

RESTRICTIONS ON THE REIMBURSEMENT POLICY WITH REGARD TO RETAIL MARKETING OF MEDICINAL PRODUCTS IN POLAND

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Abstract: On January 1, 2012, the law of 12 May 2011 on the reimbursement of medicines, food products of special nutritional purpose and medicinal products, intended to tighten up the reimbursement system, came into force in Poland. The new legislative act has significantly altered the previous principles of retail marketing of products subject to publicly financed reimbursement. First of all, the prices of reimbursed products have been unified through the introduction of fixed margins and prices and a ban – completely unknown until now – on using free market sales practices. These regulations are intended to lead to the abolition of price competition and its replacement with competition as to the quality of services provided by pharmacies. At the same time, entities engaged in retail marketing of medicinal products have been imposed a number of new obligations and highly repressive penalties for failure to fulfill them. The paper analyzes the legislative changes and points out the consequences, both those which can already be seen and the predictable ones. The assumed priority and criterion of evaluation of the reimbursement policy in question is its impact on the functioning of pharmacies which, according to the premises of Polish pharmaceutical law, should play the role of public health protection institutions.

Keywords: community pharmacy, public health, legislation, pharmacist, medicinal product

According to the Polish reimbursement system, an insured patient has the right to obtain medicines dispensed in a pharmacy free of charge or at a partial charge on the basis of a prescription issued by a physician. The institution of refinancing medicines directly to the patient is not applied. The pharmacy that filled a prescription is refunded the reimbursement amount.

The European Union does not impose a strictly defined reimbursement policy with regard to medicinal products on its Member States. For it is assumed that the autonomy of internal legislation has been reserved for the compilation of lists of reimbursed drugs, their prices and reimbursement of pharmacotherapy costs. The European Union regulations in this respect relate only to the reimbursement of costs in connection with cross-border healthcare services.

The recent legislative changes in Poland have led to the transformation of the reimbursement system and quite a radical interference of the state in free market mechanisms. The present paper, while describing the rules of reimbursement of medicinal

products at the retail level, points out the scope of the changes introduced on the basis of the law of 12 May 2011 on the reimbursement of medicines, food products of special nutritional purpose and medicinal products (1). Until then, pharmacies used various mechanisms affecting the increase of drug sales and consumption for their own marketing activities. Pharmacies competed against each other above all by means of prices, which led to the appearance of “price tourism” with patients looking for medicines at the lowest, often reduced, prices. They used loyalty programs, price discounts, special offers or even awards for patients for delivering a prescription for a drug or organization of competitions for patients. It was also acceptable to offer a discount upon payment for a drug. The use of incentives in retail marketing was negatively evaluated from the perspective of professional ethics by the pharmacists’ self-governing organization, which is, however, open to pharmacists only. Pharmacy owners, who are not pharmacists, are unaffected by the pressure from the self-governing organization. Pharmacies’ conduct, in the view of Polish government, has led to the

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escalation of drug wastage and, as a consequence, the need has arisen to strengthen and tighten up the Polish drug reimbursement system at the retail marketing level.

Introduction of fixed margins and retail prices and a ban on using incentive forms

Until now, retail prices and margins have been established officially but with a maximum level, i.e., a pharmacy could dispense a reimbursed drug at a price no higher than the established one. This resulted in pharmacies competing in the field of prices of reimbursed products as well as in patients feeling confused. The law has made a very important change, namely the introduction of uniform prices and margins across all the pharmacies. Additionally, pharmacies have been obliged to collect charges arising from the officially announced lists of reimbursed drugs, without the possibility of using discounts or reductions. They have also been forbidden to use any forms of incentive to purchase reimbursed drugs at a pharmacy. Thus patients have been guaranteed that they will pay the same price for a reimbursed drug in every community pharmacy. Pharmacies are penalized for non-compliance with the established rules and offering lower prices, which means very high fines payable to the state budget. Fines imposed are equivalent to the value of the drugs sold in breach of the provisions of the law, plus up to 5% of the total sales of these products. Penalties are imposed by way of an administrative decision of the Minister of Health.

It must be noted that ensuring fixed prices of reimbursed medicines affects the level of confidence in pharmacies as entities operating in the health protection market and, consequently, a pharmacy is no longer associated with a typically commercial and consumer-oriented place where customers are encouraged to buy medicines. The ban on using incentives to buy medicines should to be assessed as fully legitimate, also from the perspective of the prestige of the pharmacist's profession in Poland.

