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RESTRICTIONS ON THE CONDUCT OF ADVERTISING OF MEDICINAL PRODUCTS IN POLAND AND THEIR VIOLATIONS

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Abstract: Similarly to other European countries, the Polish pharmaceutical market is in the phase of maturity characterized by limited speed of increase in sales. In connection with escalation of the competitive struggle, being the result of globalization and development of enterprises producing generic medications, the most important aim for pharmaceutical companies has been to maintain profitability on the right level. To perform this task, companies producing medications have to carry out proper marketing actions. The marketing elements include, apart from the product, the price and the distribution, also promotion which is inextricably linked with advertising. It is a special type of information message that aims at evoking a specific consumer's attitude and belief. Advertising of medicinal products is subject to detailed legislative and non-legislative regulations. The aim of the article is to present legal regulations within the scope of advertising of medicinal products and violations of these regulations based on example decisions of the Main Pharmaceutical Inspector issued in the years 2008-2010. Abundant rulings of the Main Pharmaceutical Inspector prove that both advertisements addressed to public attention and those addressed to specialists often diverge from the criteria determined by the Pharmaceutical Law. In the face of still increasing violations of the provisions of the Pharmaceutical Law act, it seems that introducing a ban on advertising or any possible financial sanctions is not a sufficient punishment for advertisers. Thus, an introduction of other, more rigorous legal regulations as a deterrent for those involved in illegal advertising of medicinal products ought to be considered.

Keywords: medicinal product, advertising, pharmaceutical law, the Main Pharmaceutical Inspector, violations

Pharmaceuticals are specific products, the production, distribution, sale and advertising of which are subject to detailed legislative and non-legislative regulations. Taking pharmaceuticals is never indifferent for an organism, while using them in a manner that is improper or non-compliant with recommendations may lead to loss of patient's health or life. Therefore, state institutions have been established supervising the quality of the process of manufacturing, sales and advertising of medicinal products. One of them is the Main Pharmaceutical Inspector, whose main task is to supervise the advertising of pharmaceuticals. Getting acquainted with the subject of the ruling activity of this authority aims at introduction to a practical use of the pharmaceutical law and examples of violations of statutory regulations.

Definition of the medicinal product

Pursuant to Article 2 item 32 of the Pharmaceutical Law act, a medicinal product "is any substance or combination of substances presented as able to prevent or treat disease in human beings or animals, or administered with a view to making a medicinal diagnosis or to restoring, correcting or modifying physiological functions of an organism through pharmacological, immunological or metabolic action". For a medicinal product to be marketed within the territory of the Republic of Poland, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products has to grant a marketing authorization for the medicinal product. The authorization is granted for the period of 5 years. An entrepreneur or an entity conducting business activity that has applied for or has been granted the medicinal product marketing authorization is referred to as a marketing authorization holder.

Due to specificity of medicinal products and their specific properties, there are various classifications of pharmaceuticals. Article 23a item 1 of the Pharmaceutical Law suggests a division of medici-

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nal products according to the assigned dispensing category:

- dispensed without physician's prescription – OTC,
- dispensed on physician's prescription – Rp,
- dispensed on physician's prescription for restricted use - Rpz,
- dispensed on physician's prescription, containing narcotic agents or psychotropic substances defined in separate regulations – Rpw,
- only for hospital use – Lz.

Advertising of medicinal products within the meaning of the provisions of the Pharmaceutical Law

All the issues and information with regard to advertising of medicinal products have been specified in detail in the Pharmaceutical Law act of 6th September 2001 and the Ordinance of the Minister of Health of 21st November 2008 on Advertising of Medicinal Products, the provisions of which are strictly related to the provisions of Directive 2001/83/WE of the European Parliament and the Council of 6th November 2001 on the Community Code Related to Medicinal Products for Human Use.

Medicinal product advertising, which, pursuant to Article 52 section 1 of the Pharmaceutical Law act, is defined as "an activity of informing on or encouraging to the use of the medicinal product with an aim to increase the number of prescriptions, delivery, sale or consumption of medicinal products", may be conducted only by the marketing authorization holder or on its order. Pursuant to Article 60 section 3 item 1, the duty of the marketing authorization holder is to ensure that advertising complies with the applicable legal regulations. Moreover, the marketing authorization holder is obliged to retain advertising specimens for 2 years following the end of the calendar year in which the advertising was distributed (Article 60 section 3 item 2).

