the main part focuses on the current state of the European and Czech Legislation.

4.1 Pharmaceutical Industry

The pharmaceutical industry has always been a heavily R&D oriented in its nature. In the past, the pharmaceutical industry has been successful in providing new valuable pharmaceuticals for treatment of illnesses, along with providing a significant contribution to understandings of symptoms and causes of diseases. In general, due to the success of this industry, people have higher live expectancy and they can live much healthier lives with lower risk of countless illnesses, McGuire, Hasskral, Bode, Klingmann, Zhan (2011). According to Backhaus (1983), the pharmaceutical industry, in modern, developed and industrialized countries, is a subject to various and extensive regulations in order to protect the consumers, as pharmaceuticals are mostly considered as potentially dangerous products. It is in general interest to supervise and regulate the production and marketing of the pharmaceuticals given that, any consumption of pharmaceuticals carries a considerable risk for the user, such as unwanted side effects, insufficient reaction or no reaction at all.

The pharmaceutical industry is a research-based industry, but the new trends in the industry turn the attention of the pharmaceutical companies from R&D to sales and marketing. According to several studies, pharmaceutical companies have been spending 19 times more on marketing than on R&D. The top 10 biggest pharmaceutical companies, including well-known companies like: Johnson & Johnson, Novartis, Pfizer, etc., have spent $98,3 billion on marketing and only $65,8 billion on R&D, which emphasises how important the marketing and the advertising in the pharmaceutical industry are, Sarich (2016).

4.2 Pharmaceuticals, food supplements and food

Nowadays, the market is full of food supplements which in terms of their structure, presentation, and nature of information on the package or in the product leaflet often resemble pharmaceuticals. So, the consumer is hardly able to differentiate between these types of products, but it is crucial to be able to recognize the difference between them, SÚKL (2014). According to the webpage Olécích.cz (1999), the customers could check the national registry of the registered drugs and if the product is not included in the database, it is a food supplement or any other product. List of the food supplements could be found on the web portal of the Chief Health Officer of Czech Republic.

4.2.1 Pharmaceuticals

According to § 2a Act. No. 378/2007 Coll., on Pharmaceuticals and on Amendments to some related acts (Act on Pharmaceuticals), as amended: "*A medicinal product shall mean a substance or combination of substances presented as having therapeutic or preventive properties in the case of human or animal diseases; or a medicinal product shall also mean any substance or combination of substances which may be used or administered to human beings or used or administered to animals with a view to restoring, correcting or modifying the physiological functions by means of a pharmacological, immunological or metabolic effect or with a view to making a medical diagnosis.".*

From the terminological point of view, the thesis uses term pharmaceutical as reference to a medicinal product not a term drug, which is used in the United States of America, and it defined by Department of health and human services (2016): "*Drug product means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients."* In the European and Czech environment, term drug is used for any chemical substance, which is intentionally consumed to achieve certain positive effects, Iversen (2006).

Metyš, Balog (2006) say, that the assessment and approval of the pharmaceuticals in the Czech Republic is within the powers of the State Institute for Drug Control, within the scope of determination of the quality, safety and efficiency of the declared characteristics. The efficiency must be evidenced by the relevant clinical studies, which have to meet the tight criteria established by legal regulations.

According to SÚKL (2016), the human pharmaceuticals are divided into 3 categories:

- medicinal products dispensed without medical prescription
- medicinal products dispensed without medical prescription with restrictions
- medicinal products on prescription

Acting in compliance with the requirements of the Act on Pharmaceuticals, the State Institute for Drug Control defines the characteristics of the medicinal products that may be supplied without a medical prescription. The criteria for the classification of human medicinal products are defined in Section 39 of Act on Pharmaceuticals.

4.2.1.1 Medicinal products on prescription

The medicinal products on prescription can be sold entirely in the pharmacies. They can cause directly or indirectly a health hazard without the supervision of medical professional even within the frame of correct ingestion. They contain the substances, whose efficiency or untoward effects must be oversighted. they are intended for a parenteral administration or the ingestion can raise serious untoward effects, O lécích.cz (2016).

4.2.1.2 Medicinal products dispensed without medical prescription with restrictions

In this category, belong the pharmaceuticals, which do not fulfil the criteria of medicinal products on prescription, but they directly or indirectly cause a health hazard, because they are frequently and broadly used incorrectly or the correct ingestion assumes the professional advice from the pharmacist. The limitation for the product dispensing could be age limit, number of packages within one dispensing or the prohibition of mail-orders. They can be sold only in the pharmacies, O lécích.cz (2016).

4.2.1.3 Medicinal products dispensed without medical prescription

The medicinal products dispensed without medical prescription are also called OTC (over-the-counter) pharmaceuticals and they can be sold in the pharmacies or mail-ordered via internet webpage of pharmacy, which has also a brick-and-mortar store. These pharmaceuticals have lower level of toxicity and lower level of untoward effects. They can be used for treatment of diseases, which patient can determine on its

own (self-diagnosis) and the risk of health hazard, due to wrong ingestion, is low, O lécích.cz (2016).

4.2.2 Food supplements

SÚKL (2012) says, that the regulation of food supplements falls within the powers of the Ministry of Health of the Czech Republic and it is governed by Act No 110/1997 Coll., on Foodstuffs and Tobacco Products and on Amendments to Some Related Acts, as amended. A food supplement is defined in §2g, of the Food Act as: *"food whose purpose is to supplement ordinary nutrition and that is a concentrated source of vitamins and mineral substances or other substances with a nutritional or physiological effect contained in the food independently or in a combination designated for direct consumption in small measured quantities."* All the obligations for the food supplement are specified in the Decree No 225/2008 Coll., on the requirements for dietary supplements and fortification of foodstuffs and between the most important obligations belongs to include the warning text "food supplement" on the package and not to impute the attributing qualities related to preventing, treating or curing human diseases to the food supplement. Some packages contain HEM number, which is a reference number of decision of the Ministry of Health of the Czech Republic on the product.

During the registration procedure, only the safety of the product is controlled by the Ministry of Health of the Czech Republic., which means that their long-term use will not injure people's health, compering to registration procedure of pharmaceuticals, which also check the efficiency of the product, SÚKL (2014).

According to section 4, par. 1, of Decree No. 225/2008 Coll., food supplements differ from the food, that they are used in the form of capsules, pastilles, tablets, pills, bags of powder, ampules of liquid, drops or other simple forms of liquids and powders designated for consumption in small measured quantities, and are marketed as such. This is a transposition of paragraph a) of Article 2 of Directive of the European Parliament and of the Council 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

4.3 Advertising

The adverting is a part of communication mix, which belongs to the marketing, which could be described, according to Kotler (2016, p. 26): *"as the process by which companies create value for customers and build strong customer relationships in order to capture value from customers in return."* Kotler (2016) also adds, that marketing is not just a selling and an adverting, but it is more broader process of understanding the customer's need and wants and satisfying them via delivering the product.

According to Brandastic, Inc. (2015), marketing could be differentiated on the direct and indirect one. Direct marketing use more personal approach, which target specific groups, evens individuals. Indirect marketing is considered as the media approach.

However, the increase of unsolicited advertising in the traditional channels of direct mail and telemarketing, and the new communication channels of advertising by phone, e-mail, Internet has attracted public attention and concern, Phelps, Johnson, Gonzenbach (1994). According to Winston (1993), the policymakers respond to these concerns by conducting hearings, passing legislation, and implementing new rules, to regulate some forms of direct marketing. On the other hand, this approach also put a high pressure on the company itself, because they should evaluate, if the advertising has not a negative impact on their image, credibility, and dignity, which evolved to self-regulation mechanisms of the companies, Belch (2009).

Tellis, Ambler (2008) say, that nowadays, the advertising can be understood as form of mass and non-personal communication, with the purpose of informing the consumer, but also of changing their attitude, behaviour or beliefs and it belongs to the most important forms of paid promotion. The objective of any businesses is to captivate the attention of the customers and to be better than the competition, thus the businesses sometimes turn to controversial, even further to unfair practices in advertising to exaggerate the quality of their products. Fallacious arguments or the emotional appeals could have bigger effect on certain people than non-manipulative advertising. However according to PricewaterhouseCoopers (2009), the issue of manipulative advertising brings out the discussion on the role of moral principles and legality. So, it is necessary to set up clear limits and to adjust the regulations in time, seeing as marketing in general, is tremendously evolving industry. The new trends in pharmaceutical advertising show the shift from traditional mass-market to a target-market approach to increase its revenue.

4.3.1 Advertising in the pharmaceutical industry

The available material can be divided into 3 categories: promotional, nonpromotional and scientific. The difference between promotional and non-promotional could be tricky, because it doesn't have to be always clear. Promotional information is related to the advertising and sales materials to the products. These materials could be distributed to patients through various marketing campaigns or they could be distributed to healthcare professionals through the network of the representatives of the pharmaceutical companies. The non-promotional materials contain information about the diseases or the treatment, curing processes and it doesn't contain any information about the products. Scientific information is usually the summary of results of the research and the development programme or other scientific data provided in journals or presented at the meeting or conferences, Francer, Izquierdo, Music, Narsai, Nikidis, Simmonds, Woods (2014).

Vaňková (2005) says, that the common practise is to use well-known person in the advertising, who recommends the product. The advertising on the pharmaceutical is a little bit special in this area, compering to other advertisements, because some of occupations cannot participate in the advertising, such as: healthcare professionals or actors, who play a role of the doctor.

The regulation of the advertising on the pharmaceuticals did not exist for a such long time in the Czech Republic (previously in the Czechoslovakia). The foreign pharmaceutical companies enter the market during the 1990s, which caused a creation of some regulations. Until 1992, there was not any regulation concerning marketing activities of the pharmaceutical companies. Till 2002, only the basic regulations were in place and the supervision was highly limited. The ministry of Health of the Czech Republic was formally in charge of the supervision. Later, the Czech Republic started to implement the directives from the European Union, which established tighter legal framework. The adverting on the food supplement was not limited till the second half of 1990s, O lécích.cz (2016). According to SÚKL (2015), The most important change in the supervision on the adverting regulations was in June 2002, when the State Institute for Drug Control has become the competent authority responsible for surveillance over advertising of human medicinal products, due to Act No 138/2002, amending the Act on advertising regulation.

4.4 Legal Requirements and Guidance

In almost all countries around the world, the development, manufacturing and marketing processes of pharmaceutical products depend on governmental approval and must follow strict regulations, because pharmaceutical products can have direct effect on human health, so they have been regarded as potentially dangerous, Whewell (2010, p. 162). A comprehensive national and supranational legal framework, therefore, exists to avoid risks in connection with the development, manufacture, distribution, marketing, and use of pharmaceutical products. In the following, law means legal provisions adopted by the legislative organ (i.e., parliament), regulation means legal provisions made by an institution of the executive (i.e., the government) on the basis and within the limits of an authorization given by the law.

On the following pages, the thesis provides legal framework for the unfair practise from the point of view of private law, which is not that much a common practise in the Czech Republic. So, the main focus is on the regulation for the advertising from the public law perspective in the European and the Czech perspective.

4.4.1 Private law on the advertising

In general, the use of the unfair practices could be defined as obstruction of the competition, during which the participant behaves dishonestly, immodestly, wrongly, unfairly or in unsuitable way, Večerková (2005). The advertising on the human pharmaceuticals is strictly regulated by the public law, but the private law has irreplaceable place, because the public law often refers to the private law. According to § 2a Act No. 40/1995 Coll., on advertising regulation, the comparative advertising on pharmaceuticals for the human consumption or on the health care is admissible only after fulfilling the conditions specified by Civil Code, i.e. targeting the persons entitled to prescribe or dispense these human pharmaceuticals and/or to provide such a health care. So, the public and private law overlap each other in some areas. The most important law in private law regulations is an Act No. 89/2012 Coll., civil code.

One of the unfair practises is a misleading advertising, regulated by the §2977 Civil Code, as: *"Misleading advertising is advertising which relates to business activities or profession, aims to promote the sales of movable or immovable things or the provision of services, including rights and duties, which misleads or is capable of misleading the persons to whom it is addressed or whom it reaches by its presentation or*

in any other way, and is thus evidently capable of affecting the economic behaviour of such persons."

The comparative advertising is heavily interconnected with the European legislation, Directive No. 84/450/EHS, as amended by the Directive No.97/ 55/ES and No. 2005/29/ES, which deals with a misleading and comparative advertising in the European Union. So, the member states cannot divert from it. In the Czech Republic, the comparative advertising is regulated by the §2980 Civil Code. The comparative advertising directly or indirectly identifies another competitor, or his goods or services, but could be permitted, if it is not misleading, and compare only the goods or services which satisfy the same need or which are intended for the same purpose. It must not disparage a competitor, its position, its activities or its results, or their identification, or unfairly benefits therefrom, and it must not copy and imitate the products, which have registered under the trademark.

4.4.2 Public law on the advertising in the European Union

According to the European Union (2017), the legal system of the EU differentiates between regulations and directives. Regulations have direct and binding effect in the member states, whereas directives must be transferred separately into the national law. The pharmaceuticals and the medical devices as products are part for a single market, and therefore the EU holds competency for their authorisation through evaluation and supervision, European Parliament (2017)

At the beginning, it is important to emphasise, that the regulation of the advertising on the pharmaceuticals is regulated via directives, which is important from two aspects. First, if the directives are not imported into the Czech legislation, they are not biding for the pharmaceutical companies. Second issue arises in a moment, that the Czech legislation is contrary to European law, so in this case, pharmaceuticals companies can appeal to European court of Justice. The most important directive, which regulate the area of the advertising on pharmaceuticals is a Directive No. 2001/83/ES, which codifies the legal framework for the human pharmaceuticals, which was amended in 2004 by the Directive No. 2004/27/ES, Žamboch, Bída (2006). This directive lays down the procedures in the European community for an authorization and supervision of medicinal products for human and veterinary use and establishes a European Medicines Agency, Kocián Šolc Balaštík, advokátní kancelář, s.r.o. (2005). The Directive 2004/27/EC sets up the main purpose for the regulation, as: "*The main purpose of any regulation on the manufacture and distribution of medicinal products for human use should be to safeguard public health. However,*

this objective should be achieved by means which do not hinder the development of the pharmaceutical industry or trade in medicinal products in the Community."

The Directive 2004/27/EC also defines, the crucial framework for the advertising. According to the directive, Member states shall prohibit an advertising on pharmaceuticals on prescription, so only on pharmaceuticals, which can be uses without the intervention of a doctor, and on the pharmaceuticals, which contain psychotropic or narcotic substances, also to prohibit a distribution of the pharmaceuticals for a purpose of promotion and to ban the advertising to the general public of the pharmaceuticals the cost of which may be reimbursed.

Among the other European directives and regulations, it is necessary to mention a Regulation No 726/2004, which sets out the procedures for the authorisation and supervision of medicinal products for human and veterinary use. We can also include the jjudgements of the European Court of Justice, as a source of the European laws as well.

4.4.3 Public law on the advertising in the Czech Republic

The main regulation of the advertising in the Czech Republic is given by the Act No. 40/1995 Coll., on regulation of advertisement and changes and amendments of the Act No. 468/1991, Coll. of Laws, on operation of sound and television broadcasting, as amended by later regulations:

- Amendment: 258/2000, Coll. of Laws.
- Amendment: 231/2001, Coll. of Laws.
- Amendment: 256/2001, Coll. of Laws.
- Amendment: 138/2002, Coll. of Laws.
- Amendment: 320/2002, Coll. of Laws.
- Amendment: 132/2003, Coll. of Laws.
- Amendment: 217/2004, Coll. of Laws.
- Amendment: 326/2004, Coll. of Laws.
- Amendment: 480/2004, Coll. of Laws.
- Amendment: 384/2005, Coll. of Laws.
- Amendment: 444/2005, Coll. of Laws.

- Amendment: 25/2006, Coll. of Laws.

The amendments transport the European directives and regulations into the Czech legislation. The general provision for the advertising regulation are specified by the paragraphs §1 and §2, which are binding for all types of advertising and paragraph §5, §5a and §5b further specify the regulations of the advertising of pharmaceuticals and paragraph §7 specifies the supervision bodies.

4.4.2.1. General provisions for advertising

The general provisions set certain conditions for the regulation of the advertising, which is unfair practice, comparative advertising and specify the advertising for the tobacco products, human pharmaceuticals, veterinary pharmaceuticals, food and infantile nutrition and also regulates the advertising for alcoholic drinks, products for plant protection, fire-arms, ammunition and for funeral services. It specifies the general requirements on the advertising and its broadcasting, Act on regulation of advertisement.

According to Act on regulation of advertisement, the advertising is defined as any form of an announcement, notification or any other presentation through communication medias, which purports to support the entrepreneurial activities, especially support the consumption and sales of goods, construction, renting and sales of properties, sales and utilize the rights and obligations, rendition of services or the promotion of the trademark, which is specified by the §1 at Act No. 137/1995 Coll., on trade marks (the *"Trade Mark Act"*). The general provisions also specify the sponsorship as a contribution provided with the purpose to support the production or sales of goods and services or other sponsor activities.