The retail margin, unlike it was before, is now calculated on the wholesale price of the product, being the basis for the limit in a given limit group. Formerly, the margin depended solely on the price of the drug. It means that, regardless of which product from a particular limit group is sold by a pharmacy, the margin obtained by it will be exactly the same. As a consequence, the pharmacy's profitability is reduced through the decrease in its profits. In addition, the pharmacy is financially burdened by official discounts on drug prices. Both the financing limit value and the limit group are notified in the Minister

of Health's announcements published every two months. This can signify frequent changes in the financing limits or even reshuffles within the limit groups. If a pharmacy purchases a product from a warehouse before an announcement is published, and sells it already after the publication of an announcement reducing the financing limit for the product, it might obtain the minimum margin, or even lose on the transaction. Neither the warehouse nor the manufacturer can protect the pharmacy from such risk.

Pharmacy - pharmaceutical warehouse relations

Until now, it has been possible to offer non-uniform wholesale margins to community pharmacies. At present, companies manufacturing or marketing drugs liable to reimbursement from public funds cannot make the conclusion or formulation of the provisions of a contract dependent on the acceptance or fulfillment of another obligation or use non-uniform conditions in these contracts. Contracts concluded in breach of the above ban are deemed fully or partly invalid. It is inadmissible to use discounts and reductions on the drug manufacturer-warehouse-pharmacy line.

In free market economy, entities which are contractors for one another are the ones who negotiate business terms. Until now, a pharmacy has been granted higher discounts for, e.g., prompt payment for an invoice, while now this is impossible. It appears that the interference with the free market mechanisms on the drug manufacturer-warehouse-pharmacy line, imposing the state control on the functioning of the reimbursed drugs market, has no direct impact on the stability and transparency of the system. The direct impact only manifests itself in the pharmacy-patient relationship, which has apparently been subjected to proper interventionism of the state. Depriving a pharmacy of the possibility of negotiating and influencing its own budget contradicts the rules of a free market. The legislator has, however, decided that only comprehensive control guarantees the tightening of the drug reimbursement system. Pharmacies have been obliged to follow the established rules concerning relations with wholesale trade entities and they must, during an inspection, provide information on the provisions of each contract or agreement in any form binding them to a pharmaceutical warehouse. Non-compliance with the statutory rules is punishable by a fine.

Pharmacy's duty to enter a prescription fulfillment contract

Until now, pharmacies have been reimbursed the costs of dispensed reimbursed drugs, i.e., reim-

bursement by virtue of the law (*ex lege*). They only needed a valid license to operate a pharmacy which automatically authorized them to fulfill prescriptions financed with public funds. From January 2012, every pharmacy is obliged to enter into contracts with the national payer, i.e., the National Health Fund (NHF), authorizing them to dispense reimbursed drugs. Such a contract is also signed by the pharmacy manager. The contract stipulates a number of restrictive fines on the pharmacy for non-compliance with its provisions. In addition, the national payer, through the system of appeals from their arbitrary decisions, practically prevents the pharmacy from pursuing its rights in a potential dispute at court. This strengthens the payer's monopolist position and worsens the legal situation of the pharmacy.

Duty to inform of equivalents of prescribed drugs

The contemporary pharmacist's role is to educate, counsel and provide the patient with adequate information on the treatment ordered (2, 3). The pharmacist's informative role is a significant social function in the health protection system. The pharmacist should provide services related to counseling on drug usage, special pharmacological surveillance of the chronically ill and the education of newly diagnosed patients. The pharmacist should evaluate the patient's understanding of the doctor's recommendations, thus minimizing the probability of a mistake. Co-operation with the patient should also include the reduction of the risk of drug-related problems arising from simultaneously following the advice of several doctors or inadequate self-treatment. The provisions of the Annex to Resolution 97/2 (4) of the Council of Europe indicate that the pharmacist should inform the patient of the possible adverse events, interactions, contraindications, risks of iatrogenic conditions and necessary precautions. Resolution RsAP (2001) 2 of the Council of Europe concerning the pharmacist's role in the framework of health security (5) points to pharmacists' duty to give patients recommendations on the proper usage of drugs, even in the written form. Polish professional legislation refers to the pharmacist's duty to give information and advice on the effects of medicinal products and usage of medical devices.

The new law concerning the reimbursement rules refers to the duty to inform the patient of the possibility of purchasing an equivalent of the drug prescribed by the doctor. However, the following conditions have to be met:

- 1) both drugs must be liable to reimbursement,
- 2) the prescribed drug and the dispensed drug must have:

- the same international name,
 - the same dosage,
 - the same pharmaceutical form, and it is admissible for the suggested pharmaceutical form to be similar but not leading to therapeutic differences,
 - the same therapeutic indication,
- 3) the retail price of the suggested drug cannot exceed the limit and retail price of the prescribed drug.