Article 56 prohibits advertising of medicinal products:

- which have not been authorized for marketing in the territory of the Republic of Poland,
- authorized for marketing without the necessity to obtain the respective marketing authorization (specified under Article 4 - imported medicinal products, when their use is indispensable for saving patient's life or health, authorized for marketing in the country from which they are imported),
- providing the information inconsistent with the Summary of Product Characteristics (SPC).

The Summary of Product Characteristics has not been precisely defined in the Pharmaceutical Law act, but it may be described as a document containing basic information on the medicinal product that is subject to approval by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in the process granting the medicinal product marketing authorization. On the other hand, the Pharmaceutical Law act in Article 11 specifies in detail the list and order of the data to be obligatorily included in the SPC. It performs an informative function, regardless of who it is addressed to. The problem of presenting the data consistent with the SPC regards mainly the advertising of medicinal products in the OTC dispensing category addressed to the general public. The advertisers pay attention to the fact that it is necessary for the advertising to use simple language that is understandable for an average person and easy to comprehend. Therefore, advertisers find it difficult to meet the requirement of conformity of the advertising with the content of the SPC. At the same time, it must be noticed that presenting the information in conformity with the SPC does not require quoting of its content, but formulations and expressions used in advertising have to reflect completely all the information contained in the SPC without leading to any inaccuracies or contradictions to the document. (1)

Advertising addressed to the general public

Product advertising should be reliable, precise and objective promotional information. Medications are chemical compounds, which used improperly may cause many damages to a human organism. Pharmacotherapy requires not only physician's knowledge and experience, but also patient's awareness and self-control. Thus, it is important that the producer informs the physician on all indications, contraindications, adverse reactions, methods of dosage, interactions with other medications and patient's compliance with these recommendations.

Article 57 of the Pharmaceutical Law act prohibits addressing the advertising to the general public related to the medicinal products:

- dispensed exclusively on the basis of a prescription,
- containing narcotic agents and psychotropic substances,
- entered in the lists of reimbursed medications in accordance with separate regulations or authorized for dispensing without prescription, if their name is identical with that entered in these lists.

Pharmaceutical products available without prescription are commonly known as OTC and allow

patients for self-treatment. For a medication to obtain the OTC dispensing category, it must be safe in use in a short period (3-5 days), in specific ailments easy to be self-diagnosed by the patient.

From the early 1990s, we have observed a sudden development of self-treatment among patients in Poland. The fact is related to social and political changes that happened at that time, with creation of a free market and appearance of commonly available medicinal products. Self-treatment was defined in the Declaration of the WHO Regional Office for Europe of 1986 specifying the range of medicinal products used independently by patients as:

- self-medication: using drugs by consumers in treating self-recognized illnesses and symptoms. In practice, the term also includes mutual treatment by family members or friends, especially, when a child is being treated (2);
- self-care: related to conducting simple diagnostics and therapy independently by an educated patient, e.g., in diabetes, epilepsy, asthma, allergy (2).

Self-treatment of patients is facilitated by development of Internet pharmacies, the share of which in the market is still indicating growth tendencies. The growing share of Internet pharmacies in the market in the nearest years may also be influenced by an increased interest in and trust to online shopping (3). The advantages of shopping in e-pharmacies includes, among other things: time saving, shopping comfort, wide choice and easy possibility of comparing products as well as shopping discretion.

