Chief Pharmaceutical Inspectorate

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Advertising of medicinal products

Medicinal product advertising is an activity based on informing about or encouraging the use of a medicinal products in order to increase the number of prescriptions, enhance the supply or consumption of medicinal products. The advertisement may be based on:

- > visiting persons authorised to prescribe medicinal products or trading in medicinal products by sales representatives or medical sales representatives;
- > supplying samples of medicinal products
- > sponsoring promotion meetings addressed to persons authorised to prescribe medicinal products or trading in medicinal products;
- > sponsoring conferences, conventions and scientific congresses addressed to persons authorised to issue prescriptions or trade in medicinal products.

Such advertisement may be conducted only by a Marketing Authorisation Holder or on MAH behalf.

Medicinal product advertisements may be grouped as follows:

- > advertisements directed to the general public,
- > advertisements directed to persons authorised to prescribe medicinal products or persons trading in medicinal products.

Each above-mentioned types of advertisement may have the following form:

- > an audio-visual form,
- > an audio form,
- > a visual form.

Medicinal product advertising is regulated by the Pharmaceutical Law Act (Polish Journal of Laws/Dz. U. of 2008 no. 45, item 271, as amended.) and the Regulation of the Minister of Health on medicinal product advertisement dated 21 November 2008 w (Polish Journal of Laws/Dz. U. no. 210, item 1327) and is subject to restrictions specified therein:

- > it cannot be misleading and should present the medicinal product in an objective manner, and inform the recipient about its rational use,
- > it may not be based on offering or promising any benefits, in a direct or indirect manner, in exchange for purchasing a medicinal product or delivering proof that a medicinal products has been purchased,
- > it may not be directed to children nor contain any elements that are directed to children,
- > a medicinal product may not be presented by celebrities, scientists, persons having medical or

pharmaceutical education, or suggesting that they have such education,

- > it may not refer to recommendations of celebrities, scientists, persons having medical or pharmaceutical education or suggesting such education,
- > it may not give the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail,
- > it may not suggest that the health condition of a healthy person will be enhanced by taking the medicinal product,
- > it may not suggest that the health of a person can be worse in case of not taking the medicine; this prohibition does not refer to vaccination campaigns referred to in Article 57 sec. 2,
- > may not suggest that a medicinal product is a foodstuff, cosmetic or other consumer product,
- > it may not suggest that that the efficacy or safety of the medicinal product is result of the fact that it is natural,
- > it may not assure that the effects of taking the medicinal product are guaranteed, unaccompanied by side effects or are better than, or equivalent to, those of another treatment or use of another medicinal product.
- > it may not lead to mis-self-diagnosis by indication of detailed representation of a case history or symptoms,
- > may not refer to in an improper, alarming or misleading way to therapeutic indications,
- > it may not contain any improper, alarming or misleading terms, graphical representations of changes in the human body, bodily injuries or the action of a medicinal product on the human body or parts thereof.

Medicinal product advertisement should contain information compliant with the Summary of Product Characteristics, and if it is directed to the general public, it should also contain the following warning:

"Before use, read the patients leaflet or consult a doctor or pharmacists as every medicinal product used improperly threatens your life or health."

Advertisement of medicinal products based on delivering free samples of the product is a special kind of advertisement. It may be only directed to persons authorized to prescribe medicinal products, provided that:

- > the person authorized to prescribe medicinal products submitted a written request to a sales representative or a medical sales representative for delivery of a medicinal product sample,
- > the person delivering samples maintains a register of delivered samples,
- > each sample is not larger than the smallest package marketed in the territory of the Republic of Poland,
- > each delivered sample is labelled with the following phrase "free sample not for sale",
- > each delivered sample is accompanied by a copy of the Summary Human Product Characteristics or the Summary Veterinary Product Characteristics,
- > the number of samples of the same medicinal product delivered to one person does not exceed five packages a year.