It needs to be emphasized that the price of the suggested substitute product can be equal to or lower than the price of the drug ordered by the physician.

The manner of giving information to the patient as such is a disputable matter. The common practice at pharmacies is to display a special poster. It seems, however, that giving information should be understood as an activity requiring a certain involvement, hence not equivalent to making information available. Moreover, in accordance with the literal wording of the law, the duty to inform of the possibility of substituting the drug with a different one should be fulfilled by the person dispensing drugs. And that person can only offer the patient a direct conversation. Turning the patient's attention to the poster hardly seems professional and is inconsistent with the intention of the legislator who used the perfective form of the verb "to inform", emphasizing the duty to start and effectively end the information process itself.

The duty to dispense a cheaper equivalent of the prescribed drug

The pharmacist should be able to control ensuring the accessibility of drugs at moderate prices to patients (6, 7).

The information duty, arising from the reimbursement law, is associated with the duty to fulfill the patient's request to be dispensed a different reimbursed drug whose price is lower than the price of the product prescribed. It must be stressed that the legislator does not provide for the possibility of substitution outside the framework of reimbursed drugs. Dispensing a non-reimbursed drug (meeting the criterion of the same medicinal substance, the same dosage and pharmaceutical form) should be considered, under the applicable law, a violation of professional competences. Pursuant to the provisions of the Regulation of the Minister of Health of 8 March 2012 on medical prescriptions (8), the fulfillment of a prescription signifies the dispensing of the drugs it includes, not providing for the possibility of any interference in the ordered treatment by the pharmacist.

The fulfillment of the criterion concerning the presence of the same medicinal substance, the same dosage or the same form raises no doubts. The other restrictions, however, are not so obvious and give rise to much controversy over the pharmacist's role. And so, an equivalent of the drug suggested by the physician can only be dispensed upon a clear and categorical demand of the patient, and it must meet the conditions of a lower price and the same indications as well as the reimbursement coverage of both drugs (the prescribed and dispensed one).

The previous conditions of reimbursed drugs' substitution were not so restrictive and took into account the demands for a broader participation of the pharmacist in the choice of pharmacotherapy. The consequence of the present solutions is placing the pharmacist in the role of a dispenser of prescribed drugs, instead of a counselor.

Pharmacists are concerned about their financial responsibility towards the National Health Fund and the responsibility towards the patient in the event of substitution for the pharmacotherapy ordered. The prescription fulfillment contract between a pharmacy and a provincial branch of NHF sets out the financial consequences of failure to provide information or dispense a cheaper equivalent of the prescribed drug. Another controversy is aroused by the possibility of dispensing a drug not meeting the criterion of the same indications, which can happen to employees guided by routine and the conviction that the presence of the same substance should be a sufficient basis for substitution. If a patient suffers harm as a result of using a drug substituted by a pharmacist and the drug does not have the same indications as the prescribed drug, i.e., it was used off-label, they will be entitled to lay their claims against the pharmacist, not the manufacturer of the drug. What is more, the pharmacist will be exposed to the risk of repayment of the reimbursement of the drug used off-label.

Prohibition on advertising pharmacies and their activities

From January 1, a prohibition on advertising pharmacies and their activities, including those related to the dispensing of reimbursed drugs, has been in force. The prohibition can be considered as the legislator's belief in the special role and prestige of the pharmacy as a health protection institution. Polish law imposes similar restrictions on hospitals, outpatient centers and persons conducting medical or nursing and obstetrical practice.

The restrictions on the advertising of pharmaceutical services provided at a community pharma-

cy are under the supervision of provincial pharmaceutical inspectors who, should a violation be discovered, order to cease such activities and may impose a financial penalty of up to 50,000 zlotys.

Nonetheless, the new provisions of the law do not contain a definition of the advertising of a pharmacy's activities but only point to the types of content who are treated as information, namely the details concerning location and opening hours. Therefore, it is necessary to refer to the judicial decisions to date suggesting the meaning of this term. Pursuant to the decisions of Polish courts, advertising of a pharmacy should encompass any activities related to informing and encouraging customers to purchase a medicinal product or medical device at a particular pharmacy, aimed at raising their sales. The term "advertising a pharmacy's activities" should also be understood as the intention to encourage prospective customers to purchase the merchandise sold in the pharmacy – irrespective of its forms and methods and the means used for it – provided that its goal is to raise the sales of medicinal products or medical devices.