The phenomenon of self-treatment influences an improvement in the health condition of the population - it increases the comfort of living and prompts an active use of various forms of prophylaxis, but, if it is conducted in a manner that is ignorant or goes beyond patient's knowledge and competences, it may cause more damages than benefits. A negative consequence of patients' self-treatment is the so called "mask effect" - a patient suffering from heartburn for several months or years postpones visiting a specialist and delays a professional diagnosis as the preparations preventing heartburn and bringing relief, at the same time, mask the symptoms of e.g., stomach ulcers or cancer. Patients' self-diagnosis and treatment on their own may result in various interactions between the medications they use. The problem also involves older people taking several medicinal products to treat various illnesses, which are often prescription medications. In addition, there may be interactions between medications and alcohol, food or herbal preparations. It is a polypragmasy problem that involves using an excessive amount of medications, even for trivial ailments, and simultaneous taking of several preparations that may interact with each other. Self-treatment should only happen in cases with typical symptoms, characteristic for the most frequently occurring diseases or ailments, when patient's self-diagnosis does not raise any doubts and the commonly available pharmaceuticals are enough to eliminate or counteract these ailments. In any other case, it is necessary to consult a physician.

Pursuant to Article 55 section 2 of the Pharmaceutical Law, advertising of a medicinal product cannot suggest or guarantee that:

- a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail,
- even a healthy person taking the medicinal product can enhance such person's health,
- failure to take the medicinal product may deteriorate the health of the specific person,
- the medicinal product is a foodstuff, cosmetic or represents other consumer goods,
- the efficacy or safety of use of the medicinal product arises from its natural origin.

Moreover, the advertising content cannot lead to erroneous self-diagnosis and cannot ensure that taking the medicinal product guarantees the appropriate effect and is not accompanied by adverse reactions (Article 55 section 2 items 1-3). In order to minimize the number of cases in which a patient avoids medical consultations, the legislator obliged the advertisers to include warnings in advertising materials:

- in visual advertisements: "Before using the medication, read the leaflet including indications, contraindications, data on adverse effects and dosage as well as information on using of the medicinal product or consult a physician or a pharmacist as each drug used improperly may endanger your life or health" (4),
- in audiovisual advertisements: "Before using the medication, read the leaflet or consult a physician or a pharmacist as each drug used improperly may endanger your life or health" (4).

The above mentioned provisions have been strengthened by Article 53 section 1 prohibiting misleading advertising. Medicinal product advertising should present the product objectively and should inform on its reasonable use. Advertising may be considered misleading when it causes a conviction about or imagination of the product that is not in conformity with the actual state.

Pursuant to Article 53 section 2, an advertiser cannot promise or guarantee any benefits for pur-

chasing or using the medicinal product. Such activities are highly unethical and prohibited. Pharmaceuticals are not consumer goods so their use should depend on patient's morbidity rather than benefits resulting from purchasing them.

The legislator, in Article 53 section 3, prohibits addressing medicinal product advertising to children. Also, advertising cannot contain any element addressed to children. Children are not fully aware consumers or patients, are not able to receive an advertising message in a rational and critical manner and, thus, cannot be the addressees of medication advertising, even if it is intended for them.

Both the Pharmaceutical Law act (Article 55 section 1 item 1) as well as the Medical Code of Ethics (Article 63 item 2) and Code of Ethics for Pharmacists (Article 19) prohibit advertising of medicinal products by healthcare professionals or by persons suggested to be healthcare professionals (5, 6). In addition, such advertising cannot involve celebrities or scientists and cannot refer to their recommendations (Article 55 section 1 of the Pharmaceutical Law act). Such activities are prohibited as patients, trusting healthcare professionals or celebrities, would be more willing to follow their recommendations, even subconsciously.

Advertising addressed to persons qualified to prescribe medicinal products

Advertising of medicinal products addressed to persons qualified to prescribe medicinal products and to persons trading in medicinal products, pursuant to Article 54 item 1 of the Pharmaceutical Law, should contain information consistent with the Summary of Product Characteristics and information on assigning the dispensing category (Article 23a item 1). In addition, if advertising refers to medicinal products entered in the lists of reimbursed medications, it should also contain the information on the official retail price and the maximum amount of supplementary payment made by the patient.

All data and information supplied to the specialists should be accurate, up-to-date, verifiable and come from reliable sources (Article 54 item 2). This aims at enabling the recipient to form his or her own, objective opinion of the efficacy and the therapeutic value of the medicinal product concerned.