The Act on regulation of advertisement, also specifies the communication medias via the advertising is distributed or broadcasted, are defined as any means, which allow transmition of the advertising, especially:

- periodicals
- non-periodical publications
- sound and television broadcasting
- on-demand audio-visual media productions
- audio-visual productions
- computer networks

- audio visual work carriers
- posters and leaflets

According to Act on regulation of advertisement, in the advertising process, there are 3 main participants, who are involved, from the moment of the advertising till it is broadcasting.

- submitter, a legal entity or natural person that has placed and order for the advertisement. In case, that the advertising is missing an information about the entity, which placed an order for the broadcasting, it is called an anonymous announcement
- processor, a legal entity or natural person that has processed the advertisement for itself or another legal entity or physical person. If the processor creates the advertising for himself, he is also a submitter
- propagator, a legal entity or natural person engaged in public broadcasting of the advertising.

It is forbidden to create an advertising on goods, services or other performances or values, which sales, renditions and broadcast are in contradiction with the legal regulations and on the advertising, which is unfair practice, according to Consumer Protection Act. According to Act on regulation of advertisement, a distribution of unsolicited advertising in paper form is also prohibited, in case that it accosts the addressee, because he previously indicated, that he doesn't wish to receive it. It is prohibited to distribute the advertising. on public places outside the business premises other than through the advertising or promotional agents or institutions. The publicly accessible places, where advertising is prohibited, are specified by the communities. The communities has also power to set period of time in which advertising is forbidden and all the types of communication media, which must not be used to distribute the advertising

The advertisement must not contradict good manners, and especially must not contain any discrimination, based on race, sex or nationality or strike at religious convictions or national sentiments, menace morality in a generally unacceptable way, denigrate human dignity, contain elements of pornography, violence or elements based on inducing fear and it must not support behaviour damaging the

health or menace the safety of individuals or property or acts damaging the interests of environmental protection, Act on regulation of advertisement.

According to Act on regulation of advertisement, in case, that the advertising targets the persons younger than 18, it must not promote a behaviour that menace their health or mental or moral development, utilize the special confidence in their parents, legal representatives or other persons or show them in an inappropriate manner in the dangerous situations.

4.2.2.2. General provisions for advertising on the human pharmaceuticals

According to § 5 Act. No. 40/1995 Coll., on advertising regulation and amending Act No. 468/1991 Coll., on radio and TV broadcasting, as amended, as an advertising for the human pharmaceuticals is also consider all the information, incentive and all the forms of persuading, which should stimulate the prescription, supply, sales or the consumption of human pharmaceuticals, which includes:

- all the visits of sales representatives of human pharmaceuticals to persons, who are authorised to prescribe, supply, dispense the human pharmaceuticals
- the supply of samples of human pharmaceuticals
- the support of the prescription, dispensing, sales or the consumption of human pharmaceuticals through the material or money reward, gift or consumption competition
- the sponsorship of scientific congresses with the participation of industry experts, which should result into the prescription, dispense, sales of human pharmaceuticals.
- the sponsorship of scientific congresses with the participation of industry experts, and reimbursement of expenses for travel and accommodation related to their participation.

However, the provisions of this act are not applicable to the labels and information leaflets, which are govern by special regulations and laws: Act No. 79/1997 Coll., as amended and notice No. 473/2000 Coll., which specify the details about registration with its changes and procedure for its renewal, determination of method of issuance of pharmaceuticals, way of announcing and evaluation of the untoward effects and the scope of the announcement of the usage of the unregistered pharmaceutical. Also, to the correspondence, which is necessary to answer specific ques-

tions concerning about the human pharmaceutical and other supplementing materials, which have non-advertising nature and to the sales catalogues and price lists, in case, that they do not contain the description of the characteristics of human pharmaceuticals. Further, the provisions don't apply to notification, caution/warning and provision of information concerning, for example: changes of package, warning about undesirable effects of a human medicinal preparation, references on human health, if they do not contain any direct or indirect information or a reference to the human pharmaceutical. All the information, which are part of the advertising, must correspond to the summary of product characteristics, according to § 2 Act No. 79/1997 Coll.. The advertising must encourage a rational ingestion through the objective presentation of the pharmaceutical without the overstatements.

The general provisions for the advertising on the human pharmaceuticals, which are set in § 5 Act No on advertising regulation, are supplemented with 2 subparagraphs § 5a and § 5b, which deal with advertising targeting the general public and healthcare professionals. The subject of the thesis is only the advertising on human pharmaceuticals targeting general public. So, only the § 5a subparagraph will be described in more details. The biggest difference between these 2 advertisings is, that the advertising targeting healthcare professionals can contain the advertising on the pharmaceuticals on the prescription.

4.2.2.2. Advertising on human pharmaceuticals targeting general public

The advertising on human pharmaceuticals targeting general public is regulated via § 5a Act. No. 40/1995 Coll., on advertising regulation and amending Act No. 468/1991 Coll., on radio and TV broadcasting, as amended, excluding pharmaceuticals, which are part of the vaccination campaigns, which are approved by Ministry of Health.

The subject of the advertising, which targets the general public, can be only a human pharmaceutical, which the composition and the method of ingestion is conceived to be used without the diagnosis has been set or just based on the advice from the pharmacist. It must be part of medical treatment, on which the supervision of the doctor is needed. The advertising targeting the general public must not target the human pharmaceuticals, which are prescription-only medicines or contain the opiates and psychotropic substances, specified by §2a Act No. 167/1998 Sb., on addictive substances, as amended. It is forbidden to provide the samples of human pharmaceuticals to the general public for a promotion purpose

According to Act on regulation of advertisement, the advertising, which target general public must be formulated in a way, that it is clear that the product is a human pharmaceutical. It must contain the name of the human pharmaceutical as stated in the registration decision, and in case, that the human pharmaceutical contains only one active substance, the advertising must include also the general name of the substance. It must also include and information necessary for the appropriate ingestion/use and clearly visible and readable appeal to read the package/information leaflet carefully.

The advertising on the human pharmaceuticals, which have not been a subject to the evaluation of efficiency as part of the registration procedure, according to § 24a Act No. 79/1997 Coll., as amended by Act No. 129/2003 Coll., can only contain the information, which are on the packages or product leaflets in accordance with special law regulations, § 26c and 26d Act No. 79/1997 Coll., as amended by Act No. 129/2003 Coll. and by the notice no. 288/2004 Coll.

According to Act on regulation of advertisement, the advertising, which target general public must not evoke an impression that, that the consultation with the doctor or the healthcare/medical treatment are not necessary, because the pharmaceuticals could be used for self-diagnosis. It must not indicate, that the effects of the human pharmaceutical ingestion are guaranteed and that they are not connected with any untoward effects, or that they are better than other human pharmaceuticals or medical treatment. It must not suggest that the use of the pharmaceuticals will improve the health of the person, who use it, i.e. it will be better than the person, who does not use it. It is prohibited, that to suggest that failure to use a human medicinal preparation could have a negative effect on the health of the individuals, with the exception for a vaccination actions approved by the Ministry of Health.

Based on the Act on regulation of advertisement, the advertising must not exclusively target people aged 15 or younger or include recommendations of scientist, health care professionals, or other persons, which could influence the consumption of the medicine, due to their real or anticipated social status. Also, it is prohibited to suggest that the pharmaceutical is a food, cosmetic product or another consumer good, or suggest, that the safety and efficiency is guaranteed by its natural origin, because the substance could have various origin and the safety and efficiency guarantees are given only through fulfilling the necessary requirements during the registration procedure. It must not be misleading and cause, that the user will make wrong self-diagnosis, due to providing a detailed description of a specific procedure of the treatment.

According to Act on regulation of advertisement, it must not inappropriately, exorbitantly or misleadingly point to the method of the possible treatment and also it must not inappropriately, exorbitantly or misleadingly show the illustration of changes on human body or its parts, caused by illness, accident or by the use of the medicine. The relevant illustrations, which describe the efficiency of the pharmaceutical, must not be repulsive and the submitter of the advertising must always provide the evidence of the efficiency. Only scientifically approved effects can be imputed to the pharmaceuticals.

If the advertising is intended as a remark of certain human pharmaceutical, it must not contain anything else than the name of the pharmaceutical, under which is registered or its international non-proprietary name, in case it exists, or the trademark. According to WHO (2016): " *International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name."*

4.2.2.5. Supervision of law-abidingness

The important aspect of every regulation and law is its enforcing. According to § 7 of Act on advertising regulation, there are several institutions, which are assigned to control all the advertising in the pharmaceutical industry:

- The Council for Radio and Television Broadcasting, which is responsible for the all the broadcasting on television or radio in the Czech Republic.
- The State Institute for Drug control, which control the advertising and sponsoring in area of pharmaceuticals for human consumption.
- The Ministry of Health of the Czech Republic, which control the advertising and sponsoring in are of health care.
- The State Phytosanitary Administration, which controls the advertising on products for plants protection.
- The Institute for State Control of Veterinary Biologicals and Medicines, which control the advertising for veterinary pharmaceutical products.
- The office for personal data protection, which control the unsolicited advertising spread through the electronic medias.
- District Business Registration and Licensing Offices, which deals with other minor problems violating the laws.

The Submitters, processors and contractors should cooperate with the supervision institutions during the proceedings. This was insured by a creation of a set of obligations for a case of future legal proceeding, arisen from § 7a Act on advertising regulation, such as keep a copy of each advertising for the duration of 5 years, from the day, on which the advertising was aired for the last time and lend the copy of the advertising to supervision institutions for free for the necessarily required period of time, including all the supplementary information and records about the involved parties, like propagators, contractors, submitters, usually within 5 working days. All the obligations are also binding to submitters, contractors and the propagators of teleshopping. The supervision institution can consider the statement in the advertising as incorrect or misleading, if the demanded evidence was not provided to the supervision institution at given period or in insufficient amount. The supervision institutions do not have only powers to rule on a violation of the regulation, but they were given powers to enact abolishment or termination of the advertising. They can also prohibit illegal comparative advertising or on advertising, which is an unfair practice and to suspend the inception of broadcast of illegal comparative advertising or on advertising, which is an unfair practice, according to Act No. 634/1992 Coll., on consumer protection. These powers were given to supervision institutions by the § 7a Act on advertising regulation. They can also demand a publishing a corrective statement to advertising, which was found as illegal

4.5 Ethics in the advertising on the pharmaceuticals

There are 2 institutions in the European Union and the Czech Republic, which focus on the ethics in the advertising on the pharmaceuticals. The European Federation of Pharmaceutical Industries and Associations (EFPIA) with seat in Brussels (Belgium), which is a federation of the 33 national associations and 40 leading pharmaceutical companies. Indirectly, it represents another 1900+ smaller pharmaceutical companies. The aim of the federation is to represent pharmaceutical industry in Europe, EFPIA (2017). The federation put together an EFPIA Code, which is a summary of guiding principles for pharmaceutical corporations, healthcare professionals and patients, representing the EU Commission initiative on ethics and transparency in the pharmaceutical sector, EIFPIA (2013).

The EFPIA Code had to be implemented on the national levels. So, the Czech Republic, represented in the federation by the International Association of Pharmaceutical Industries, created 39 pages long “Code of Conduct”. The pharmaceutical industry binds itself to provide pharmaceuticals fulfilling the highest standards of safety, efficacy and quality provide and supports them by comprehensive technical and informational services and to be professional in a communication with general public, healthcare professionals and other public health officials. It also describes the necessary obligations for the content and the communication channels for promotion materials, such as journal advertisement, printed promotional materials, audio-visual promotional material, computer based promotional material, mailings, documents transfer media, promotional competitions, which mainly copy the European and Czech legislation on advertising of pharmaceuticals, AIFP (2017).

5 Practical part

The practical part of the diploma thesis is divided into 2 equally important subparts. The first subpart focusses on the ruling in the 18 legal proceedings and 2 law suits, due to a violation of an obligations of Act on advertising regulation. The legal proceedings are led by State Institute for Drug Control and The Council for Radio and Television Broadcasting, which have been given the authority to monitor and control the advertising by the §7 of Act on advertising regulation, which has been described in details in the section 4.2.2.5.. The law suits are judged by Municipal Court in Prague, as Court of Appeal to decisions of State Institute for Drug Control and The Council for Radio and Television Broadcasting. Second subpart summarizes the most common violations of Act on advertising regulation and examine the sensitivity of target groups on advertising on the human pharmaceuticals and its regulation

5.1 Legal Analyses

Tab. 1 Legal proceedings of The State Institute for Drug Control

File num.	Company name	Violation of substantive provision of Act on advertising regulation	Sanction (CZK)
9989/08	Zentiva, a.s.	§5a article 2 letter a), §5b article 2	183 000
	KAP CZ, s.r.o.		15 000
sukls28734 /2008	GlaxoSmithKline, s.r.o.	§2 article 3 letter a)	300 000
	MARK/BBDO, a.s.		15 000
79534/2009	MUCOS Pharma CZ, s.r.o.	§5a article 7 letter i)	175 000
sukls37950 /2010	PRO.MED.CS Praha a.s.	§5a article 5 letter d)	150 000
	Mr. Vladimír STAŇEK – grafické studio Vlado		10 000
SUKLS197016 /2011	EULEK-PHARMA s.r.o.	§5a article 5 letter a) c) d)	150 000
SUKLS164519 /2011	SCHLECKER a.s.	§5a article 5 letter a) c)	75 000
sukls28544 /2015	Vitabalans CZ, s.r.o.	§5a article 2 letter a)	150 000
sukls260933 /2012	ALK A/S	§5a article 2 letter a)	150 000
	ASCO-MED, spol. s r.o.		150 000
Sukls210047 /2013	Teva Pharmaceuticals, s.r.o.	§5a article 5 letter d)	200 000
sukls128017 /2013	Medicom International s.r.o.	§5a article 2 letter a)	150 000
	Ex-press.cz, spol. s r.o.		25 000
sukls190424 /2013	Abbott Laboratories, s.r.o.	§5a article 8	160 000
	PHARMALINK s.r.o.		20 000
sukls172187 /2009	ASI Prag s.r.o.	§5 article 4	100 000
18470/07	Wyeth Whitehall Czech s.r.o.	§2 article 3 letter	380 000

Source: The State Institute for Drug Control

Tab. 2 Legal proceedings of The Council for Radio and Television Broadcasting

File num.	Company name	Violation of substantive provision of Act on advertising regulation	Sanction (CZK)
2012/536/had /TER	TEREZIA COMPANY s.r.o.	§ 5d article 2 letter d)	100 000
2010/415/had /Zen	Zentiva, k. s.	§5d article 3	100 000
2012/79/FOL/ Eur	Europlant s.r.o.	§5a article 5 letter c)	20 000
2012/487/had /All	Allivictus s.r.o.	§5d article 2 letter d)	1 800 000
2014/1068/ha d/WAL	Walmark, a. s.	§5d article 2 letter d)	1 100 000

Source: The Council for Radio and Television Broadcasting

Tab. 3 Case laws from the Municipal Court in Prague

File num.	Company name	Violation of substantive provision of Act on advertising regulation	Sanction (CZK)
2008/1088/Had/Gre	GREEN – SWAN PHARMACEUTICALS CR, a. s.	§5d article 3	400 000
2008/960/had/Nov	Novartis, s. r. o.	§5a article 5 letter d)	400 000

Source: The Municipal Court in Prague

5.1.1 Zentiva, a.s. and KAP CZ, s.r.o.

The State Institute for Drug Control conducted a legal proceeding against the Zentiva, a.s. and KAP CZ, s.r.o., due to a violation of an obligation arisen from § 5a article 2 letter a) of Act on advertising regulation, for submitting and processing an advertising on a pharmaceutical on prescription Cinie, which targeted general public and professionals, and also due to the violation of an obligation arisen from § 5b article 2 of Act on advertising regulation, because the advertising was missing necessary component for targeting the healthcare professionals.

The State Institute for Drug Control set a fine upon Zentiva, a.s. in amount of 183 000 CZK, according to § 8a article 6 letter b) of Act on advertising regulation

and also fine upon KAP CZ, s.r.o. in amount of 15 000 CZK, according to § 8a article 7 letter a) of Act on advertising regulation.

The advertising was in a form of a board, containing a diagnostic test of Czech Headache Society, which was in a form of closed questions, with possible YES/NO answers. Under the test was also a statement: *"If you answer at least 3 questions with YES answer, you may suffer from a migraine"*. Hence, the board contained a logo of the product Cinie with the substance name Sumatripan, it violated the law, because the advertising targeting general public mustn't be on pharmaceuticals on prescription and also because it contained just a name of the substance without other obligatory information necessary for the professionals, so it violated the § 5b article 2 as well.

5.1.2 GlaxoSmithKline, s.r.o. and MARK/BBDO, a.s.

The State Institute for Drug Control conducted a legal proceeding against GlaxoSmithKline, s.r.o. and MARK/BBDO, a.s. due to violation of the obligation arisen from § 2 article 3 letter a) of Act on advertising regulation, because the advertising used the motive of fear, when it aggressively pointed at ubiquitous presence of the risk of an infection via the transmition from an infected blood, containing a hepatitis.

