PRICING OF MEDICINES IN POLAND – TWO-YEAR OVERVIEW OF HOW THE NEW LAW AFFECTED COSTS OF REIMBURSEMENT

ISPOR 17th Annual European Congress
Amsterdam, The Netherlands, 8-12 November 2014

Szmurło D, Władysiuk M, Plisko R
HTA Consulting, Cracow, Poland

Background

Poland is located in Central Europe and with its 38.5 million inhabitants is the 6th largest country in the European Union (after Germany, France, United Kingdom, Italy and Spain). Poland Gross Domestic Product (GDP) per capita amounts to 9,900 EUR and is 66% of the EU-27 average (purchasing power standard, 2012). Healthcare spending are 7.0% of GDP, which is well below the 9.0% EU average. Expenses in absolute values are even lower, as GDP of Poland is much lower than in other European countries. Private spending account for nearly 30% of the total healthcare costs.

The Polish healthcare system is based on obligatory insurance which covers 98% of population. Health policy is created by Ministry of Health, financing of majority of health services is the responsibility of National Health Fund.

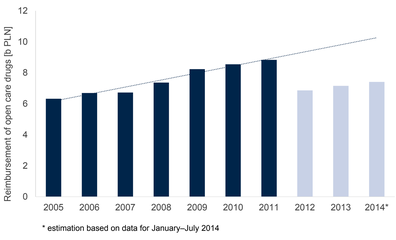
Despite relatively low per capita health expenditures, Polish pharmaceutical market is among the largest in Europe, with market value estimated at 5,1 billion EUR in 2011.

Costs of reimbursement before 2012

In 2005 around 20% of National Health Fund spending on healthcare services were spent on reimbursement of open care drugs – 6.3 billion PLN (1.6 billion EUR). In the following years costs of reimbursement were increasing by 450 million PLN annually (110 million EUR). During 2005–2011 those costs have increased by 40% – up to 8.8 billion PLN (2.2 billion EUR). At the same time total budget of NHF have increased by 75% (33 up to 58 billion PLN, 8 up to 15 billion EUR). In 2011 costs of reimbursement of open care drugs constituted 15% of NHF health services budget.

Higher costs of reimbursement were mostly driven by increase in demand for drugs for chronic diseases.

Figure 1. Costs of reimbursement of open care drugs in Poland



* estimation based on data for January–July 2014

The new reimbursement law

Such rapid growth of costs of reimbursement led to redesign of the drug pricing mechanisms. As a result a new law which brought revolutionary changes to the healthcare system was introduced in 2012[2]. The law implemented numerous mechanisms that were aimed at reduction of overall costs, the most influential being:

- negotiations of prices during the reimbursement submission process,
- strong internal and external reference pricing,
- new method of calculation of reimbursement limit,
- lower retail and wholesale margins,
- implementation of risk-sharing agreements,
- drug budget was set at 17% of NHF budget for healthcare services, should this amount be exceeded a payback mechanism would be activated.

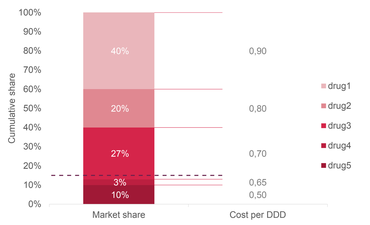
Some regulations created formal obstacles in obtaining prescriptions for reimbursed products. Often antibiotics were prescribed with 100% co-payment due to fines that could be paid by physicians prescribing drugs without formal confirmation (antibiogram) of the type of bacteria patients were infected with.

The idea of internal reference pricing was functioning in Poland even before 2012, however the new law significantly changed it. Before, reference groups were created for each dose of drug (i.e. 200 mg pills) and branded and generic drugs with the same active ingredient and dose were grouped together, so that drugs within a single group could be easily switched. The reimbursement limit was set at the cheapest drug in the group. If a patient preferred branded drug to generic, he would pay the excess cost.

The new rules of internal reference pricing led to creation of jumbo groups. Often different active ingredients are grouped together, as long as they have the same reimbursement indication and similar efficacy. On top of that all doses are usually placed within the same group, as well as different drug formulation or different mechanisms of action (long- / short-acting). The same applies to branded and generic drugs. The reimbursement limit is now set at the cheapest drug whose cumulative share is 15% of the sales in the group – see example presented on Figure 2, in this case the limit is determined by drug3. New reimbursement list is issued every two months and with such frequency prices of drugs and reimbursement limits are changing.

