ADVERTISING OF REIMBURSED MEDICAL DEVICES IN POLAND: REGULATORY PRACTICE IS SLOWLY TAKING SHAPE

It is not prohibited to supply samples of reimbursed medical devices, in fact it constitutes an acceptable form of advertising, the Polish Main Pharmaceutical Inspector (MPI)\(^1\) stated in a decision issued in July.

The MPI was called upon to deal with the issue of admissibility and rules applicable to advertising of reimbursed devices since the entry into force of the Polish Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Use and Medical Devices (the "Reimbursement Act"). It seems that the authority’s approach may be also applied to other forms of advertising envisaged in the Polish Pharmaceutical Act\(^2\).

Advertising of medical devices, unlike medicinal products, has rarely drawn much attention. The latter has for some time already been extensively regulated both at the European and national level. On the other hand, marketing of devices, since its deregulation\(^3\), has generally followed the patterns applied in advertising of medicines. Thus, marketing activities envisaged in the Polish Pharmaceutical Act (regulating advertising of medicines) such as sponsoring of conferences for healthcare professionals, offering of gifts or supplying of product samples, were commonly used forms of advertising of medical devices\(^4\). Yet, the enactment of the Reimbursement Act\(^5\) led to questions about the legality of these practices. The confusion was due to the ambiguous wording of art. 49. 3 of the Reimbursement Act (as it now stands) prohibiting a business entity engaged in manufacturing or marketing of reimbursed products from making conditional sales, discounts, rebates, bonuses, bundling and loyalty programs, donations, prizes, trips, gambling, betting, all forms of lending for use, package deals, all kinds of coupons and vouchers, as well as providing other material or personal benefits not mentioned by name to healthcare service providers or healthcare professionals entitled to prescribe medicines.

---

1. Główny Inspektor Farmaceutyczny.
3. Advertising of medical devices is regulated in art. 8 of the Act on Medical Devices, which, broadly speaking, prohibits misleading advertising.
4. They were, however, regulated in the codes of business practices applied by the medical devices industry.
5. The Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Purposes and Medical Devices dated May 12, 2011.
The existence of clear rules on advertising of medicines (implementing European legislation) justified the uninterrupted application of the rules on advertising of reimbursed medicines (in particular relating to sponsoring of conferences, offering of gifts and supplying of samples). However, it was not clear whether – considering the usually restrictive and literal interpretation applied by the pharmaceutical inspectorate – similar marketing activities used in relation to medical devices would not be contested. It was quite easy to imagine the pharmaceutical inspectorate qualifying and sanctioning the offering of gifts and supplying of samples of the products as donations and sponsoring of conferences as providing (material or personal) benefits, if these activities related to reimbursed medical devices.

And indeed, in a decision of May 28, 2012 the Mazowiecki Voivodeship Pharmaceutical Inspector (MVPI) imposed a fine on a distributor of reimbursed medical devices for violation of art. 49. 3 of the Reimbursement Act. The MVPI considered supplying of free samples of medical devices labeled “SAMPLE demonstration product for educational purposes. Not for sale” not only as making donations but also as providing personal benefits to healthcare service providers and healthcare professionals entitled to prescribe medicines.

The MVPI’s approach was fortunately questioned by the MPI. Following the distributor’s appeal, the MPI issued a decision on July 26, 2013, where – unlike the MVPI - it focused on the concept of advertising and analyzed the purpose of art. 49. 3 of the Reimbursement Act: "[ ] the wording of the provision does not give grounds for restricting the rights of individuals to advertise their products. [ ] Nothing in [the Act on Medical Devices] prohibits the advertising of medical devices." The MPI stressed the need to consider the underlying purpose of the provision in question. The introduction of art. 49. 3 of the Reimbursement Act was not intended to block the advertising of reimbursed products that is not prohibited by other regulations, but to eliminate pathological situations. In the opinion of the MPI, there are no grounds for arguing that supplying of product samples, which is a popular marketing tool, constitutes a donation, or other benefit referred to in art. 49. 3 of the Reimbursement Act. This activity – explicitly provided for in the Pharmaceutical Act – is permissible in the case of reimbursed medicines. If it was considered illegal with respect to medical devices this would lead to discrimination of these products.

The approach of the MPI based on teleological interpretation of the new law and acceptance of existing marketing practices in the medical industry should be generally welcomed. There seems to be no reason to object to its more general application, covering other forms of advertising provided for in the Pharmaceutical Act.
Yet, open questions still remain, such as whether, in the case of advertising of reimbursed medical devices the restrictions provided for in the Pharmaceutical Act are also applicable. In the case of supplying product samples it should be clarified whether, in particular, in order to avoid liability for violation of Art. 49.3 of the Reimbursement Act while advertising reimbursed medical devices, one is bound by a restriction on the number of samples to be supplied, the obligation to keep records or prohibition on supplying samples to patients. In its decision the MPI did not question the supplying of product samples to patients. The absence of any argumentation in this regard does not, however, mean that any far-reaching conclusions can be drawn.

One can now only hope that the approach described above will find its way into the future practice of the pharmaceutical inspectorate.
This memorandum has been prepared solely for the purpose of general information and is not a substitute for legal advice.

Therefore, WOLF THEISS accepts no responsibility if – in reliance on the information contained in this memorandum – you act, or fail to act, in any particular way.

If you would like to know more about the topics covered in this memorandum or our services in general, please get in touch with the contacts listed above, or with:

WOLF THEISS  
ul. Mokotowska 49  
00-542 Warsaw  
Tel. +48 22 3788 900  
www.wolftheiss.com