The State Institute for Drug Control set a fine upon GlaxoSmithKline, s.r.o. in amount of 300 000 CZK, according to § 8a article 6 letter b) Act on advertising regulation and also fine upon KAP CZ, s.r.o. in amount of 15 000 CZK, according to § 8a article 7 letter a) Act on advertising regulation.

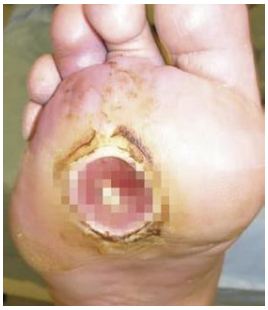
The advertisement on the human pharmaceutical Twinrix, which was published in a magazine *"Fit for life"* on 22.6.2006, contained an accentuated text: *"Can you find 0,00004 millilitres of blood on this page?"* and the blood drops were randomly laid out below this text. Also at the bottom of the advertising, there was a text, containing following sentences: *"Only this small amount is enough for transmition of a hepatitis."*, *"You never know, where and how you can get infected. Only a small wound could cause blood-to-blood transmition. You can get illness via the sexual contact with infected person, piercing, using another's razor, sport injury, even during the first aid in case of an accident."* and *"Hepatitis could lead to liver failure, cirrhosis of the liver and carcinoma, which in many cases end with death. Only protection against the hepatitis is a vaccination."* At the end of the advertisement was a logo of the product Twinrix with the text: *"First combined vaccination against hepatitis A and B".*

5.1.3 MUCOS Pharma CZ, s.r.o.

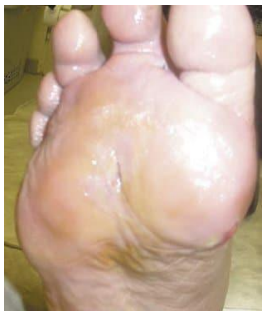
The State Institute for Drug Control conducted a legal proceeding against MUCOS Pharma CZ, s.r.o. due to violation of the obligation arisen from § 5a article 7 letter i) of Act on advertising, because the leaflet *"Wobenzym, help you with wound treatment"* used for the advertising, contained a suggestive description of 2 stories of patients, who described the process of a treatment of an infection of their legs, which could cause wrong self-diagnosis by the readers. The leaflet was distributed in amount of 70 000 pcs to waiting rooms in medical institutions in February 2008,

The State Institute for Drug Control set a fine upon MUCOS Pharma CZ, s.r.o. in amount of 175 000 CZK, according to § 8a article 7 letter a) of Act on advertising regulation.

4 pages long leaflet contained on its first page an illustration of the package of pharmaceutical Wobenzym and also a picture of a leg of adult man, which had an open wound on its sole foot covered by text: "It's prohibited show these pictures due to Act on advertising regulation." However, inside the leaflet, there are two stories of patients, Mr. Antonín (60) and Mr. Ladislav (79), who suffered from the chronical illnesses of their legs. Stories are supplemented with photos of the chronical wounds, including the descriptions of the wounds before and after the treatment, using the Wobenzym. Pictures *"before and after"*, from Wobenzyn internet webpage, are used as an illustration of the pictures used in the advertising,



Before



After

Fig. 1 Illustration of the wound before and after the treatment
Source: http://wobenzym.cz/diabeticka-noha-bercovy-vred/

5.1.4 PRO.MED.CS Praha a.s. and natural person Mr. Vladimír STAŇEK – grafické studio Vlado

The State Institute for Drug Control conducted a legal proceeding against PRO.MED.CS Praha a.s. (a submitter) and a natural person Mr. Vladimír STAŇEK – grafické studio Vlado (a processor) due to a violation of an obligation arisen from § 5a article 5 letter d) of Act on advertising regulation, because the advertisement on the pharmaceutical Ambrosan, did not contain appeal to read the product leaflet. The advertising was in form of 15 city banners on street Legerova, Prague toward Nusle Bridge from 1st February 2009 to 31. March 2009 and only 6 of them were missing the appeal.

The State Institute for Drug Control set a fine upon PRO.MED.CS Praha a.s. in amount of 150 000 CZK, according to § 8a article 6 letter b) of Act on advertising regulation and also fine upon natural person Mr. Vladimír STAŇEK – grafické studio Vlado in amount of 10 000 CZK, according to § 8a article 7 letter a) of Act on advertising regulation.

The advertising was in a form of 15 city banners, which followed one after another alongside street Legerova, Prague. Intention of the submitter and the processor was to create a consecutive advertising, which was disproved later in the proceeding by State Institute for Drug Control. 15 city banners contained following text:

1. Is your cough slowing you down?
2. Does your cough tear you out?
3. Try Ambrosan! (This city banner contained the appeal to read the product leaflet and other obligatory information, arisen from the law)
4. Ambrosan against the cough!
5. Ambrosan will help!
6. Pastilles, capsules even cough drops!
7. Picture of the advertising leaflets and packages of the human pharmaceutical Ambrosan (This city banner contained the appeal to read the product leaflet and other obligatory information, arisen from the law)
8. Ambrosan for whole family
9. Is your cough slowing you down?
10. Does your cough tear you out?
11. Ambrosan will help!

12. Pastilles, capsules even cough drops!
13. Picture of the advertising leaflets and packages of the human pharmaceutical Ambrosan (This city banner contained the appeal to read the product leaflet and other obligatory information, arisen from the law)
14. Ambrosan for whole family
15. Ambrosan for your first-aid kit with logo of PRO.MED.CS

The city banners n. 4, 5, 8, 11, 14 and 16 did not contain an obligatory appeal to read the product leaflet.

5.1.5 EULEK-PHARMA s.r.o. in liquidation

The State Institute for Drug Control conducted a legal proceeding against the EULEK-PHARMA s.r.o. in liquidation, due to a violation of an obligation arisen from § 5a article 5 letter a), c), d) of Act on advertising regulation, because as a submitter of the advertising in a form of online webpage "www.lekarna-online.com", on the human pharmaceuticals: Apo-Ibuprofen, Aspirin, Ataralgin, Ibalgin, Ibumax 400, Ibuprofen Al 400, Robitussin, Sinecod, Sinupret, Solmucol, Stoptussin, Tussin, BromhexinEgis, Bromhexin, Coldrex Broncho, Ditustat, Acylcoffin, Acylparin Effervescens, Acylpyrin, Anopyrin, Apo-Ibuprofen, Hedelix, ACC 100, ACC 200, ACC Long, Ambrobene, Biotussil, Stodal, Mucosolvan, Ambroxol AL, Paralen Extra, Saridon, Tomapyrin, Valetol, Voltaren Actigo, Voltaren Emulgel, Nurofen, Panadol Extra Rapide, Panadol Rapid, Paralen, Diclofenac, Dicloreum, he did not clearly formulate, that the advertising is on the human pharmaceuticals and also the advertising was without the appeal to read the product leaflet and without the clear indication, how to ingest it as well.

The State Institute for Drug Control set a fine upon EULEK-PHARMA s.r.o. in liquidation in amount of 150 000 CZK, according to § 8a article 6 letter b) of Act on advertising regulation.

The online advertising webpage, was conceived as the internet pharmacy on a web address *"www.lekarna-online.com"* and it contained an advertising on the pharmaceuticals and on other products, which were not the medical products, such as: gift Ideas, teas, deodorants, infant products, hygienic products, kids' nutrition, beauty products, vitamins, minerals, food supplements and healthy food. Each product had there its own subpage, which looked similar for all the products, no matter if the product was a pharmaceutical or not. It contained: name of the product, cata-

logue number, retail price, *"our price"*, VAT and element called *"money saved"*. However, the online webpage was missing a clear differentiation between the pharmaceuticals and other consumer goods. This could lead to mislead of patients, that all the products stored on the webpage have similar position on the market. In addition, the advertising on the pharmaceuticals was missing an appeal to read the product leaflet and the clear indication, how to ingest it.

5.1.6 SCHLECKER a.s.

The State Institute for Drug Control conducted a legal proceeding against the SCHLECKER a.s., due to a violation of an obligation arisen from § 5a article 5 letter a) c) of Act on advertising regulation, because it processed an advertising in form of leaflet with name *"It's never been here before! New clever pharmacy"*, on the human pharmaceutical Paralen Grip 24 pastilles and products Proenzi 3 +180 pastilles and Oyster mushroom 50 pastilles and Biodeur deodorant powder 3 x 1g, which are not the pharmaceuticals and also the processor forgot to clearly formulate, that the advertising is on the pharmaceutical and to include a clear indication, how to ingest it.

The State Institute for Drug Control set a fine upon SCHLECKER a.s. in amount of 75 000 CZK, according to § 8a article 3 letter f) of Act on advertising regulation.

The advertising was in a form of one-sided leaflet and contained 4 frames for each product. The advertising on the pharmaceutical Paralen Grip was in the top-right frame, including the picture of the package, prices before and after the sale and the text: "*substances of the Paralen Grip pastilles are paracetamol (against pain and fever), fenylefrin (for air passages relieve) and dextromethorphan (for cough relief).*" At the bottom of the leaflet, there was a list of SCHLECKER pharmacies and the warning: *"We do not prompt you to unappropriated, excessive and baseless ingestion of the pharmaceuticals. We only offer a better price. Always read the product leaflet and the ingestion of the pharmaceuticals always consult with your doctor or pharmacist.*" The warning of unappropriated, excessive and baseless ingestion is not the clear indication, how to ingest it. Also, the advertising on the pharmaceutical was not clearly separated from the other products and could evoke the feelings, that all 4 products have same the position on the market.

5.1.7 Vitabalans CZ, s.r.o.

The State Institute for Drug Control conducted a legal proceeding against the Vitabalans CZ, s.r.o., due to a violation of an obligation arisen from § 5a article 2 letter a) of Act on advertising regulation, because it processed an advertising, on the internet webpage *"www.vitabalans.com"* on the pharmaceutical Zopitin 7,5 mg, which is a pharmaceutical available only on prescription.

The State Institute for Drug Control set a fine upon Vitabalans CZ, s.r.o., in amount of 150 000 CZK, according to § 8a article 7 letter f) of Act on advertising regulation.

The advertising on Zopitin 7,5 mg had been accessible from the official webpage *"www.vitabalans.com"* of the party to action since august 2011. Advertising was placed in a bookmark *"News – New Hypnotics"* and contained a logo of the company Vitabalans oy and sentences: "*For the problems with falling asleep, sleeplessness and early awakening"* and "*Only efficient substance registered in Czech Republic"*, followed by the picture of the package and the appeal to read product leaflet. The access to the advertising was not protected by the warning, that the content is designed for the healthcare professionals and did not demand any confirmation from the user, that he is a healthcare professional.

5.1.8 ALK A/S and ASCO-MED, spol. s r.o.

The State Institute for Drug Control conducted a legal proceeding against the ALK A/S (a submitter) and ASCO-MED, spol. s r.o. (a processor), due to a violation of an obligation arisen from § 5a article 2 letter a) of Act on advertising regulation, because they submitted and processed an advertising, in a form of broadsheet, on the pharmaceutical Grazax 75 000 SQ-T, which is available only on prescription.

The State Institute for Drug Control, set a fine upon ALK A/S and ASCO-MED, spol. s r.o., in equal amount of 150 000 CZK, according to § 8a article 7 letter b) of Act on advertising regulation.

The broadsheet with name *"Your guide to Grazax product"*, which meant to be distributed in amount of 1700 pcs for 9 months, from February 2011 to November 2011, had 8 pages, which were divided into 7 chapters: *„What are the allergy vaccines?", "Hay fever" "allergy vaccines", "What is GRAZAX? ", „How to use GRAZAX", „Possible side effects" and „Another information".* The advertising was definitely meant to target general public, because it contained following sentences with highlighted words: *"Hay fever is long-term chronical illness, which could affect* ***Your*** *daily life, if*

*it's untreated, by decreasing **Your** concentration in work or school, poor sleep, and could cause difficulties in **Your** social life."*, *"In addition, if you have more than one allergy, it increases **Your** risk of an occurrence of the new allergies or an asthma. The pastille contains an essence of a grass pollen, which help **You** to create a natural tolerance for a grass pollen."*, *"GRAZAX could also affect the sources of **Your** hay fever."* and *"If **You** forget to take pastille in the morning, take it later the day, if it's possible, otherwise continue in daily usage.* The product is, in general, presented as first allergy vaccine in form of pastilles.

5.1.9 Teva Pharmaceuticals, s.r.o.

The State Institute for Drug Control conducted a legal proceeding against the Teva Pharmaceuticals, s.r.o. (a processor), due to a violation of an obligation arisen from § 5a article 5 letter d) of Act on advertising regulation, because as the processor of the advertising on Vicks SymtoMed Complete lemon, forgot to mention an appeal to read the product leaflet.,

The State Institute for Drug Control set a fine upon Teva Pharmaceuticals, s.r.o. in amount of 200 000 CZK, according to § 8a article 7 letter a) of Act on advertising regulation.

The advertising was distributed via the magazine "*MAXIMUM health/care/consultancy AUTUM 2013"*, in amount of 200 000 pcs. On its 12th page with title *"Advertising."*, there was a name of the product, a logo of the VICKS and a large text: "*Only hot drink, which relieve you from 6 symptoms of the fever and cold: flu, headache, paint of muscles and joints, sore throat, clogged nose and cough. 3 substances: paracetamolum 500 mg, phenylephrini hydrochloridum 10 mg, guaifenesinum 200 mg.*" The advertising was also completed by the short information about the product, in small letters, containing: the name of the pharmaceutical, its substances, indications, contraindications, special notification, interactions, a part dedicated to pregnancy and breast feeding, untoward effects, precautions for storage, size of the package, name of marketing authorisation holder, registration number, date of the registration/last revision and text: *"Familiarize yourself with the Summary of the product specifications, before the pharmaceutical delivery. Product is over-the-counter pharmaceutical. Product isn't reimbursed from the public health insurance".* According to the State Institute for Drug Control, the sentence: *"Familiarize yourself with the Summary of the product specifications, before the pharmaceutical delivery."*, is not a clearly visible and readable appeal to read the product leaflet.

5.1.10 Medicom International s.r.o. and Ex-press.cz, spol. s r.o.

The State Institute for Drug Control conducted a legal proceeding against the Medicom International s.r.o. (a submitter) and Ex-press.cz, spol. s r.o. (a processor), due to a violation of an obligation arisen from § 5a article 2 letter a) of Act on advertising regulation, they submitted and processed an advertising, targeting general public, on Minerva, which is a human pharmaceutical available only on prescription

The State Institute for Drug Control set a fine upon Medicom International s.r.o. in amount of 150 000 CZK, according to § 8a article 6 letter b) Act on advertising regulation and also fine upon Ex-press.cz, spol. s r.o. in amount of 25 000 CZK, according to § 8a article 7 letter a) of Act on advertising regulation.

The advertising on Minerva human pharmaceutical had been distributed in a form of brochure with title *"For heavenly beautiful skin"* in amount 3600 pcs from a total printed 15 000 pcs, since January 2013. On 17 pages. The brochure provided detailed answers for 9 questions, like: *"What is acne?", "Which hormones does the combined pastille contain?", "Who can ingest the pastilles?".* The brochure was targeting general public and can be definitely understood as the advertising by its design. The whole brochure is attractively designed and with its title: *"For heavenly beautiful skin"*, it is clear, that the aim of the brochure is to gimmick up the effects of the product for general public, especially for women. In addition, the broadsheet is supplemented by the menstrual period calendar, which can be separated from the broadsheet. Whenever the calendar will be used, the person will get in touch with product, because it contains the Minerva logos.

5.1.11 Abbott Laboratories, s.r.o. and PHARMALINK s.r.o.

The State Institute for Drug Control conducted a legal proceeding against the Abbott Laboratories, s.r.o. (a submitter of the advertising) and PHARMALINK s.r.o. (processor of the adverting, due to a violation of an obligation arisen from § 5a article 8 of Act on advertising regulation, because they submitted and processed an advertising, as reminder on the pharmaceutical Influvac, in a form of stick-on label *"Influvac, protect yourself better against the flu"* and it did not fulfil all the obligations for this type of the advertising.

The State Institute for Drug Control set a fine upon Abbott Laboratories, s.r.o. in amount of 160 000 CZK, according to § 8a article 6 letter b) of Act on advertising regulation and also fine upon PHARMALINK s.r.o. in amount of 20 000 CZK, according to § 8a article 7 letter a) of Act on advertising regulation.