The absence of a statutory definition of a pharmacy's advertising leads to attempts at circumventing the law that prohibits advertising. Some entities running pharmacies try to change their name to one which is in fact an advertising slogan (e.g., Low Price Center Pharmacy). The pharmacy name is stated by its owner in the application for a license to run the pharmacy. The additional words adjacent to "pharmacy" are the identification of an institution providing pharmaceutical services. The name may be changed upon obtaining a decision of the provincial pharmaceutical inspector modifying the license. Its point is to determine whether there are good reasons for the change, i.e., whether the change is justified by social interest or the party's legitimate interest. The party's legitimate interest is interest worthy of protecting and not in conflict with the law and principles of community life. Hence, applying for a change of the pharmacy name as stated in its license, to a name containing a word or words in fact being its advertisement addressed to the customer should be assessed as an intention to break the advertising ban.

Pharmacist's obligations related to administrative and formal tasks

The contemporary pharmacist's role is above all concern for the safety of the patient for whom the drug was prescribed (9-12). In order for the role to be fulfilled, the time devoted to the patient should not be limited by state administration. Now, the

Polish legislator has enlarged the catalog of the pharmacist's duties by adding purely formal, downright clerical activities, whose final aim is to reduce the quantity of the reimbursed drug prescribed by the physician or simply to dispense the drug without reimbursement. The pharmacist is supposed to play the gate-keeper's role in the reimbursement system. The legal provisions concerning the prescription fulfillment principles force the pharmacist to interfere in formal content. Pharmacists have been imposed duties related to reducing the quantity of the drug dispensed if the physician incorrectly stated the dosage, ordered the drug in a packaging unavailable in the market, did not state the treatment duration or doubled the quantity of compounded drugs. Additional obstacles in pharmacy practice are the inaccuracy and ambiguity of the legal provisions and the acceptable latitude in their interpretation by NHF inspectors, who control pharmacies and enforce financial responsibility for even the slightest error, which has actually no effect on the reimbursement amount (e.g., a weakly impressed stamp can lead to the rejection of the prescription reimbursement). This results in excessive and unnecessary formalism in the pharmacist's contacts with a patient filling a prescription and distorts the nature of their mutual relations.

The pharmacist is obliged to verify prescriptions for their possible forgery. If the authenticity of a prescription for a reimbursed drug is suspicious, the pharmacist must report the fact to the supervisory bodies and NHF, and confiscate the document.

CONCLUSION

Retail marketing of reimbursed medicinal product in Poland is strictly controlled by the legislation and administrative authorities. The state interventionism in this domain is intended to tighten up the reimbursement system. Pharmacies have been forbidden to use any forms of encouragement to buy drugs and imposed the duty to use uniform prices and margins, which is meant to minimize price competition among pharmacies. The bans apply also to the relations between pharmacies and pharmaceu-

tical warehouses. The activities of community pharmacies are restricted even with respect to their advertising. The pharmacist's role should be limited to that of a person dispensing drugs and a gate-keeper of the reimbursement system, without promoting the advisory and educational role of pharmacists.

REFERENCES

1. The law of 12 May 2011 on the reimbursement of medicines, food products of special nutritional purpose and medicinal products (Journal of Laws of 2011, No. 122, it. 696 as amended) - (Polish).
2. Blom L., Krass I.: *Patient Educ. Couns.* 83, 285 (2011).
3. Latif A., Pollock K., Boardman H.F.: *Patient Educ. Couns.* 83, 336 (2011).
4. Resolution AP (97)2 on the development of the function of pharmacists and the adaptation of their initial training. Adopted by the Committee of Ministers on 30 September 1997.
5. Resolution ResAP (2001) 2 concerning the pharmacist's role in the framework of health security. Adopted by the Committee of Ministers on 21 March 2001.
6. Resolution AP (93) 1 on the role and training of community pharmacists. Adopted by the Committee of Ministers on 23 1993.
7. Cutler T.W., Stebbins M.R., Smith A.R., Patel R.A., Lipton H.L.: *Med. Care* 49, 343 (2011).
8. Regulation of the Minister of Health of 8 March 2012 on medical prescriptions (Journal of Laws of 2012, it. 260) – (Polish).
9. Duquet N.: *J. Pharm. Belg.* 66, 97 (2011).
10. Arora T., Anand G., Sharma S., Sharma P., Arora A.G., Anand K.: *Int. J. Pharm. Sci. Rev. Res.* 11, 119 (2011).
11. Samuel N., Einarson A.: *Int. J. Clin. Pharm.* 33, 882 (2011).
12. Nishihara S.: *Yakugaku Zasshi*, 131, 865 (2011).

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