Practical implications of the new shape of reference groups and new limit- setting rules are that patients cannot always switch to drugs that are the cheapest. I.e. in case when few active ingredients are grouped together and they have different unit cost or when a drug does not have a linear price with respect to dose – higher doses are usually cheaper and patients have to co-pay more for low doses. If a patient wants to use the same brand of drug – its price may vary in the two-month periods, in extreme cases it can change from very low to very high co-payment. If a patient wants to use the cheapest drug available, it may be the case that he will have to change brands every two months.

Figure 2. Determining reimbursement limit in a reference group



Those regulations had great impact on costs of reimbursement, both from the NHF and patient perspective:

- prices of drugs were substantially decreased as a result of negotiations and external reference pricing,
- risk sharing agreements further reduce costs of therapy for NHF,
- strong internal reference pricing and new methods of calculation of reimbursement limit resulted in higher co-payment of patients – costs were partially shifted from NHF to patients,
- due to formal obstacles for some drugs costs were totally shifted from NHF to patients.

Summary

OBJECTIVES: *Rapid increase of costs of reimbursement in Poland led to redesign of the drug pricing mechanisms. As a result a new law which brought revolutionary changes to the healthcare system was introduced in 2012. The aim of this work is to summarize the two years of new drug policy in Poland and to present mechanisms that resulted in substantial savings in reimbursement costs.*

METHODS: *Few savings-generating mechanisms were implemented in the new reimbursement law: negotiations of prices, new method of calculation of reimbursement limit (resulting in higher co-payment) and also formal obstacles in obtaining prescriptions for reimbursed products (some reimbursed drugs, i.e. antibiotics, due to formal issues are prescribed with 100% co-payment). The first and the third reason result in lower overall costs of reimbursed medicines, while the second reason influences the proportion of costs borne by the National Health Fund. We have analyzed data on prices of reimbursed drugs before 2012 and after implementation of the new law (currently the prices may change every two months). We have then compared the amount of sales of those drugs, costs of reimbursement and patients' co-payment. For some reference groups (i.e. oral aromatase inhibitors) we made in-depth analysis of pricing mechanisms.*

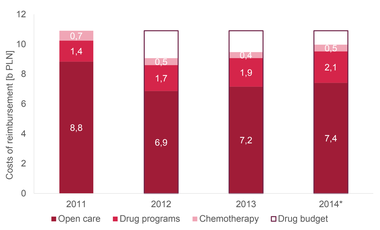
RESULTS: *In 2012 total public expenditures amounted to 2.3 billion EUR, 83% of the planned budget, which gave 460 million EUR savings as compared to 2011. In 2013 the drug budget was executed in 87%, resulting in 430 million EUR savings. Saving were driven by price negotiations, but also by mechanisms of lowering the reimbursement limit, i.e. in case of oral aromatase inhibitors the reimbursement limit was lowered by half during 2012-2013.*

CONCLUSIONS: *The new reimbursement law resulted in substantial savings in costs of drugs. The success is however relative, as costs of drugs were partially shifted towards patients.*

Costs of reimbursement after 2012[1]

In 2012, the first year after implementation of the new reimbursement law, total public expenditures on drugs (incl. also foodstuffs and medical devices) amounted to 9.1 billion PLN (2.3 billion EUR), 83% of the planned budget (10.9 billion PLN, 2.7 billion EUR), which gave 1.8 billion PLN (460 million EUR) savings as compared to 2011. In 2013 the drug budget was executed in 87%, resulting in 1.4 billion PLN (430 million EUR) savings.