The advertising was in a form stick-on label, suitable for the doors for physicians' offices and hospitals. It showed the old couple, who are protecting themselves under the blanket against the attack of the schematic sketch of the viruses and the text: *"protect yourself better against the flu"* and the in the front of the label are following statements: *"Vaccination is made here", "Influvac", "Strong protection", "www.influvac.cz", "vaccine against the flu".* In case, that the advertising serves as reminder of human pharmaceutical, it mustn't contain anything else than a name, according to marketing authorisation, or its international nom-protective name, if it exists, or the trademark. In this case, it also contains a marketing message *"Strong protection"*, internet webpage *"www.influvac.cz"* and the information about the characteristics of the human pharmaceutical: *"vaccine against the flu".*

5.1.12 ASI Prag s.r.o.

The State Institute for Drug Control conducted a legal proceeding against the ASI Prag s.r.o. (a submitter and a processor), due to a violation of an obligation arisen from § 5 article 4 of Act on advertising regulation, because it submitted and processed an advertising on the human pharmaceutical Sinupret, in which used information *"increase efficiency of the antibiotics"*, which was not according to the summary of product characteristics.

The State Institute for Drug Control set a fine upon ASI Prag s.r.o., in amount of 100 000 CZK, according to § 8a article 6 letter b) and § 8a article 7 letter a) of Act on advertising regulation.

The advertising on Sinupret was distributed via the green-white leaflets, which contained a picture of woman's face with flower on her nose, followed by 2 sentences: *"Sinupret for every nose!"* and "*Sinupret, relieve to your nose during the cold and runny nose"* and a logo of ASI Prag s.r.o.. Inside the leaflet, there was a description of the product and pictures of the herbs and following statement: *"Sinupret - effective treatment of cold, runny nose, sinusitis ... increase efficiency of the antibiotics".* This marketing message can raise a presumption, that Sinupret will increase efficiency of the antibiotics. According to the approved summary of product characteristics, there are not any indications, that the product could increase or effect the treatment by antibiotics in anyway. It only indicates, that the product can be used as a supportive therapy for the antibacterial treatment.

5.1.13 Wyeth Whitehall Czech s.r.o.

The State Institute for Drug Control conducted a legal proceeding against Wyeth Whitehall Czech s.r.o. (a submitter and a processor), due to a violation of an obligation arisen from § 2 article 3 letter of Act on advertising regulation, because the company submitted and processed an advertising, on the human pharmaceutical Prevenar, which used the motive of fear.

The State Institute for Drug Control set a fine upon Wyeth Whitehall Czech s.r.o. in amount of 380 000 CZK, according to § 8a article 6 letter b) of Act on advertising regulation.

The advertising was distributed via the magazines *"Maminka"*, n. 9/2007, and *"Betynka"*, from June to December 2006 and on the internet webpage *"www.minibazar.com".* In the printed form of the advertising, there was a predominant text: *"My little sister Míša, as small child, felt sick and now she can't properly walk and hear."*. First part of the text described a case of child, which felt ill with pneumococcal meningitis (brain fever), which caused a hearing loss and a partial poliomyelitis (paralysis). Further the text mentioned, that we can protect ourselves against such a handicap via the use of the Prevenar vaccination, which was followed by the picture of the reputed sibling of the handicapped girl with a child drawing of his sister with crutches and himself and slogans: *"Do not hesitate"*, *"Protect your children by vaccination"*. Online version of the advertising, on *"www.minibazar.com"*, contained a picture of the reputed sibling of the handicapped girl with a child drawing of his sister with crutches and himself with text: *"My little sister Míša, as small child, felt sick and now she can't properly walk and hear"*, followed by slogans: *"Protect your children by early vaccination"*, *"Protect your children against the pneumococcal meningitis by the vaccination*" and *"Pneumococcus belongs to the most frequent sources of the serious illnesses, such as: acute purulent meningitis (brain fever) , blood-poisoning (sepsis), pneumonia, inflammation of the middle ear (otitis media)".* Wyeth Whitehall Czech s.r.o. targeted the most sensible part of the society – parents, especially mothers. So, any advertising, targeting sensible part of the society, must fulfil all the obligations given by the law without any reserves and also must care about the ethical side of it, according to the State Institute for Drug Control.

5.1.14 TEREZIA COMPANY s.r.o.

The Council for Radio and Television Broadcasting conducted a legal proceeding against the TEREZIA COMPANY s.r.o. (a submitter), due to a violation of an obligation arisen from § 5d article 2 letter d) of Act on advertising regulation, because it submitted an advertising/teleshopping promoting sea buckthorn oil, which imputed the prevention and treatment effects to the food supplement, which could be confusing for the viewers.

The Council for Radio and Television Broadcasting set a fine upon TEREZIA COMPANY s.r.o., in amount of 100 000 CZK, according to §8a article 2 letter g) and § 8a article 6 letter b) of Act on advertising regulation.

The advertising/teleshopping was aired on 28th May 2013 from 12:55:53 on TV Šlágr and it was formulated into a presentation, led by Ing. Ivan Jablonský from The Czech University of Life Sciences, in which he presented the characteristics of the sea buckthorn oil, including explicit statement: "*The internal ingestion of the product is used during the treatment of the illnesses of gastrointestinal tract, favourably effects the treatment of boils, cardiovascular diseases and it is also used for treatment of the piles*". So, the advertising imputes medical characteristics to the sea buckthorn oil, which it is prohibited, because the product does not belong to the human pharmaceuticals.

5.1.15 Zentiva, k. s.

The Council for Radio and Television Broadcasting conducted a legal proceeding against the Zentiva, k. s. (a submitter), due to a violation of an obligation arisen from § 5d article 3 of Act on advertising regulation, because the advertising/sponsor message on Calibrum Activin, which is food supplement, did not contain a clearly visible text *"Food supplement"*.

The Council for Radio and Television Broadcasting set a fine upon Zentiva, k. s., in amount of 100 000 CZK, according to §8a article 2 letter g) and § 8a article 6 letter b) of Act on advertising regulation.

The advertising, which was aired for the first time on 8th February 2010 from 19:58:49 on ČT1 and repeated 20 times on channels ČT1 and ČT2, was in a form of sponsor message of Zentiva k. s., which was the official partner of Czech Olympic team on the Winter Olympic games in Vancouver. In the TV spot, there was a skier, who made a flip in the air, followed by a shot on the package of the vitamins Cali-

brum Activin with the logos of the Czech Olympic team and Zentiva k. s. and the sentences: *"Official partner of Czech Olympic team 2008-2012"* and "*Programme sponsor"*. The spot was appended by the sounds of skies and slogan: *"Multivitamins Calibrum return you in the game".* Even in the sponsor message, which refers to the pharmaceutical, there must be a clear formulation of the warning, that the product is a food supplement, otherwise it could be confusing for the viewers, because they could misplace it with the human pharmaceutical.

5.1.16 Europlant s.r.o.

The Council for Radio and Television Broadcasting conducted a legal proceeding against the Europlant s.r.o. (a submitter), due to a violation of an obligation arisen from § 5a article 5 letter c) of Act on advertising regulation, because the submitted advertising on the human pharmaceutical Švédské kapky RIVIERA, did not contain a clear indication, how to ingest it.

The Council for Radio and Television Broadcasting set a fine upon Europlant s.r.o., in amount of 20 000 CZK, according to §8a article 2 letter g) and § 8a article 6 letter b) of Act on advertising regulation.

The advertising was aired on the radio station COUNTRY RADIO on 28th November 2011 at 7:40:13, 8:58:14, 9:41:33, 10:19:57 and it contained male and female voice, who were reading following transcript:
Male voice: *"Even our grandmothers have advised to use the Švédské kapky RIVIERA, when you have a problem with the digestion and no appetite."*
Female voice: "*Original Švédské kapky RIVIERA will help you, when you have a stomach-ache, during the flatulency, the lack of the appetite and the problems with a digestion. Only these with red seal are the authentic ones. Ask for them in your pharmacy."*
Male voice: *Registered as a human pharmaceutical. Closely read the product leaflet. In case of untoward effects, consult them with your doctor or pharmacist."* However, the clear indication, how to ingest the pharmaceutical, was missing.

5.1.17 Allivictus s.r.o.

The Council for Radio and Television Broadcasting conducted a legal proceeding against the Allivictus s.r.o. (a submitter), due to a violation of an obligation arisen from § 5d article 2 letter d) of Act on advertising regulation, because they submitted and advertising promoting Allivictus, which contained a statement: *"Allivictus tincture, made from original Czech garlic, supports the immunity system, solves cold, flu*

and infection." So, the consumer could be confused by the effects of the product, that it can prevent and treat the diseases.

The Council for Radio and Television Broadcasting set a fine upon Allivictus s.r.o., in amount of 1 800 000 CZK, according to §8a article 2 letter g) and § 8a article 6 letter b) of Act on advertising regulation.

The advertising was aired on 12th September 2011 from 2:33:26 on television channel Prima Televize. The spot begun with the shot on the athlete with badminton racket and on the net, followed by the moment from the game, appended by audio annotation: *"Petr Koukal, multiple Czech champion in badminton."* After the couple of moments, there was a shot on Petr Koukal, packing his stuff, and followed by a comment: *"Just when he was getting between the world elite, the illness came."* Afterwards, he explained his situation in his own worlds: *"My fight with cancer was the most difficult match in my life. Now, I'm going back to the shape, besides the training, Allivictus helps me."* The next scene took place in the changing area, where he opened a wardrobe and ingested the Allivictus and commented the situation as: *"I tried to balance the chemotherapy with something purely natural. I believe, that Allivictus strengthens my weakened immunity system."* At the end of the spot, there was a short statement: *"Allivictus, immunity in every drop".* It's prohibited to mystify the customers by imputing the medical effects to the food supplement, because the customer can get an illusion, that Allivictus help to prevent and treat cold, flu and infection and have positive effect during the treatment of a such a serious illness, as cancer is.

5.1.18 Walmark, a. s.

The Council for Radio and Television Broadcasting conducted a legal proceeding against the Walmark, a. s. (a submitter), due to a violation of an obligation arisen from § 5d article 2 letter d) of Act on advertising regulation, because they submitted a marketing message, which was imputing the prevention and treatment effects of attenuation of the inflammation of the joints to the food supplement Proenzi 3+.

The Council for Radio and Television Broadcasting set a fine upon Walmark, a. s. in amount of 1 100 000 CZK, according to §8a article 2 letter g) and § 8a article 6 letter b) of Act on advertising regulation.

The marketing message was aired on 30.10.2011 from 18:15 on NOVA channel, in a form dialog in the TV show "*Rady ptáka Loskutáka"* in its teleshopping part "*Tipy Ptáka Loskutáka*", when the host of the show led a dialog with a nutrition specialist Ivan Mládek:

Host: "*When you have a problem with your knees or you are diagnosed with tennis elbow, it's just too late for any prevention, but it's never too late to care about your joints. The answer will be given by the nutrition specialist Ivan Mach."*
Mr. Mach: *"The solution is relatively easy,* ***there is a food supplement Proenzi 3+ with its active substances, which get into your hurt knee, strengthen it, supress the inflammation and replenish the structural component of cartilage, spongy bone and the connective tissues.****"*
Host: *"Is its efficiency somehow documented?"*
Mr. Mach: *"Not only documented, but also proved. Substances of the product belong to the sysadoa group, which are slowly absorbent* ***substances with the anti-inflammatory effect****, which was proved by many scientific researches, available on Proenzi webpage."*
Host: *"Who can use the product?"*
Mr. Mach: *"Target market for this product is people over 40 years old, but it doesn't mean, that the product can't be used* ***as prevention by younger people, who overtax their joints by carrying the heavy weights, hard labour or by the professional sport and even the overweight people and much older ones****."*
The bold text, in the transcript, shows the evidence of imputing of prevention and treatment effects to the food supplement Proenzi 3+, which is prohibited by the law.

5.1.19 GREEN – SWAN PHARMACEUTICALS CR, a. s.

The law suit, in which GREEN – SWAN PHARMACEUTICALS CR, a. s. appealed to Municipal Court in Prague against the decision of The Council for Radio and Television Broadcasting, to set a fine upon GREEN – SWAN PHARMACEUTICALS CR, a. s., due to a violation of an obligation arisen from § 5d article 3 of Act on advertising regulation, because the company should submit an advertisement on a product Intersun, which was registered and approved by Ministry of Health as a food supplement. However, the advertisement did not contain a clearly visible and readable text *"food supplement"*. The text in the advertisement had white colour and it was placed at pale yellow background and it was visible only for 2 seconds. The advertising was aired in 73 repeats on TV channels Prima and Nova in premiere on 6. 5. 2008 at 8:41:16 on TV channel Prima. The general public could commute the human pharmaceutical for the food supplement, due to short airtime and non-contrastive warning text of *"food supplement*"

The Council for Radio and Television Broadcasting set a fine upon GREEN – SWAN PHARMACEUTICALS CR, a. s. in amount of 400 000 CZK.

The company GREEN – SWAN PHARMACEUTICALS CR appealed against the decision of The Council for Radio and Television Broadcasting to Municipal Court in Prague, which made an appellate review on the decision. Municipal Court in Prague found the fine legitimate on 30. 6. 2009. The court, among other evidences, watched the advertisement on Intersun and confirmed, that the information about the *"food supplement"* wasn't clearly visible.

5.1.20 Novartis, s. r. o.

The law suit, in which Novartis, s. r. o. appealed to Municipal Court in Prague against the decision of The Council for Radio and Television Broadcasting, to set a fine upon Novartis, s. r. o., due to a violation of an obligation arisen from § 5a article 5 letter d) of Act on advertising regulation, because Novartis, s. r. o. submitted an advertisement on product Lamisil, which didn't contain a clearly visible appeal to read the product leaflet, which was fined by The Council for Radio and Television Broadcasting in amount of 400 000 CZK.

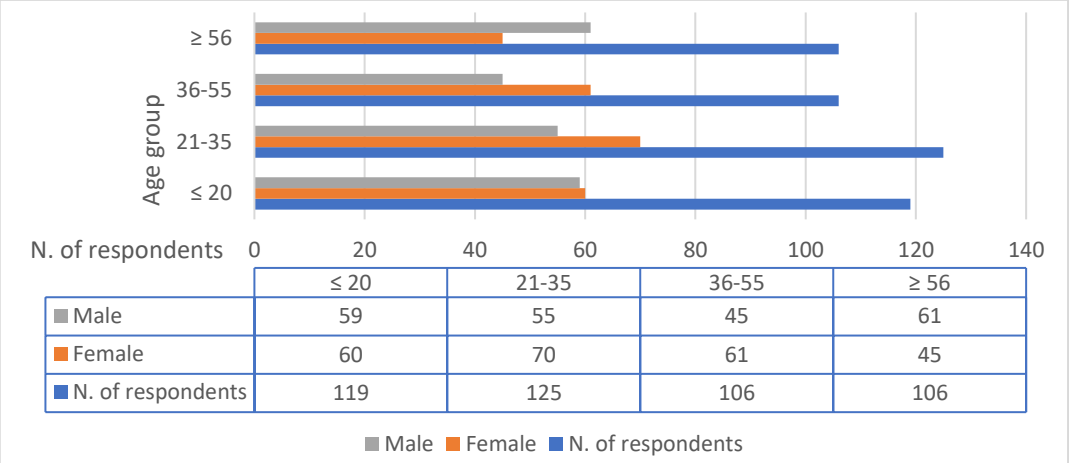
The advertisement was in a form of 20 second length TV spot, which contained multiple images of the man, who treated his foot with a liniment, suddenly the Lamisil 1x tube flew by man's head, which was followed by the detail shot on the tube, then by picture with liniment application on the bottom side of the foot and picture showing man and woman, touching their feet. At the end of the spot, there was a shot on Lamisil 1x package with highlighted text: *"1 application is enough"*, under which is small and hardly readable text with 2 rows: *"Lamisil 1x – dermal dilution 1%. The pharmaceutical for a single-shot use, contains terbinafine, carefully read the product leaflet."* Everything was supplemented with an audio: *"Do you think, that the treatment of the mycosis takes ages? Try new revolutionary Lamisil 1x. Only one application will create a medical layer, which lasts for many days and eliminate the mycosis. That´s why only one application is needed! Fully enjoy the gentle touches once again! Lamisil 1x – 1 application is enough!"*

The decision of The Council for Radio and Television Broadcasting was confirmed by the Municipal Court, because it would be too difficult for the consumer to orientate oneself in the plot, catch and read the appeal to read the product leaflet during 3 seconds, the appeal was shown. The size of the text is not a decisive criterion, because the compact perception must be taken into account, like an airing time, supporting text, graphical design and others.

