The main objective of this dissertation is to identify the impact of the introduced mechanisms for regulating generic medicines in the 2011 Reimbursement Act on the medicines market in Poland and to indicate the observed trends in the years 2012-2018.

The Reimbursement Act, as a key piece of legislation regulating the principles of medicines financing in Poland, was aimed at implementing a more transparent reimbursement system, improving the functioning of the principles of medicines financing and, most importantly, increasing accessibility for patients with better control over expenditure.

Four hypotheses were set for the purpose of the dissertation, which were verified in the course of the dissertation:

• H1. The Reimbursement Act, through regulatory mechanisms, has led to a reduction in public payer spending on reimbursed medicines, including prescription medicines.

• H2. The Reimbursement Act in the area of open-access medicines (prescription medicines) has increased the availability of new generic medicines for reimbursement (number of unique substances, new products - trade names and sales volumes)

• H3. The level of co-payment for reimbursed prescription medicines, including generics, has decreased between 2012 and 2018 (co-payment per 1 patient DDD - all reimbursed medicines/generics)

• H4. The introduction of generics has increased the availability of prescription medicines by therapeutic area (number of packs, number of DDD, number of products)

H1. The Reimbursement Act, through regulatory mechanisms, has led to a reduction in public payer spending on reimbursed medicines, including prescription medicines.

The research hypothesis formulated can be verified positively. The introduction of the Reimbursement Act, together with mechanisms leading to price reductions through the introduction of more medicines, has led to savings in the open medicine market, which is dominated by generic medicines. Expenditure on medicines available in pharmacies between 2012 and 2018 was lower than expenditure on these medicines in 2011.

The introduction of the Reimbursement Act has led to a reduction in the public payer's total expenditure on reimbursement of medicines in the short term. The introduction of the Reimbursement Act, together with mechanisms leading to price reductions through the introduction of more medicines, led to savings by the NHF in the open medicine market, which is dominated by generic medicines. The 2011 level of total reimbursement expenditure on reimbursed medicines was exceeded in 2015, but the 2010 level of expenditure on reimbursed prescription medicines was only reached in 2018 (bearing in mind that savings from risk-sharing instruments introduced for medicines available in pharmacies are not visible in the calculations).Thus, a decreasing share of the reimbursement value incurred for all reimbursed medicines available in pharmacies in relation to the total reimbursement budget can be observed (82% in 2011, 75% in 2012 and 67% in 2018).

H2. The Reimbursement Act in the area of open-access medicines (prescription medicines) has increased the availability of new generic medicines for reimbursement (number of unique substances, new products - trade names and sales volumes).

Generic medicines are mainly financed under the list comprising medicines available in the pharmacy (List A) and medicines financed under chemotherapy (List C). The decrease in the number of reimbursed unique substances after 2012 was partially offset by the inclusion of new products in the reimbursement (mainly further generic equivalents in the relevant indications) or new packaging of

previously reimbursed medicines [10]. Generic medicines account for more than 80 per cent of the volume market for prescription medicines, which means that they have a decisive impact on increasing patients‘ access to medicines by both increasing the number of available products and reducing patients’ co-payments. At the same time, during the period under review, the number of generic products increased by 400 items, and additionally the share of generics in terms of the number of packs as well as the volume of daily utilisation of medicines, i.e. the number of DDD, increased. An analysis of patients‘ outlays on medicines available at the pharmacy between 2012 and 2018 shows a graduał decrease in the share of generic products in patients’ total outlays from around 85.8% in 2012 to less than around 79.5% in 2018.

In the case of generics, an increase in NHF expenditures can be observed both in absolute terms by nearly 30%, i.e. from PLN 4.51 billion in 2012 to about PLN 5.86 billion in 2018 (average annual increase of 4.4%), as well as in relation to total pharmacy reimbursement expenditures in the analysed time period by almost 5 percentage points from 68.9% to 73.3%. Total patient spending on reimbursed open-list prescription medicines in 2018 was lower than in 2012 by approximately PLN 70 million, despite a significantly higher number of reimbursed packages (364.7 million in 2012 and 426.3 million in 2018). This is mainly due to price decreases of individual medicines resulting mainly from generic competition as well as the introduction of the 75+ programme.

H3. The level of co-payment for reimbursed prescription drugs, including generics, has decreased between 2012 and 2018 (co-payment per 1 patient DDD - all reimbursed drugs/generics).

An important development is the decrease in NHF and patient co-payment per 1 DDD for reimbursed prescription medicines. The NHF reimbursement per DDD for each reimbursed prescription drug in 2012 was PLN 0.62, while in 2018 it was PLN 0.58, which translates into a decrease of 7%. The decrease in patient co-payment is much greater - a decrease in payer expenditure per DDD of approximately PLN 0.08, or 12.8%, between 2012 and 2018. One of the successes of the Reimbursement Act is the decrease in patient co-payment, which amounted to approximately 25% in the analysed period for all prescription medicines. For generics, the decrease was greater at over 30%.

H4. The introduction of generics has increased the availability of prescription medicines by therapeutic area (number of packs, number of DDD, number of products).

The calculations performed in this thesis show that the public payer's expenditure on reimbursed medicines after the introduction of the Reimbursement Act did not change significantly compared to the earlier period before the introduction of the Reimbursement Act. At the same time, the financial resources saved allowed for the reimbursement of more individual medicines as well as the introduction of new substances.

The introduction of the Reimbursement Act resulted in the removal of 23 active substances in the first announcement. At the same time, 887 fewer items were included in the first announcement compared to the previous list of reimbursed medicines (from the end of 2011). This was due to the lack of agreement with the Economic Commission and the removal from reimbursement of medicines with a well-established position in therapeutics without registered indications in the SmPC.

The highest outlays of the public payer for generic drugs were consumed by products financed in cardiovascular diseases, i.e. c. PLN 1,156 million in 2018 compared to PLN 1,103 million in 2012 (a 5% increase), followed by drugs used in gastrointestinal and metabolic diseases at PLN 859 million compared to c. PLN 720 million in 2012 (an increase of 15%) and medicines with an unspecified therapeutic area (ATC code - V), whose cost to the NHF amounted to c. PLN 843 million compared to c. PLN 466 million in 2012 (an increase of more than 80%).

The implementation of the Reimbursement Act allowed for a reduction in the volume of expenditure on reimbursed drugs, including generic drugs. The Payer is also systematically regulating this issue by decreasing the spending on generic drugs, but at the same time regulating patients' co-payment (e.g. by introducing the 75+ drugs, i.e. covering co-payments for the elderly). The relative decrease in expenditure on medicines in relation to expenditure on all guaranteed benefits is worrying. This may create difficulties in achieving further savings for the payer or generating lower patient co-payments, which is already becoming apparent in prescription drugs. The dynamics of the number of new molecules entering reimbursement indicates that the introduction of new generic medicines in open medicine will be limited in the long term (lack of new medicines, price erosion in the currently existing limit groups).