Free-of-charge delivery of product samples is also considered as medicinal product advertising. This form, however, has been subject to many limitations. It may only take place provided that the person qualified to prescribe medicinal products submitted a written request for the supply of a medicinal product sample to a medical or sales representative (Article 54 section 3 item 1). Moreover, another condition is that the person supplying the sample maintains records of the samples supplied (Article 54 section 3 item 2). Each supplied sample cannot be larger than one smallest medicinal product presentation authorized for marketing, should be marked "free sample – not for sale" and accompanied by the Summary of Product Characteristics (Article 54 section 3 items 3-5). In addition, the number of samples of the same medicinal product delivered to the same person shall not exceed five smallest medicinal product packs authorized for marketing per year (Article 54 section 3 item 6).

In connection with avoiding practices non-compliant with the law or ethical norms, Article 58 section 1 of the Pharmaceutical Law imposes certain limitations on advertisers and persons qualified to prescribe medicinal products with regard to offering and accepting pecuniary advantages. An exception regards the objects of value not exceeding the amount of 100 zlotys, related to medical of pharmaceutical practice, bearing the mark advertising the specific company or medicinal product (Article 58 section 3).

The Pharmaceutical Law in Article 52 section 2 items 5 and 6, provides for a possibility of promotional meetings sponsorship, conferences, meetings and scientific congresses for persons qualified to prescribe medicinal products or for persons trading in medicinal products. Such meetings are usually devoted to a new medicinal product. During the meetings, complex factual information should be presented on a given medication, confirmed by reliable research, including properties of the product, its efficacy, indications, contraindications, adverse effects, etc. It is prohibited to finance and organise such meetings at which hospitality manifestations are not limited to the main purpose of the meeting. Thanks to the possibility of participation in training and educational meetings, physicians are able to fulfil their obligation of professional training (7).

Violations in advertising of medicinal products

The Main Pharmaceutical Inspector (MPI) supervises the compliance with the provisions of the Pharmaceutical Law with regard to advertising of medicinal products. Every year, several dozens of decisions are issued by the MPI reporting violations in drug advertisements. Between 2008 and 2010, the MPI issued almost 150 decisions, some of which were removed. Advertisers usually violate the law in the context of the same, repeated provisions. In order to make it easier for the needs of the article, they have been thematically grouped.

Misleading advertising of a medicinal product

The MPI issued a decision with regard to advertising of the products "Strepsils with natural honey and lemon" and "Strepsils Intensive" addressed to the general public in the form of a joint TV spot for both medicinal products (GIF-P-R-450-33-6/LB/08; 8. 08. 2008). The MPI indicated a possibility of misleading the recipient due to using a common name "Strepsils" in advertisements of two medicinal products with different ingredients and indications for use. The marketing authorization holder considered the allegations of MPI as unfounded, explaining that there are many various types of medicinal products from "Strepsils" family functioning on the market, the common feature of which is relieving sore throat. Moreover, it recognized that the advertisement was clearly divided into two parts presenting separately "Strepsils with natural honey and lemon" and "Strepsils Intensive" in addition to containing a common part for these two preparations, which is compliant with marketing rules. Finally, the MPI upheld its original decision that the construction of the advertising spot and presentation of the products with different properties may mislead the recipient.

Advertising addressed to the general public containing information inconsistent with the Summary of Product Characteristics

An example is the advertising of the medicinal product Cholinex conducted by GlaxoSmithKline Pharmaceuticals S.A., which was addressed to the general public in the form of a radio spot and contained e.g., the slogan: "Cholinex moistures your throat" (GIF-P-R-450-90-4/JD/07/08; 16. 04. 2008). The MPI issued a decision in this case, recognizing that the above mentioned phrase used in the advertisement was not reflected in the approved SPC. The opinion was confirmed by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The marketing authorization holder provided explanations, mentioning that item 5.1. of the SPC contains data on pharmacodynamic properties - "addition of choline causes increased salivation, which adds to the anti-inflammatory effect". Moreover, it used the dictionary definitions of the word "moisten". Finally, the MPI did not agree with the explanations of the marketing authorization holder, recognizing them as not convincing enough and emphasising the fact that its decisions have to be based on the most important document allowing for verification of the data on the medicinal product, which is the SPC.