5.2 Sensitivity on the advertising on the pharmaceuticals and its regulation

5.2.1 Target group description

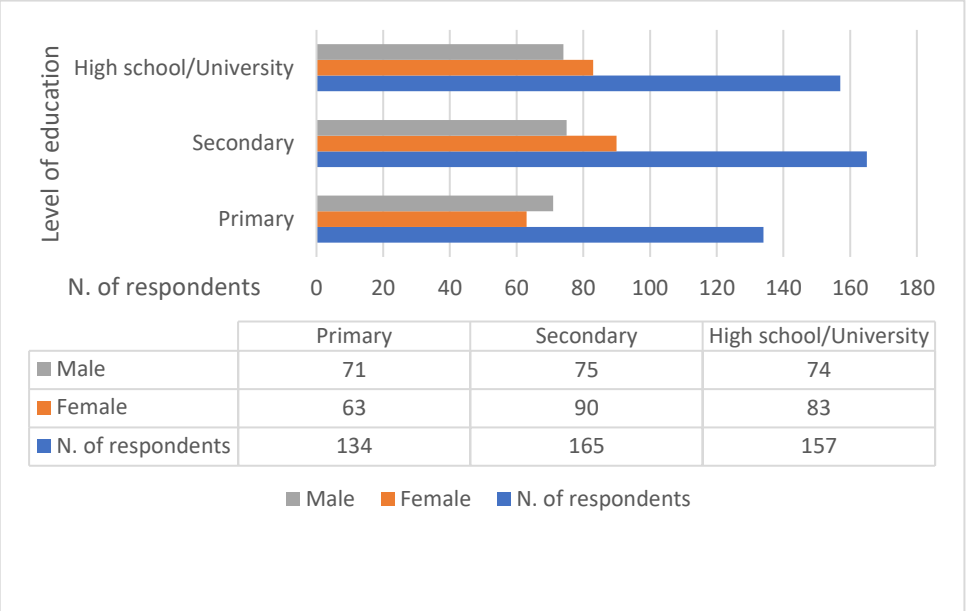
The secondary data was obtained via the questionnaire, which was distributed from 15th to 30th of April 2017. Total number of respondents collected was 456. 329 respondents (72,15% of all the respondents) answered via online form of the questionnaire and 127 respondents (27,85% of all the respondents) used a paper form. The gender ratio was slightly in a favour of female respondents, because number of answers from female respondents was 236 (51,75% of all the respondents), compering to 220 answers collected from male respondents (48,25% of all the respondents). The partial goal of the questionnaire was to obtain 100 respondents in each age category: ≤ 20, 21-35, 36-55 and ≥ 56 years, which was successfully achieved. The following graph shows the distribution of the respondents among the each age category, including the gender distribution within the age group.



	≤ 20	21-35	36-55	≥ 56
Male	59	55	45	61
Female	60	70	61	45
N. of respondents	119	125	106	106

Fig. 2 Distribution of respondents between genders and age group
Source: Questionnaire, n=456

The age category with highest number of respondents was group with the age range 21-35. The lowest number of respondents was simultaneously achieved within group with the age range 36-55 and over 56 years. The questionnaire also observed a distribution of the respondents according to the level of education, which is presented on the graph, including the gender distribution within the group.



	Primary	Secondary	High school/University
Male	71	75	74
Female	63	90	83
N. of respondents	134	165	157

Fig. 3 Distribution of respondents between the level of education and genders
Source: The questionnaire, n=456

The most numerous group of respondents, according to level of education, was the group with secondary level of education, followed by high school/university and primary level. Based on the collected respondents, further analysis of the results, based on the level of education, will be left out, because it would be distorted and it would just copy the results based on the distribution of the respondents between the age groups, because from 134 respondents with primary education, 108 respondents belong also to youngest age group.

5.2.2 The general questions on advertising on pharmaceuticals

The questions targeting the adverting on the pharmaceuticals start with the question on the most frequent type of advertising media via the respondents come across the advertising on pharmaceuticals.

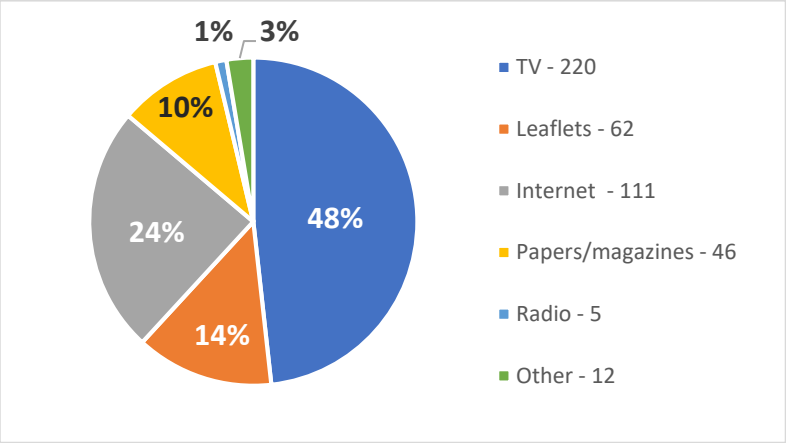
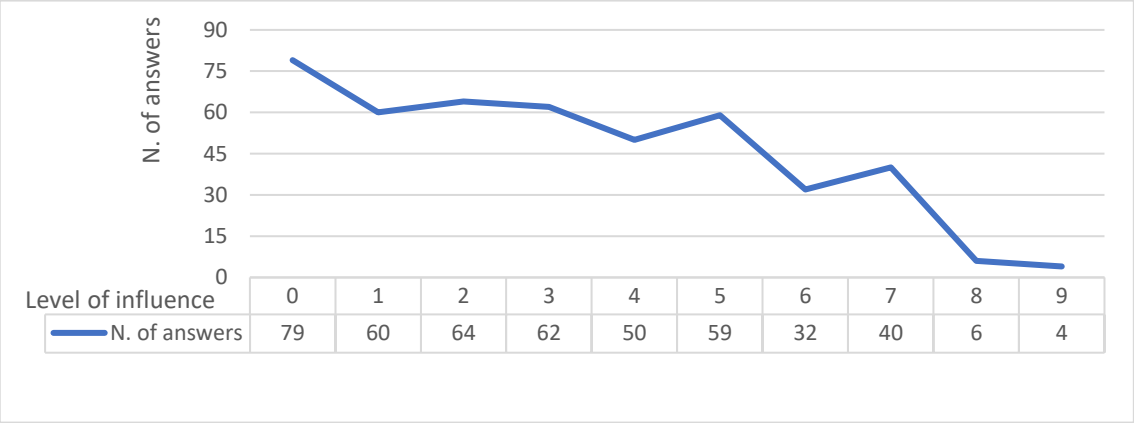


Fig. 4 Types of media
Source: The questionnaire, n=456

The most common type of media via the respondents came across the advertising on pharmaceuticals was with a big lead, a television, with 220 answers. Followed by the internet with 111 answers. Within the other category, respondents mentioned billboards 4 times (0,87% from the total number of answers) and the waiting rooms of the medical practices 8 times (1,75% from the total number of answers). We can see the trend, that the youngest generation prefer the "new" sources, like internet.

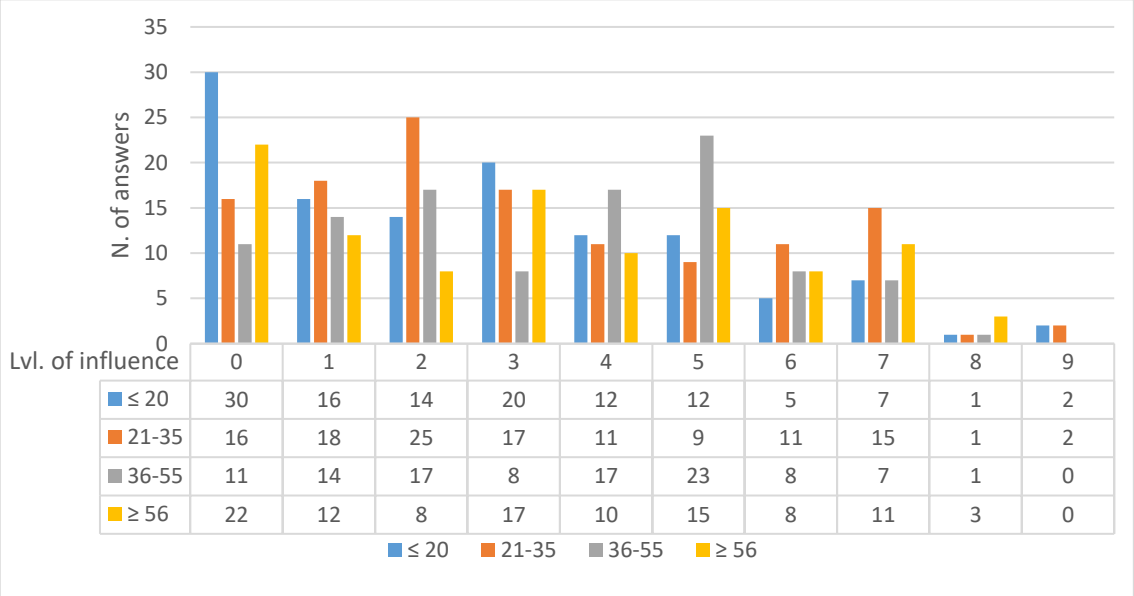
The second general question examined, how much are the respondents influence by the advertising during the purchase of over-the-counter pharmaceuticals. The answers were obtained via scale from 0 – 9, which 0 represents minimum and 9 represents maximum. The average value was 3,125 and the median of the values was 3. In general, the adverting doesn't play a significant role in the purchase of the OTC pharmaceuticals. Also, there is not a significant difference in the decision-making process of male and female respondents the average influence on both groups was almost similar to the average.



Level of influence	0	1	2	3	4	5	6	7	8	9
N. of answers	79	60	64	62	50	59	32	40	6	4

Fig. 5 Influence of advertising on the OTC pharmaceuticals on consumer
Source: The questionnaire, n=456

However, we can observe in the next table and graph, which show the level of influence of the advertising on the groups, divided by the age:



Lvl. of influence	0	1	2	3	4	5	6	7	8	9
≤ 20	30	16	14	20	12	12	5	7	1	2
21-35	16	18	25	17	11	9	11	15	1	2
36-55	11	14	17	8	17	23	8	7	1	0
≥ 56	22	12	8	17	10	15	8	11	3	0

Fig. 6 Amount of influence among each age group
Source: The questionnaire, n=456

The most influenced group by the advertising is the age group 21-35 years old, because the average of the group is higher than the general average, which is equal to 3,125. The less influenced group is the oldest target group with lowest average.

Tab. 4 Average influence of the advertising on each age group

Age group	≤ 20	21-35	36-55	≥ 56
Average	3,1356	3,2050	3,1253	3,1029

Source: The questionnaire, n=456

5.2.3 Formal aspects of the advertising

The first block of questions in the questionnaire targeting the formal aspect of the advertising on pharmaceuticals, such as: necessity to mention the correct ingestion/use of the pharmaceutical, necessity to provide an appeal to read the product leaflet. The question: *"Is it important, that the advert contains information, how to ingest the pharmaceutical"* was based on the cases:

- The Council for Radio and Television Broadcasting against Europlant s.r.o.
- The State Institute for Drug Control against SCHLECKER a.s.
- The State Institute for Drug Control against EULEK-PHARMA s.r.o.

Mentioned companies forgot to include in the advertising, clearly visible text with the information, how to correctly ingest the pharmaceutical. The purpose of the question is to evaluate the current regulations from the point of the final consumer. If it is important for them to know this information directly from the advertising.

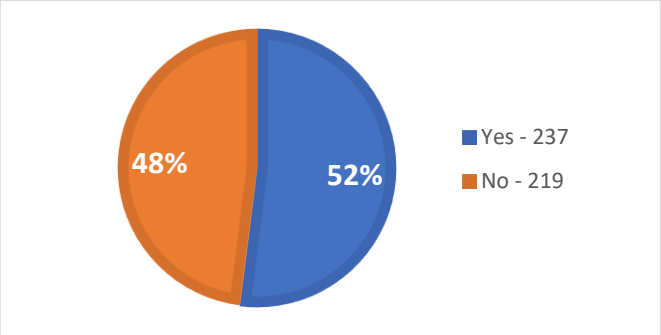


Fig. 7 Importance to include a clearly visible indication, how to ingest the pharmaceutical
Source: the questionnaire, n=456

In general, more respondents go along with the current regulation and it is important for them to know this piece of information directly from the advertising.

There is not any significant difference in opinions between genders. Answers of female respondents were: 120 for Yes and 116 for No and in case of male respondents: 117 for Yes and 103 for No. However, in case of the distribution of respondents among the age categorizes, we can observe a trend in their opinions.

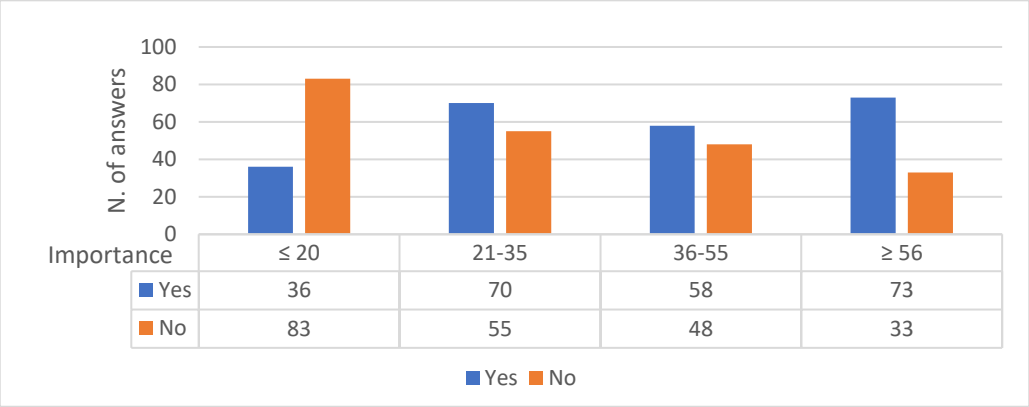


Fig. 8 Importance to include a clearly visible indication, how to ingest the pharmaceutical, based on the age category
Source: The questionnaire, n=456

The graph above shows, that the importance to know, how to correctly ingest the pharmaceutical, increases with the age of the respondents. Between the youngest age group (n=119), the proportion is 69,75% (83 answers) for No and only 30,25% (36 answers) for Yes. However, in the oldest age category (n=106), the proportion is inverse: 68,87% (73 answers) for Yes and 31,14% (33 answers) for No.

Between the common mistakes of the companies was an omission of the appeal to read a product leaflet, which was documented in the following cases:

- The Council for Radio and Television Broadcasting against Novartis, s. r. o.
- The State Institute for Drug Control against EULEK-PHARMA s.r.o.
- The State Institute for Drug Control against PRO.MED.CS Praha a.s. & natural person Mr. Vladimír STAŇEK – grafické studio Vlado

So, the question: "*Is it important for you, that the advertising contains an appeal to read the product leaflet?*", had a purpose to estimate the importance of this appeal in the adverting on pharmaceuticals between the respondents.
The answers for this question were more significant on the overall scale compering to the previous question. All the respondents tended to the opinion, that this appeal is a necessary part of the advertising. 57% of respondents were in favour of current

situation of the regulation and 43% of respondents found the obligation to provide an appeal as unimportant.

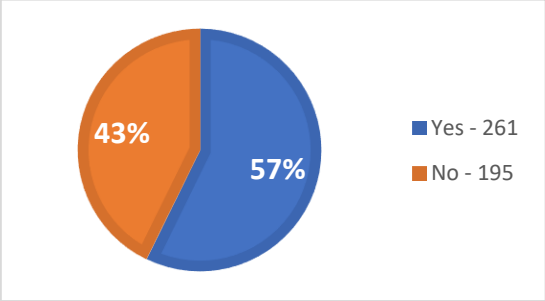


Fig. 9 Importance to include an appeal to read the product leaflet
Source: the questionnaire, n=456

There was not any significant trend among the categorizes of respondents, based on their age. The opinions of each age group correspond to overall statistics. However, the answers from the respondents, based on their gender, show the deviation from the overall statistics. Male respondents are more sensitive compering to the female respondents, because the overall statistics shows, that 61,36% of male respondents answered Yes on this question, compering to only 53,39% of female respondents.

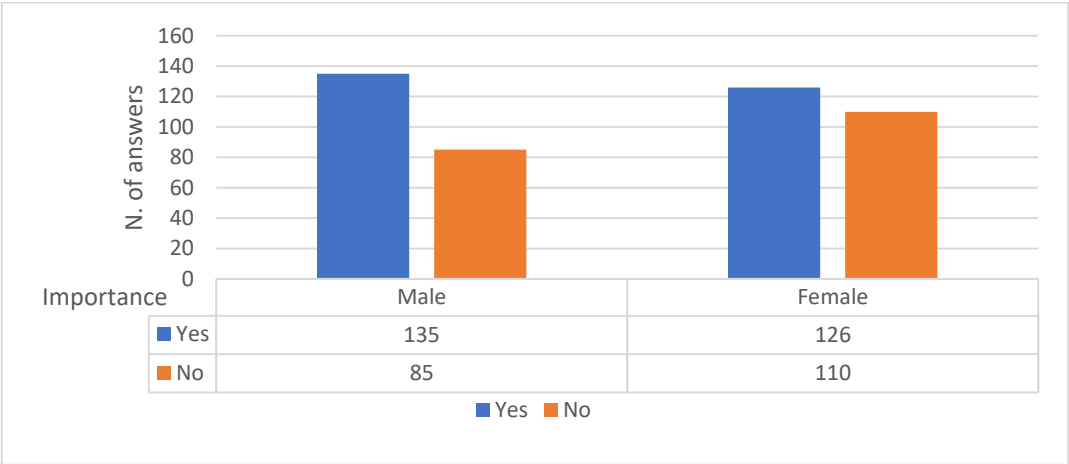


Fig. 10 Importance to include an appeal to read the product leaflet, based on the gender
Source: The questionnaire, n=456

Very important aspect of the advertising on the food supplements is to include a clearly visible and readable text or warning, that the product is a food supplement not a pharmaceutical, to prevent a confusion of final consumers, which was presented on the following cases:

- The Council for Radio and Television Broadcasting vs. GREEN – SWAN PHARMACEUTICALS CR, a. s.
- The Council for Radio and Television Broadcasting vs. Zentiva, k. s.

So, the following questions observe the necessity of placement of this appeal and the experience and opinion of the respondents on the advertising on the food supplements.

Based on the collected answers, the respondents had a strict opinion on the importance of this warning. 90% of all the respondents provided support to the current regulation and emphasise the necessity of the placement of this warning, which protect them against the replacing the pharmaceutical by the food supplement.

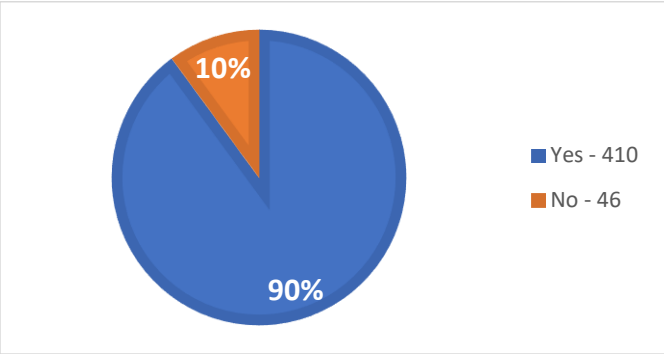


Fig. 11 Necessity of the placement of the text *"Food supplement"*
Source: The questionnaire, n=456

Tab. 5 Distribution of the opinion on this problem among the genders and age groups

	N. of answers Yes	N. of answers No	Percentage for Yes	Percentage for No
Male	199	21	90,45%	9,55%
Female	211	25	89,41%	10,59
≤ 20	108	11	90,76%	9,24%
21-35	113	12	90,40%	9,60%
36-55	91	15	85,85%	14,15%
≥ 56	98	8	92,45%	7,55%

Source: The questionnaire, n=456

As a one potential explanation of this strict opinion could be a previous experience with the misleading advertising on food supplement. So, the question above

was supplemented by a question on the previous experience: *"Have you ever been misled with replacing the pharmaceutical by the food supplement, due to missing warning text, wrong size and colour of the text or short airing time?".*

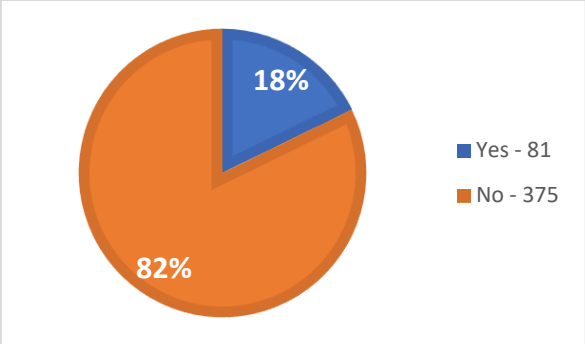


Fig. 12 Have you ever been misled by the adverting on the food supplement
Source: The questionnaire, n=456

81 respondents (n=456) had a previous experience with the misleading advertising on the food supplement. Only 4 from them (n=81) answered No on previous question, which means, that 77 respondents answered Yes. So, we can observe a correlation between the previous experience with misleading advertising and necessity to include a warning text for the food supplement.

The current regulation specifies, that the advertising has to contain text *"Food supplement*" and it has to be clearly visible and readable, but there are no other specifications for the text. So, another question examined, if there is a necessity to introduce an uniform labelling for the food supplement and pharmaceuticals, to prevent their replacing.

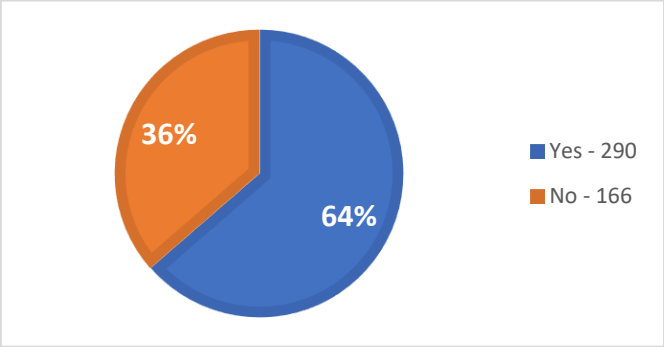


Fig. 13 Do you think, that it is necessary to introduce a uniform labelling
Source: the questionnaire, n =456

The overall statistics shows, that 64% of respondents are for tighter or more detailed regulations, which specify the warning, that the product is not pharmaceutical, but a food supplement. The respondents had an opportunity to provide own

ideas on the warning specification. The most mentioned type was unique symbol or logo for each product, which should be placed on the package and in the advertising. Another idea was a different colour plate or colour design, stamp with text *"This is not a pharmaceutical!„* and in case of an audio-visual advertising a verbal warning. Also in this case, we can observe a correlation between the necessity to introduce the uniform labelling and previous experience with the misleading advertising on food supplement, because from the 81 respondents, who answered positively on the question focusing on the previous experience with misleading advertising, 71 of them (87,65%) are also in a favour to introduce a uniform labelling.

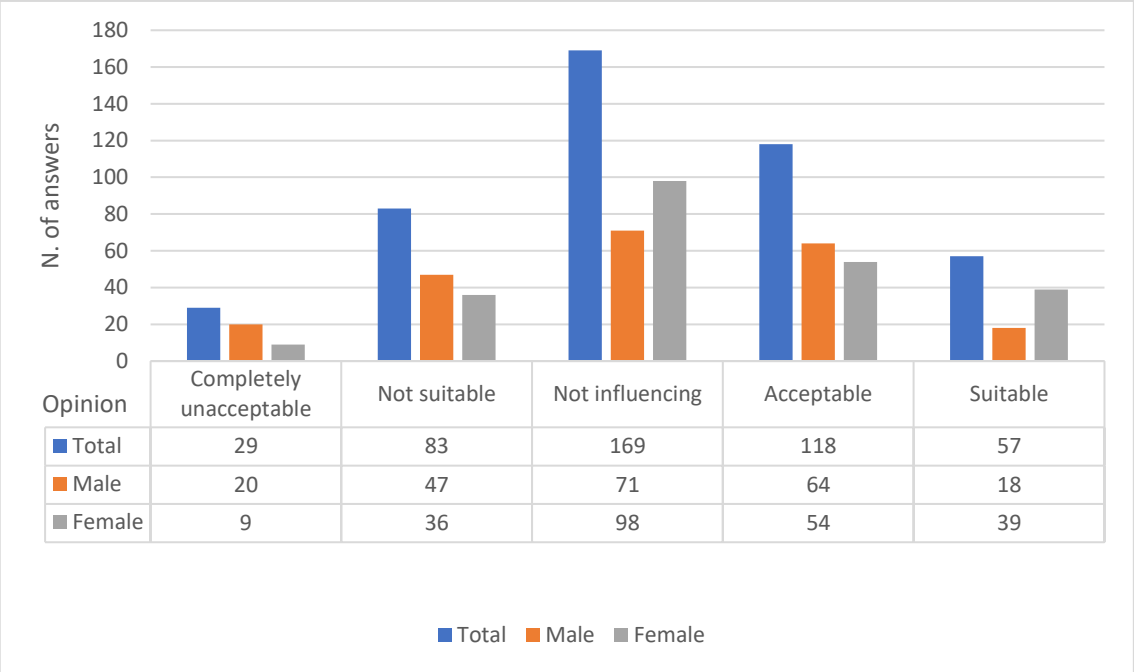
5.2.4 Content of the advertising

The content of the adverting was also a subject of many reviews of The Council for Radio and Television Broadcasting and the State Institute for Drug Control, because it contains advertising elements, which could mislead the final consumer or contradict good manners, like to menace morality in a generally unacceptable way or the use of the motive of fear.

Usage of motive of fear in the advertising is prohibited by the legislation, but we observed several cases of the violation of this regulation, like:

- State Institute for Drug Control against Wyeth Whitehall Czech s.r.o.
- State Institute for Drug Control against GlaxoSmithKline, s.r.o. & MARK/BBDO, a.s.

It belongs between the strictest controlled area of the advertising by the State Institute for Drug Control with the highest sanctions, as we can see in the table Tab. 1. The questionnaire contained a replication of the content of the advertising on the vaccination against hepatitis from the companies GlaxoSmithKline, s.r.o. and MARK/BBDO, a.s., with aim to observe an opinion of the respondents on the usage of the motive of the fear and it was supplemented by the question, which examines the knowledge of the respondents on the legality of this element.



Opinion	Completely unacceptable	Not suitable	Not influencing	Acceptable	Suitable
Total	29	83	169	118	57
Male	20	47	71	64	18
Female	9	36	98	54	39

Fig. 14 Opinions on the adverting on the vaccination against the hepatitis
Source: The questionnaire, n=456

The results show, that most of the respondents (37,06% of all the respondents) are not influenced the motive of the fear used in the advertising, which means, that the advertising doesn't evoke any negative or positive emotions. Rest of the answers could be divided into 2 groups: respondents, who are positively influence by the advertising (representing the respondents with acceptable and suitable opinion on the advertising) and negatively influenced ones, which represent the opinion not suitable and completely unsuitable, and it should be prohibited. Total number of positive responses is 175 and total number of negative responses is 112. Percentage division of these 3 main opinion trends is shown on the pie graph below.

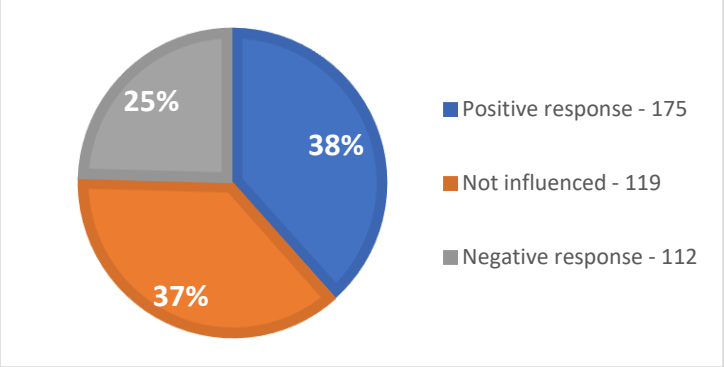


Fig. 15 Division of 3 main opinion trends
Source: The questionnaire, n=456

Based on the results, we can say, that the advertising fulfilled its goal and positively influenced the respondents, which could be dangerous, because it stimulated the emotions of the respondents. So, this is an argument for such a strict control by The State Institute for Drug Control. The male respondents have more distinctive opinion, compering to the female respondents and they also have more negative response to the adverting.

Tab. 6 Distribution of the opinions on the adverting on the vaccination, based on the genders

	N. of male answers (n=220)	N. of female answers (n=236)	% of male answers on total	% of female answers on total
Positive response	82	93	37,27%	39,41%
Not influenced	71	98	32,27%	41,52%
Negative response	67	45	30,46%	19,07%

Source: The questionnaire, n=456

Based on the results of the target groups, divided by the age, we can observe a trend, that the usage of the fear in the advertising have more negative impact with the increasing age, because youngest respondents tend to be positively or not influenced, compering to the oldest generation, which tends to be more likely negatively or not influenced.

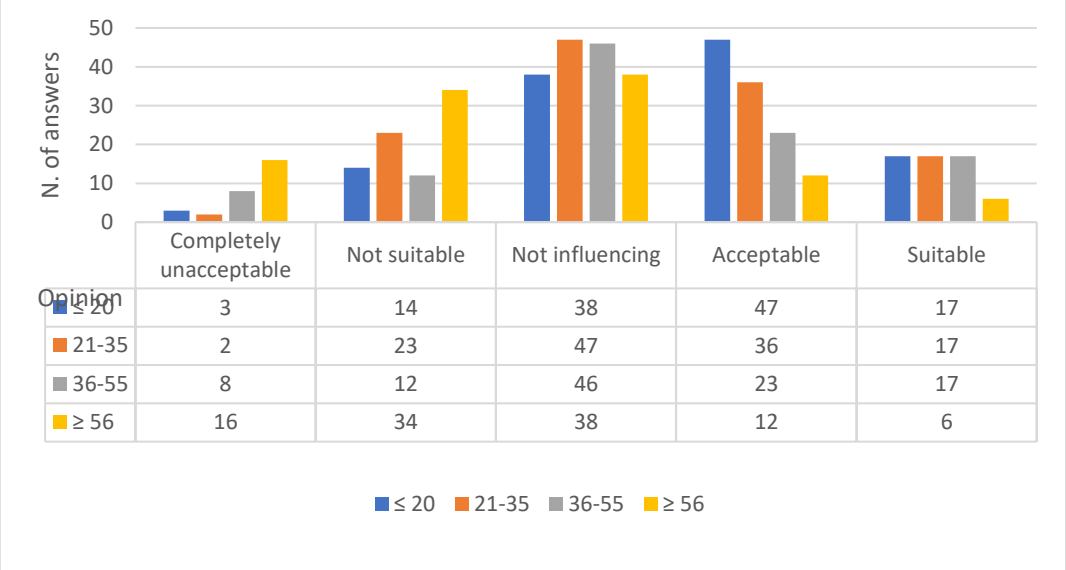


Fig. 16 Opinions on the adverting on the vaccination against the hepatitis, between the age groups
Source: The questionnaire, n=456

As it was mentioned, the usage of the motive of fear is prohibited by law. However, 71% of the respondents thought, that the usage of the motive of the fear is legal and it doesn't violate the law. Such a high number is alarming and it may be a reason for such a strict control by the State Institute for Drug Control.

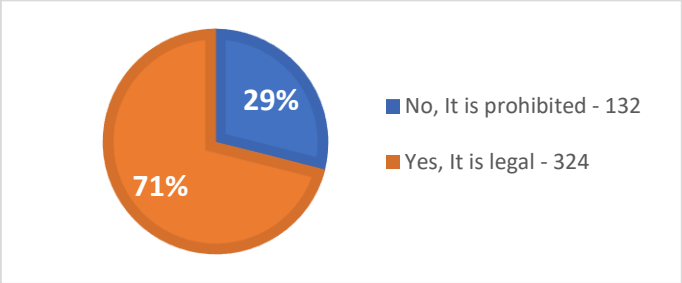


Fig. 17 Legality of the use of the motive of fear in an advertising on the pharmaceuticals
Source: The questionnaire, n=456

The knowledge of the regulation increases with the age of the respondents, as it is shown on the following graph:

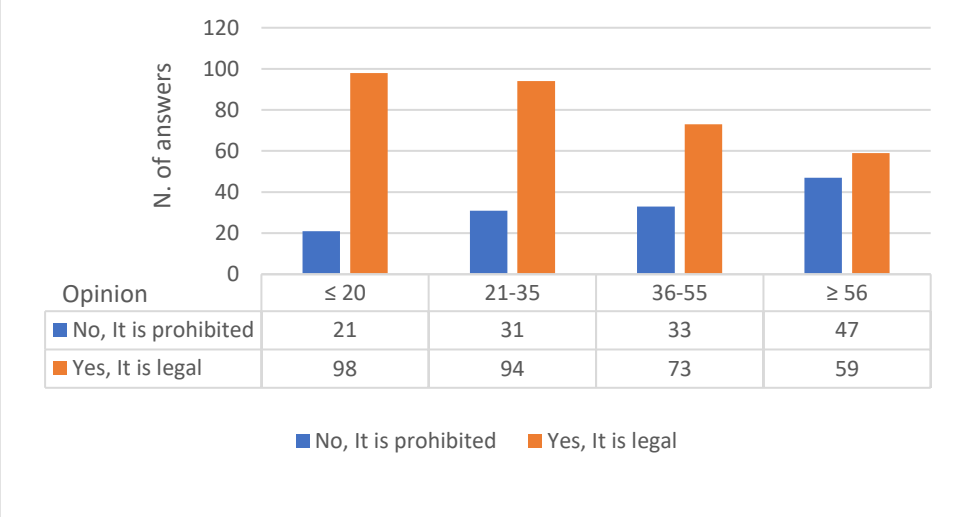


Fig. 18 Legality of the use of the motive of fear in an advertising on the pharmaceuticals, based on the age category
Source: The questionnaire, n=456

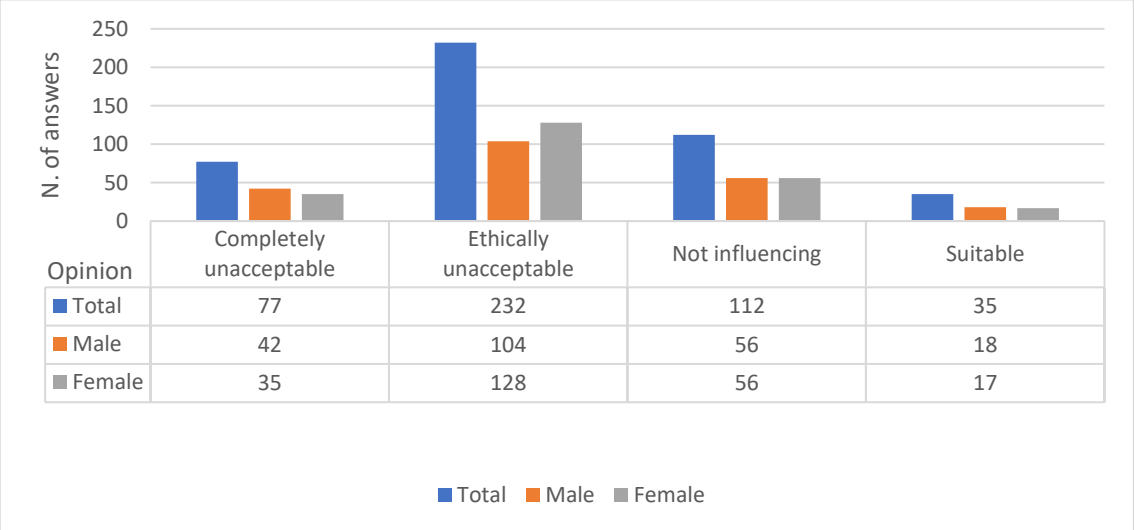
82,35% of the respondents in the youngest group (n=119) thought, that the usage of the motive of the fear is according to law, which is higher by 11%, than the average of all the respondents, and only 17,65% of the youngest respondents correctly answered on the question, which is alarming. The proportion of the correct answers, between the oldest respondents, increases, but it is still in favour of the

legitimacy. 55,66% of the oldest respondents thought, that it is legal. In general, the results of the oldest target group are 16% below the average of all the answers.