Ensuring about the guarantee of the appropriate effect

According to the MPI, an advertisement violating Article 55 section 2 item 2 of the Pharmaceutical Law act was the leaflet of the medicinal product Ketoprom Gel 25 mg/g, addressed to the general public and entitled "Strong attack on pain!", "Always at a good price" (GIF-P-R-450-82-4/MSZ/07; 30. 01. 2008). Moreover, the advertising leaflet included the following content:

"Safe:

- *Acting in the pain spot protects your alimentary tract.*
- *Odorless, colorless gel - it does not make your clothes greasy or dirty."*

The MPI in its decision, recognized that, taking into consideration "the Contraindications", "the Adverse Effects" and "the Special Warnings and Precautions Concerning the Use", resulting from the SPC, the preparation cannot be considered safe. In addition, the advertisements contained an inscription "Effective", placed under the picture of Ketoprom gel, which violates the provision with regard to ensuring about the guarantee of the appropriate effect. The MPI considered the above mentioned violations as unlawful, focusing in particular on the fact that the advertisement referred to a product dispensed without physician's prescription and lacked the warning about the necessity to read the leaflet attached to the pack or to consult a physician or a pharmacist.

Advertising of medicinal products dispensed on physician's prescription addressed to the general public

The MPI issued a decision addressed to the Polish Federation for Women and Family Planning, which placed some materials on its website www.federa.org.pl considered to be advertising of medicinal products: Cerazette, Yasmin, Evra, Postinor Duo, Esacapelle and Depo-Provera (GIF-P-R-450-61-3/JD/08; 22. 08. 2008). Providing the explanations, the party presented the statutory goals of the Federation and informed that they are accomplished by means of publishing various educational and informative materials on its commonly available website, which are not directed at advertising of any medicinal product or any pharmaceutical company. The MPI did not share this opinion and finally considered the information as advertising of medicinal products dispensed on physician's prescription, which violates Article 57 section 1 item 1 of the Pharmaceutical Law.

Advertising addressed to specialists including information that is unbelievable or inconsistent with the SPC

AstraZeneca Pharma Poland Sp. z o.o. filed a request with the MPI for conducting an inspection with regard to conformity with the Pharmaceutical Law of the advertisement of KETREL product addressed to specialists and published in the magazine "Puls Medycyny" – an independent magazine for professionals no. 20 (163) issued on 19. 12. 2007 (GIF-P-R-450-16-3/LB/08; 28. 01. 2008). According to AstraZeneca Pharma, the advertisement was misleading, unbelievable and did not provide any objective information on the rational use of the product. It was found to contain untrue content suggesting that the medicinal product KETREL is the most frequently used neuroleptic in the USA, whereas the product had not even been granted any marketing authorization in this country. In consideration of the above, the MPI made a decision on initiating administrative proceedings against CELON PHARMA Sp. z o.o. responsible for placing the advertisement of KETREL. The party explained that the advertisement had immediately been withdrawn from publication and that its aim had been to inform that the most frequently used neuroleptic in the USA is quetiapine - the active substance included in KETREL and not the product itself. The MPI, invoking the decision of the Provincial Administrative Court, considered meaningless the fact that the advertisement appeared only once and was withdrawn as there is no certainty that the negative effects of its influence have not occurred or have been removed. The MPI finally decided that the content of KETREL advertisement is misleading, unbelievable and lacking in any possibility of objective verification.

Advertising addressed to specialists involving handing or offering illegal pecuniary advantages

Another advertisement considered to be illegal was that of the medicinal product Circadin addressed to professionals in the form of a DVD including presentation of the medication and the film "Insomnia" attached to the magazine "Puls Medycyny" no. 6 (189) of 25. 03. 2009 (GIF-P-R-450-51-3/JD/09; 26. 05. 2009). In its extensive explanations, Lundbeck Poland Sp. z o.o. declared that the presentation on the DVD aimed at providing physicians with information on Circadin, while the film presented the case of insomnia, which the main character was suffering from. It was also added that "the intention of the promotional material of Circardin in question was, among other things, to inform physicians about the introduction onto the market of a melatonin preparation with controlled release as an alternative to the use of benzodiazepines and to present the development of psychotic symptoms resulting from long-term insomnia with the use of a feature film". Moreover, the party informed that the decision on attaching the film "Insomnia" had been made as a result of consultations with an experienced psychiatrist, who considered the clinical case of psychological disorders caused by insomnia presented in the film to be similar to others frequently encountered in medical practice. In addition, the educational nature of the film was emphasized and compared to knowledge taken from lectures and students' books. It was also added that the unit cost of the DVD with the presentation and the film amounted to PLN 4.10. The MPI did not agree with this point of view recognizing that attaching of the film "Insomnia" violated Article 58 section 1 of the Pharmaceutical Law as the film was not connected with medical or pharmaceutical practice in any way. It also emphasized the fact that it would be in accordance with the law if the film was shown during a scientific conference or a promotional meeting regarding Circadin, preceded by a lecture or a comment of specialists in the field of insomnia treatment and followed by drawing conclusions at the end of the film.

Advertising of a medicinal product conducted by an entity other than the marketing authorization holder or without its order

The MPI addressed its decision to AGORA S.A., the publisher of "Gazeta Wyborcza", with regard to advertising of Septolete and Stoperan noncompliant with the regulations, which were addressed to the general public in the form of announcements published in the supplement to "Gazeta Wyborcza" – "Health and Beauty" in the "Health and Beauty. In Short." section of 25. 06. 2009 (GIF-P-R-450-81-4/JD/09; 04. 09. 2009). The advertising of Septolete and Stoperan was not conducted by the marketing authorization holder or on its order. The company attorney explained that the "In Short" column contained editorial materials rather than advertising ones. Placing of the product descriptions aimed at informing readers about available on the market and newly introduced dietary supplements, medications, cosmetics and health care products. The party recognized that the published information did not have any features characteristic for an advertisement (e.g., any form of encouragement) and, thus, cannot be called such. It also referred to the provisions of the Act on Press

Law of 26th January 1984 saying that the scope of journalist activity includes the accomplishment of the goal that involves providing the society with honest information on the existing phenomena as well as to constitutional provisions which guarantee the freedom of press. The MPI did not agree with this opinion, considering the information material in question as an advertisement due to colorful visualization of the medicinal product and description of its action and properties included in the material. In the MPI's opinion, the advertising nature of the material is also supported by the phrase "it has a nice and fresh taste", which is supposed to evoke positive attitude to the product in the reader, as well as the phrase "Before using the medication, read the leaflet including indications, contraindications, data on adverse effects and dosage as well as information on using of the medicinal product or consult a physician or a pharmacist as each drug used improperly may endanger your life or health", which is a characteristic feature of medicinal product advertising. It was also added that "according to the opinion of the Main Pharmaceutical Inspector, dissemination of information about a medicinal product by a third party, and in particular about its medicinal or prophylactic properties, may be considered as advertising even if the third party is acting on its own initiative and in a manner completely independent from the producer or seller of the medicinal product - from the legal and factual point of view". The opinion was also shared by the Court of Justice of the European Union – judgement of 2. 04. 2009 in case C-421/07.

Failure to fulfil the obligations by the marketing authorization holder

Advertising considered by the MPI to be non-compliant with the applicable legal regulations was that of PAMISOL, addressed to the general public in the form of posters placed in the commonly accessible part of the Oncological Outpatient Clinic of the Polish Red Cross Maritime Hospital in Gdynia, conducted by AstraZeneca Pharma Poland Sp. z o.o. (GIF-P-R-450-7-4/LB/08; 18. 03. 2008). Posters of PAMISOL, which is a medicinal product in dispensing category Rx entered in the lists of reimbursed medications, were hung in the corridor next to the reception desk of the above mentioned Outpatient Clinic, being a place commonly accessible for patients. The party declared in the explanations that the advertisement of PAMISOL was addressed to persons authorized to issue prescriptions and had been approved as such in the acceptance process that had taken place at AstraZeneca Pharma Poland Sp. z o.o. in Warszawa. As confirmation of this fact, the following form was attached: "Printed promotional materials confirmation process control at AstraZeneca Pharma Poland Sp. z o.o. SOP/MED/2006/01". In addition, it was declared that the materials advertising PAMISOL had never been distributed among people other than those authorized to issue prescriptions. As confirmation of this view, a declaration was attached of a medical representative working in the area where the Outpatient Clinic is located, which explicitly indicated that advertising of PAMISOL was addressed to physicians. In the party's opinion, the marketing authorization holder spared no effort to make the advertising of PAMISOL compliant with the applicable regulations and may not bear any responsibility for actions of any third parties non-compliant with the law. The MPI, however, took another stand issuing a decision indicating that the task of the marketing authorization holder is not only distribution of advertising materials, but it also has the obligation to ensure that "the entire picture and message reach the addressee, who in this case is a specialist". The MPI, thus, recognized that the marketing authorization holder had not fulfilled its obligation.