Between the elements, which are prohibited by the law, belong ones, which contain explicit content i.e. the elements, which contradict the good manners, like to menace morality in a generally unacceptable way. This regulation was known to a submitter of an adverting in case:

- State Institute for Drug Control against MUCOS Pharma CZ, s.r.o.

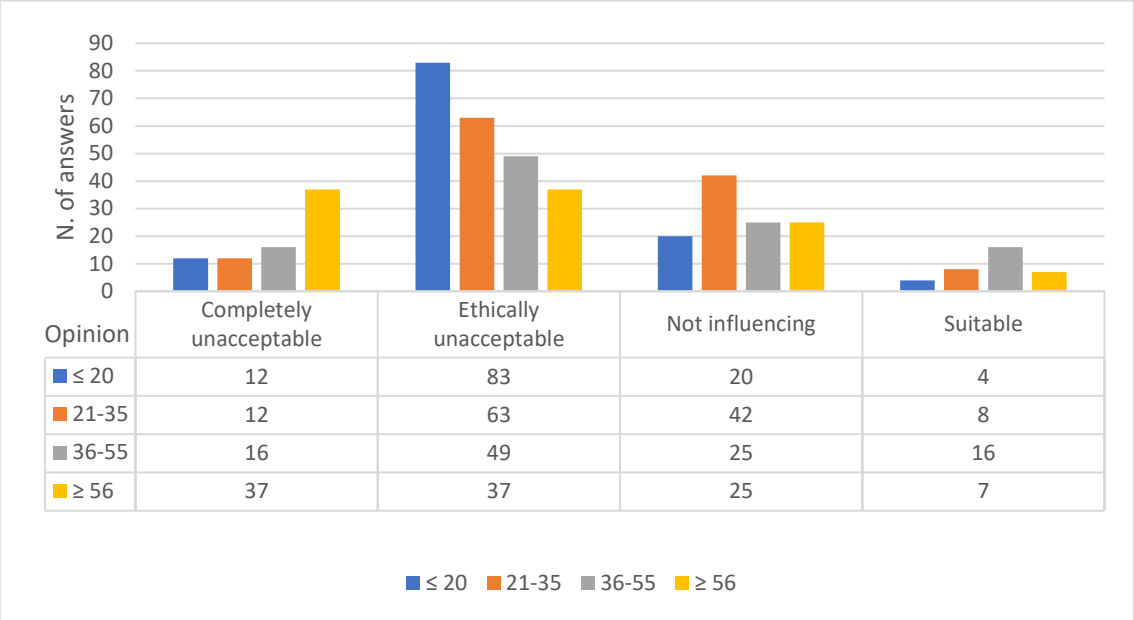
The company covered the pictures, illustrated on the 1st figure, with the text: *"It's prohibited show these pictures due to Act on advertising regulation."* The question was observing their suitability in the advertising, because recently the similar pictures were placed on the packages of the tobacco products, as reminder of the consequences of the smoking. However, these pictures could be used in a same way, to demonstrate the consequences of the untreated wounds.



Opinion	Completely unacceptable	Ethically unacceptable	Not influencing	Suitable
Total	77	232	112	35
Male	42	104	56	18
Female	35	128	56	17

Fig. 19 Suitability of the use of the elements with explicit content
Source: The questionnaire, n=456

Most of the respondents found these pictures ethically unacceptable, followed by the opinion, that they do not evoke any feelings and almost 17% of the respondents thought, that they are completely unacceptable and they should be prohibited and only small amount of the respondents found them suitable. With the increasing age, respondents tended to have more negative opinion on them.



Opinion	Completely unacceptable	Ethically unacceptable	Not influencing	Suitable
≤ 20	12	83	20	4
21-35	12	63	42	8
36-55	16	49	25	16
≥ 56	37	37	25	7

Fig. 20 Suitability of the use of the elements with explicit content, based on the age group
Source: The questionnaire, n=456

Last question, regarding the content of the advertising, observed the experience of the respondents on the advertising on the food supplements with imputed prevention and treatment effects, which is prohibited by the law. The question is based on the following violations of the regulation, which have been found during the research:

- The Council for Radio and Television Broadcasting vs. Walmark, a. s.
- The Council for Radio and Television Broadcasting vs. Allivictus s.r.o.
- The Council for Radio and Television Broadcasting vs. TEREZIA COMPANY s.r.o.

The question simply asked, if the respondent had a previous experience with a food supplement with imputed medical characteristics and the respondents had also an opportunity to provide an example of a such food supplement, if they remembered. The respondents were provided by 3 examples of the food supplements: Proenzi, Centrum vitamins, Dr.Max Simethicon.

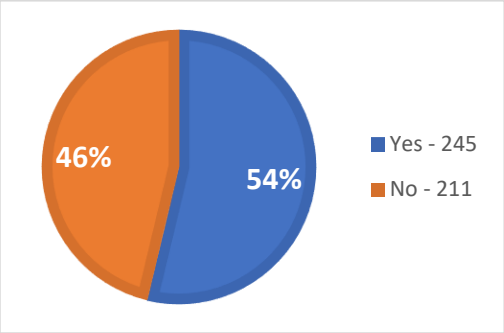


Fig. 21 Previous experience with a food supplement with imputed medical characteristics
Source: The questionnaire, n=456

The results show an interesting statistic, that 54% of all the respondents had a previous experience with the advertising, which imputes the prevention and treatment effects to food supplement. However, the results could be distorted, by the fact, that the respondents were provided by the examples of the food supplements. On the other hand, respondents provided 51 examples of the food supplement, which they thought, that they are the food supplements with imputed prevention and treatment effects. Analysis of the provided the food supplements is made in the table below.

Tab. 7 List of provided supplements by the respondents and its analysis

Name of food supplement	N. of responses	% of the answers from the total number	Is it a food supplement	Note section
Proenzi	10	18,51%	YES	
Wobenzim	9	17,64%	NO	pharmaceutical
Walmark Marťánci	6	11,76%	YES	
Vitamins (in general)	5	9,80%	YES	in general, they are food suppl.
Actimel	4	7,84%	NO	food
GS Condro	4	7,84%	YES	
Preventan	3	5,88%	YES	
Celaskon	3	5,88%	YES	
CEMIO Kamzík	1	1,96%	YES	
Koenzim Q10	1	1,96%	YES	
Walmark Urinal	1	1,96%	YES	
Biopron9	1	1,96%	YES	
Gingko Biloba	1	1,96%	YES	
Swiss Brusinky	1	1,96%	YES	
Oscillococcinum	1	1,96%	NO	pharmaceutical

Source: The questionnaire, n=456

The most mentioned food supplement was Proenzi, but this could be distorted, by providing the name of this food supplement as an example in the question, same with vitamins. Respondents also wrongly choose Wobenzym as a food supplement, because it is registered human pharmaceutical, same with Oscillococcinum. The matter of interest is the reference to the product Actimel, which is categorized as food, but the respondents had an opinion, that the adverting on Actimel could assign it some preventive effects. Maybe just a coincident, but the 9 references to the pharmaceutical Wobenzym are interesting, because the advertising for Wobenzym was

a subject of previous question on suitability of the graphical elements in the advertising.

5.2.5 Pharmaceuticals on prescription

The last group of questions targets advertising on the human pharmaceuticals on prescription, which is prohibited by the Czech legislation, in case, that it targets general public. The aim of these questions is to observe an opinion and a knowledge on a current regulation and the previous experiences of the respondents. The questions are based on 3, cases analysed in the previous part:

- State Institute for Drug Control vs. Medicom International s.r.o. & Ex-press.cz, spol. s r.o.
- State Institute for Drug Control vs. ALK A/S & ASCO-MED, spol. s r.o.
- State Institute for Drug Control vs. Vitabalans CZ, s.r.o.

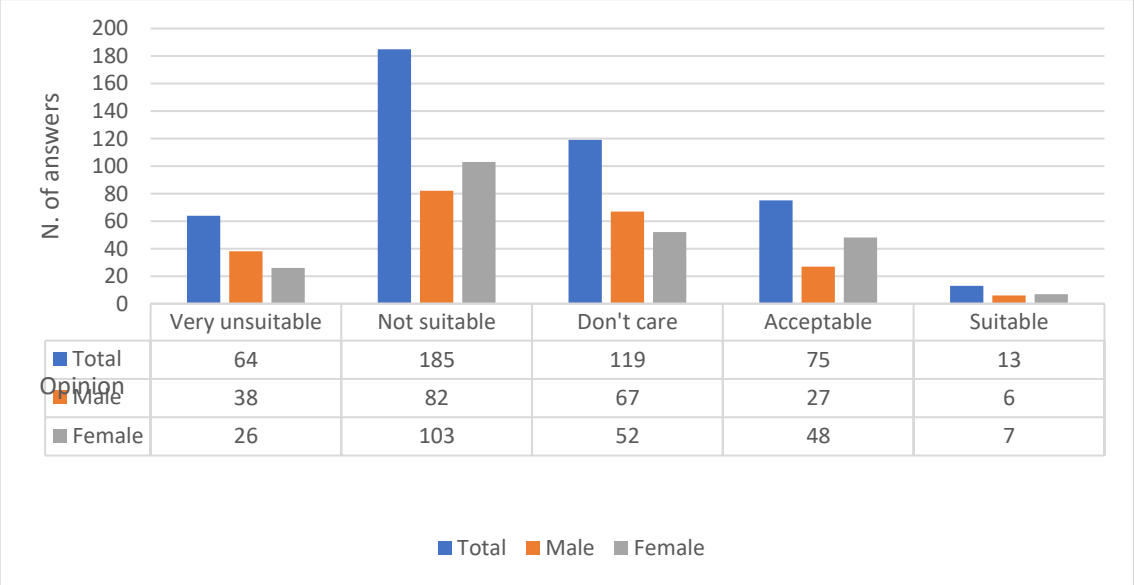


Fig. 22 Suitability of the creation of an advertising on pharmaceuticals on prescription
Source: The questionnaire, n=456

The results show, that the general opinion is, that the advertising is not very suitable, which is in line with current level of the regulations. However, we can identify 3 main trends of opinion: group of respondents, who are not influenced by the advertising, who found the advertising unsuitable and those, who found it acceptable, even suitable to be present/aired in the media.

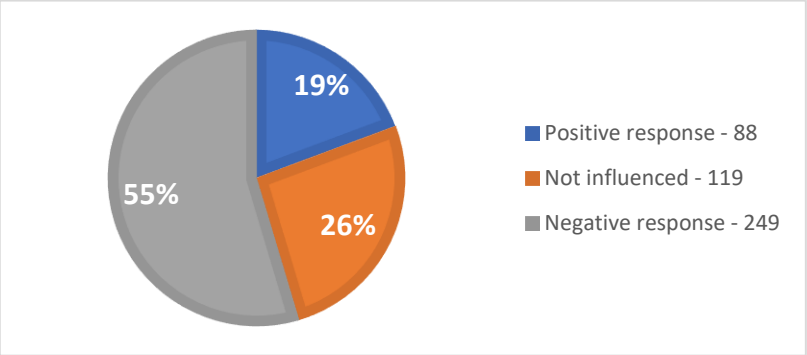
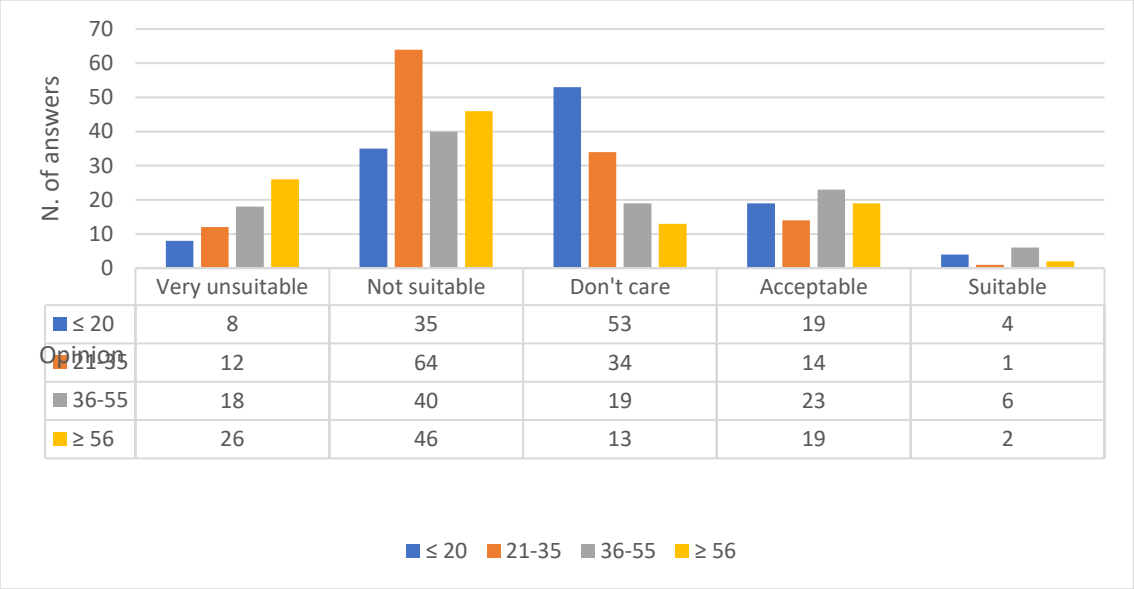


Fig. 23 Division of these 3 main opinion trends
The source: The questionnaire, n=456

Based on the results, the advertising on the pharmaceuticals on prescription evokes more negative response between the respondents. The male respondents tended to have more negative or neutral response to the advertising, compering to the female respondents, which tended to have positive to neutral response.

From the target groups, divided by the age, we can observe several things. The youngest age group tended to be less influenced group among the other groups and also the age group 21 – 35 years reacted with the most negative response. Last two target group reacted on the advertising similarly with negative to neutral response.



	Very unsuitable	Not suitable	Don't care	Acceptable	Suitable
≤ 20	8	35	53	19	4
21-35	12	64	34	14	1
36-55	18	40	19	23	6
≥ 56	26	46	13	19	2

Fig. 24 Suitability of the creation of an advertising on pharmaceuticals on prescription, based on the age categories
Source: The questionnaire, n=456

The advertising on pharmaceuticals on prescription is allowed only in case, that it targets healthcare professionals via special communication channels. So, next question observed the awareness of this fact among the general public. The general opinion is, that the adverting is allowed to be shown and aired in the medias. On the second graph, we can observe, that only 41% of respondents is aware of this regulation, when the *answer "Legal, if it targets healthcare professionals"* is consider as correct.

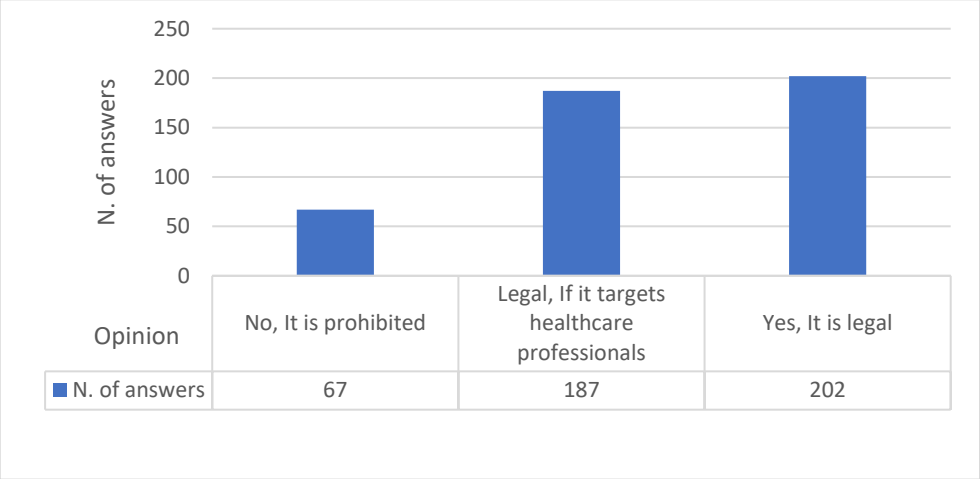


Fig. 25 Legality of creation of an advertising on pharmaceuticals on prescription
Source: The questionnaire, n=456

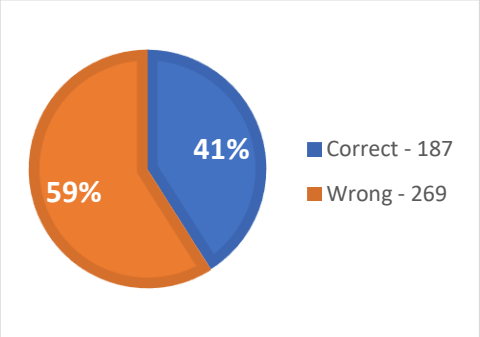


Fig. 26 Correctness of the answers
Source: The questionnaire, n=456

Interesting is to observed the fact, that the respondents consider the adverting on pharmaceuticals on prescription as more likely unsuitable to be shown and aired, but they think, that this type of the advertising is allowed by the Czech legislation.

The last question, examined the previous experience of the respondents with the advertising on pharmaceuticals on prescription. 77% respondents stated, that they did not have any previous experience with such a type of advertising, but the alarming number is, that 23% of respondents might have had a previous experience with the advertising, which has been prohibited by the regulation. This could be caused by the replacing the pharmaceutical on prescription by OTC pharmaceutical.

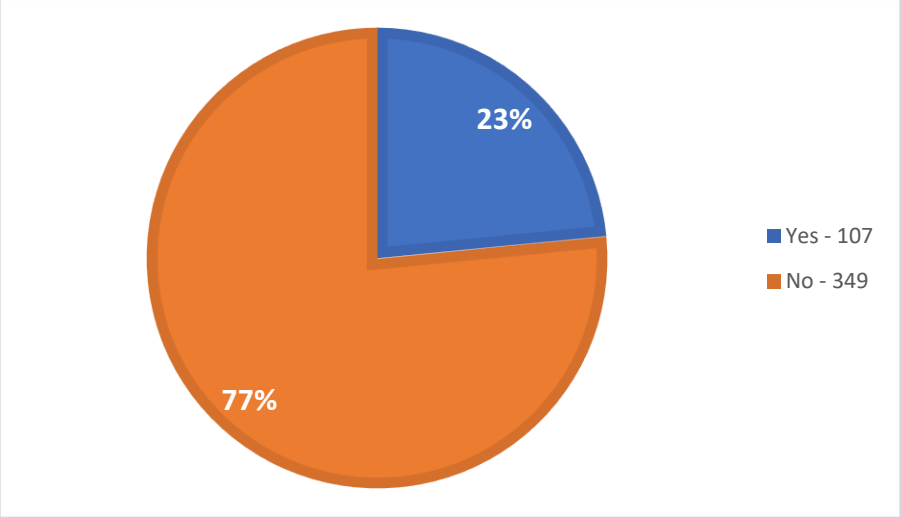


Fig. 27 Have you ever got in touch with the advertising on pharmaceuticals on prescription
Source: The questionnaire, n=456

6 The set of the recommendations

6.1 Target the advertising for different groups

The key to success is to elaborate the advertising in details and take into accounts all the variables and factors, which could affect the final perception of the advertising, like current physical state of the person (if he/she suffer from illness) or it is own personal characteristics. Males and females, young and old people perceive the advertising differently, especially the perception among the generations is different. The older generation has higher expectations concerning the observance of the rules and they are more aware of the current level of the regulation, compering to younger generation, which lacks more engagement in this area.

6.2 Choose a proper communication channel

It is also important to establish a correct communication channel, because with a quickly developing society, speeded up with the technological progress, the ordinary channels will be quickly old fashioned and also different age generation gets the information from different sources. Young generation prefers to get the information from the internet and social medias, compering to other generations, which tend to stick with the ordinary medias, like TV and leaflets.

6.3 Increase the influence of the advertising

Nowadays, the advertising on the pharmaceuticals has lower impact on the generation. To have a successful adverting campaign, we must increase the impact/influence of the advertising, make the advertising more attractive for the final consumers. Try to use more innovative solutions, maybe inspire from more influencing campaign in the different industries and make them according to regulations on pharmaceutical advertising.

6.4 Always double check the advertising

The most common mistake is an omitting of some necessary part of the regulation, such as forget to include an appeal to read a product leaflet, an information, how to correctly ingest the human pharmaceutical, especially not to forget the warning text, that the products is a food supplement. Not only these violations are fined by the supervision institutions, but they also decrease the credibility of the advertising and the company. In case of missing text "food supplement", it is perceived as a very serious problem from the public, which is in favour of even stricter regulations. The placement of the text is one thing, but we must also take into an account its size, colour toward the background and the airing time.

Make sure, that it is not possible, that the final consumer would be able to mislead the pharmaceuticals with another product, even by an accident. Do not put other products on the same leaflet page, or internet webpage, with the pharmaceuticals, because they must be strictly separated.

6.5 Using the advertising techniques to stimulate the emotions

The use of unadvisable advertising techniques, like using of the motive of the fear or pictures with explicit content is considered as a very serious violation of the law by the supervision institutions and it is heavily fined, because the technique, which used a motive of the fear, had a positive impact on the consumption behaviour. In case of the pictures with explicit content, it was perceived as ethically unacceptable, which could have uninviting impact. So, avoid to use such a technique in the advertising.

6.6 Advertising on the pharmaceuticals on prescription

Avoid a creation of adverting on pharmaceuticals on prescription, because it is prohibited to target the general public with this advertising. Only exemption is to target the healthcare professionals. Do not try to mix it, because the advertising targeting the general public and targeting the healthcare professionals must fulfil different obligations from the law.

6.7 Effects of the food supplements

Do not try to impute prevention and treatment effects to food supplements. It is a very common thing, despite the fact it is often made by an accident, but it could have a serious impact on the consumer, because it could get a feeling, that it will help his health, but the reality would be different. Only a verified effect can be imputed to the pharmaceuticals, compering with the food supplement, because they do not have to go through such a difficult registration process.

6.8 Future disputes

Currently, the adverting in the pharmaceutical industry is heavily regulated by public law and we can observe only a small amount of conflict in case of private law, because these types of disputes are typical for American legal environment. With the increasing the level of competition in a pharmaceutical industry, we could face a new trend in legal disputes. So, we have to get ready, before this situation will occur.

7 Discussion

7.1 From the point of view of the manufacturers and distributors

Still the most common type of media for the pharmaceutical advertising is a television, but internet as media becomes more popular, especially between the younger generation. However, on the overall scale, the consumption behaviour of the public tends not to be influenced by the advertising. This lays down a question, what are the most influencing factors in decision-making process on the purchase of the over-the-counter pharmaceuticals, if it is based on the advice from the doctor or pharmacist, on the recommendations from the family and friends or something else, so we can be able to use more specific targeting.

In case of the necessity of providing the information about the correct ingestion of the pharmaceuticals, the results were balanced, slightly in favour of current regulation. The questionnaire did not observe the level of importance for each respondent, but only if it is/is not important for the respondents to know the information directly from the advertising. So, there is a place for a discussion, to make the regulation softer, because this information is not that important for the final consumers.

7.2 From the point of view of the final consumer

In case of the necessity of providing the information about the correct ingestion, as it was written above it could be softer, but it would be in disfavour of the older generation, So, from the point of view of the final consumers, I would rather make an information campaign, especially between the younger generation to improve their knowledge and emphasise the importance of the regulation. This would be more favourable solution, because we can still witness several violations of this regulation. This campaign can also contain the information about the current level of regulation on the necessity to provide an appeal to read a product leaflet, because the awareness between of the respondents was below 60%.

In case of the labelling of the food supplements, the general opinion is strictly for a tighter regulation. The current regulation should be improved with more detailed description of the labelling of the food supplements and the pharmaceuticals, or even to introduce the uniform labelling for each product in a form of symbols,

logos or different colour labels. This could also solve a problem with the imputing the preventive and treatment effects to the food supplements. If there were more strict restrictions for the packages and the advertising in general, it would reduce the possibility that the marketers will try to evade the regulations.

The answers, which were in the biggest dispute with the current regulations, were on a question regarding the suitability of the advertising on the vaccination against the hepatitis, which used the motive of the fear, which is prohibited by the law. However, the general opinion was positive on this replication of the advertising, which puts a pressure on the supervision institutions, because this type of the advertising plays with the human emotions. What is even worse, that public has not an idea, that this form of the advertising is prohibited. The awareness increase with the age, but it is still on the low level. I would recommend once again some education campaigns in form of TV spot or some printed materials distributed in hospitals, schools or other state institutions, instead of lowering the level of the regulation, because influencing the consumption behaviour via the human emotions is a serious issue. The further research could analyse this advert in more details, to estimate, what exactly made the participant respond in a such way.

Using the element of the fear is not a such big issue compering to the use of the pictures with the explicit content, which was found by the respondents at least as ethically unacceptable, which supports the current level of the regulation. However, the questionnaire did not observe the knowledge of this regulation between the respondents.

8 Conclusion

The topic of the diploma thesis was the unfair practices in the marketing of pharmaceuticals and its main goal was to provide a set of recommendations or a guide for the pharmaceutical companies to avoid the violation of the laws. The goal was achieved via the overall evaluation of the current level of the legal regulations in the European Union and in the Czech Republic, by an analysis of the legal proceedings and case laws related to the violations of the laws on advertising regulation and via the questionnaire, which analysed the sensitivity and the awareness of the respondents on the current level of the regulation and techniques used in the advertisings.

The advertising on the pharmaceuticals used to be a deregulated area with low level of boundaries and supervision for a long time. It started to improve at the end of the millennium and nowadays, the advertising on the pharmaceuticals has become a heavily regulated area in the Czech Republic. However, we can still witness the multiple violations of these regulations. Since 2008, over 157 violations have been documented for various reasons. The current state can still be improved by implementation of more detailed specifications for each element of the advertising or by the education/information campaigns, which remind people their rights and increase the knowledge about the regulations.

In general, the biggest issue is omitting some basic aspects of the advertising, like providing a clear indication, how to use the pharmaceutical, to include an appeal to read the product leaflet or include the text *"food supplement"*. The more serious issue is an intentional use of certain, prohibited elements, like imputing medical characteristics to the food supplements, or a use techniques, which could have a serious impact on a consumer behaviour, like a stimulation of the emotions. For this reason, these intentional activities are more sanctioned compering to the previous ones.

So, it is important not to focus only on a strict fulfilling of the obligations, arisen from the laws, but also look at the advertising through the eyes of the consumer. If it is ethical and suitable for them to see certain elements in the advertising, to be exposed to the different advertising techniques or to face the emotions, which could change their behaviour. This should be included among the other market research activities.

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Appendix

A The questionnaire

1. Gender?
   - Male
   - Female

2. Age group?
   - ≤ 20
   - 21-35
   - 36-55
   - ≥ 56

3. Your level of education?
   - Primary
   - Secondary
   - High school / University

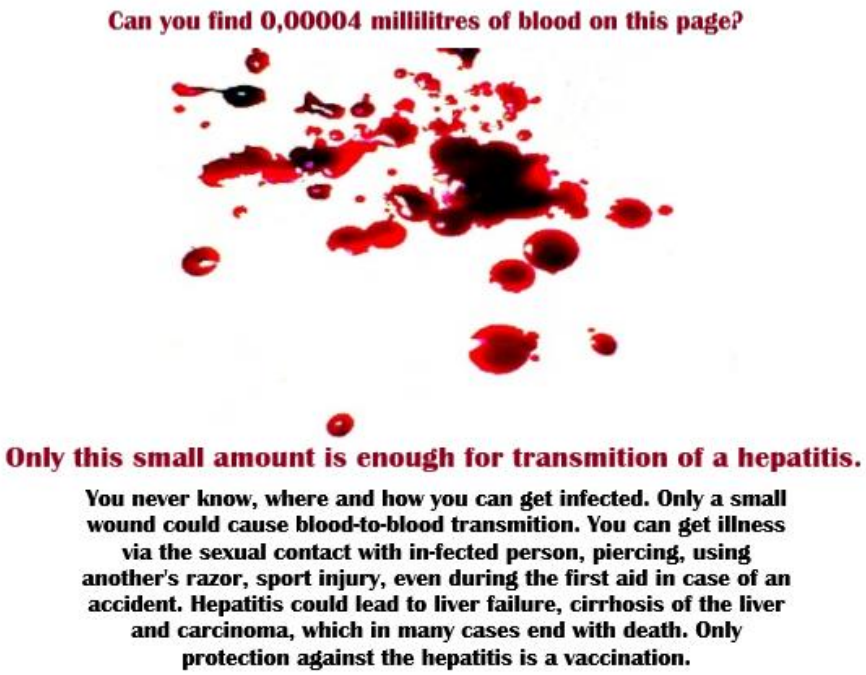
4. What is the most frequent type of the advertising media, in which you come across the advertising on pharmaceuticals?
   - TV
   - Radio
   - Leaflets
   - Papers / magazines
   - Internet
   - Other, specify:

5. Do you think, that it is suitable to make an advertising on pharmaceuticals on prescription?
   - Very unsuitable
   - Not suitable
   - I don't care
   - Acceptable
   - Suitable

6. Do you think, that it's legal to make an advertising on pharmaceuticals on prescription?
   - Yes, it is prohibited
   - Legal only in case, that it targets medical professionals
   - No, it is prohibited

7. Have you ever come across the advertising on pharmaceuticals on prescription?
   - Yes
   - No

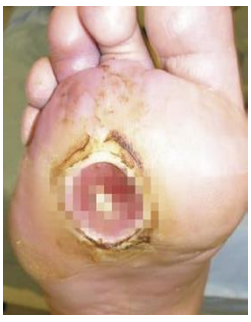
Please take a look on the following advertising:

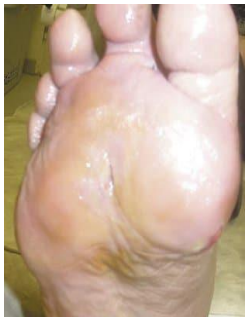


8. What is your opinion on the adverting on vaccination against hepatitis?
   - Completely unacceptable, it should be prohibited
   - Not suitable
   - Not influencing
   - Acceptable
   - Suitable

9. Do you think, that it is legal to make an adverting, which uses the motive of fear?
   - Yes, it is legal
   - No, it is prohibited

Please take a look on the following advertising elements:


Before


After

10. Do you think, that is suitable to use following graphical elements in the advertising?

- Completely unacceptable, it should be prohibited
- Only ethically unacceptable
- Not influencing
- Suitable

11. Evaluate on the scale, how much you are influenced by the adverting, while you choose OTC pharmaceuticals? (For example: Coldrex, Paralen, Endiaron, etc.) (0 – minimum, 9 maximum)

0 1 2 3 4 5 6 7 8 9

12. Is it important for you, that the advertising contains information, how to correctly ingest the pharmaceutical?

- Yes
- No

13. Is it important for you, that the advertising contains an appeal to read the product leaflet?

- Yes
- No

14. Is it important for you, that the adverting emphasises, that the product is a food supplement not a pharmaceutical?

- Yes
- No

15. Have you ever experienced an advertising on a food supplement, which emphasises treatment/preventive effects of the supplement (Example of food supplements: Proenzi, Centrum vitamins, Dr.Max Simethicon)? *(If you remember the name of the food supplement, please specify)*

- Yes
- No

16. Have you ever experienced, that you confuse pharmaceutical and food supplement, due to wrong graphical processing (small, hardly readable or missing text, wrong colour of the text, soft picture or short air time)?

- Yes
- No

17. Do you think, that would be useful to introduce uniform labelling? *(If you have any idea, how it should look like, please describe)*

- Yes
- No