Settlements of violations in advertising of medicinal products

The rulings of the Main Pharmaceutical Inspector are based on Article 62 section 1 of the Pharmaceutical Law act, which imposes an obligation on this authority to supervise the compliance with the provisions of the Act with regard to advertising of medicinal products. By way of all the above analyzed decisions, the MPI, in the procedure of immediate enforceability, ordered that all the advertising non-complaint with the legal regulations be no longer conducted and published. Before issuing the final decision, the MPI frequently consulted its opinions with specialists in particular fields as well as with the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and invoked the judgements of the Court of Justice. Asking the opinion of other specialized entities or authorities aims at strengthening the reliability and confirming the complete compliance of the MPI's decision with the law. Pursuant to Article 127 § 3 of the Act of 14th June 1960 on the Code of Administrative Procedure, after the MPI has issued its decision, the party always has the possibility to request the MPI for re-examination of the case upon filing of a proper application within 14 days following the delivery of the decision.

Nevertheless, filing of such an application does not result in staying of the execution of the decision.

In connection with huge competition between pharmaceutical companies, their marketing activity is constantly being expended, especially within the scope of medicinal product advertising. Marketing authorization holders try to make it as attractive, characteristic, "catchy" and memorable as possible. To this end, in spite of intensive ruling activity of the MPI, it is more and more frequently that various means of advertising are used that are not compliant with the applicable legal regulations. It is worth giving some thought here to the sense of the MPI's rulings based on examination of the conformity with the law of advertisements that have already been broadcast, exposed or published. A helpful solution would be to confer additional powers to the MPI or to establish a separate authority the task of which would be to verify the advertising content before granting their "marketing" authorization. Such an order would allow for reduction of the negative influence exercised on recipients by advertising non-compliant with the regulations.

CONCLUSIONS

Abundant rulings of the Main Pharmaceutical Inspector prove that both advertisements directed at public attention and those directed at specialists often diverge from the criteria determined by pharmaceutical law. In spite of constant supervision of the compliance with the regulations in advertisements, celebrities, physicians and children still appear in them, slogans are used such as "really safe", "one hundred per cent effective" as well as other assurances of incredibly high quality of the product. Also advertising addressed to physicians frequently contains information that is incomplete, unbelievable, inconsistent with the SPC, involves offering or handing of pecuniary advantages. In the face of still increasing violations of the provisions of the Pharmaceutical Law act, it seems that introducing a ban on advertising or any possible financial sanctions is not any sufficient punishment for advertisers. Thus, an introduction of other, more rigorous legal regulations as a deterrent for those involved in illegal advertising of medicinal products ought to be considered.

REFERENCES

1. Mazurek K., Sławatyniec Ł.: Advertising of Medicinal Products, pp. 11-12, LEX a Wolters Kluwer business, Warsaw 2011.
2. www.farmacjaija.pl,
3. Barwińska A., Stańczak A., Welk B., Shopping in Internet Pharmacies - Perspectives and Dangers, Medicinal Product in Poland 1 (2012).
4. The Regulation of the Minister of Health of 21st November 2008 on Advertising of Medicinal Products (Journal of Laws of 2008 no. 210 item 1327).
5. The Medical Code of Ethics.
6. The Code of Ethics for Pharmacists.
7. The Medical and Dental Practitioners Act of 5th December 1996 (Journal of Laws of 1997 no. 28 item 152).

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