Figure 3. Costs of reimbursement in 2011–2014



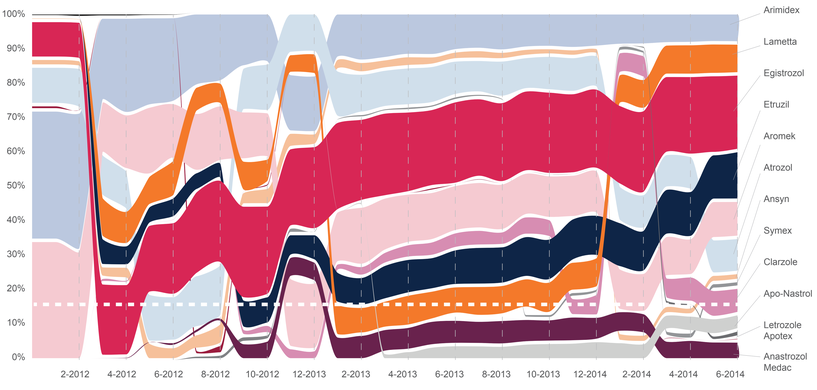
Savings were driven by price negotiations, but also by mechanisms of lowering the reimbursement limit, i.e. in case of oral aromatase inhibitors the reimbursement limit was lowered by half during 2012-2013.

For most brands co-payment dramatically increased in January 2012 as compared to 2011 and this resulted in sudden drop of sales. As a response to such reaction of the market, manufacturers of some products decreased their prices below the price of Aromek. Aromek, that was setting the limit in January-February 2012, kept its price stable. At the same time 3 new brands entered the reimbursement. The reduction of prices resulted in change of the limit-setting drug. The reimbursement limit was reduced to 4.33 PLN (1.08 EUR) per DDD (121.2 PLN, 30.3 EUR per package of anastrozole and 129.8 PLN, 32.5 EUR per package of letrozole). 6 out of 18 products were now free of charge for patients (below the limit). For all other products above-the-limit co-payment ranged from 2.1 PLN (0.5 EUR) up to 144.5 PLN (36.1 EUR) per package.

In only two months of the new law the reimbursement limit in the group of oral aromatase inhibitors was reduced by 11%. However, this decrease shifted costs of medicines to patients, as still only around 15% of them were buying their medicines free of charge. The battle for market shares continued in the following months of 2012, manufacturers were decreasing the prices to be below or at the limit level, because patients were switching to drugs with the lowest co-payment.

In mid-2012 few brands of exemestane were listed, one of them with price 25% lower than the other (generic). Even though both letrozole and anastrozole had counterpart drugs available, the introduction of counterpart exemestane caused the reimbursement limit to be lowered to its level. This brought the next substantial reduction of reimbursement limit – now being as low as 3.32 PLN (0.83 EUR) per DDD (92.9 PLN, 23.2 EUR per package of anastrozole and 99.5 PLN, 24.9 EUR per package of letrozole and exemestane). Only 2 out of 26 brands were now free of charge for patients, but their cumulative market share was barely 1%, which led to 99% of patients co-paying for their drugs – from 5.8 PLN (1.4 EUR) up to 173.3 EUR (43.3 EUR) per package.

Figure 4. Market shares of oral aromatase inhibitors in 2012–VI 2014



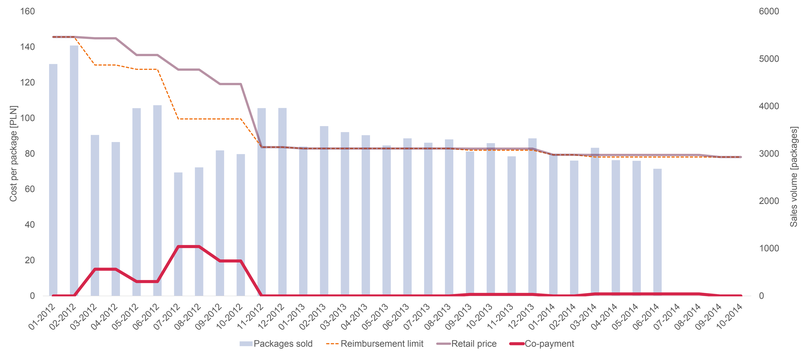
Case of oral aromatase inhibitors[1]

The class of oral aromatase inhibitors, hormonal drugs indicated for treatment of breast and ovarian cancer in postmenopausal women, include anastrozole, letrozole and exemestane.

At the end of 2011, right before implementation of the new reimbursement law in Poland, only anastrozole and letrozole were reimbursed. Due to their indication (oncology), these drugs were reimbursed with 0% co-payment. Each active ingredient had its own reference group. A weighted-average cost per package of anastrozole in 2011 was 159.0 PLN (39.7 EUR) and per package of letrozole 311.0 PLN (77.8 EUR). In 2011 total sales of those drugs amounted to 8.3m DDDs (defined daily doses), total costs of reimbursement were 17.0m EUR, while the co-payment was 54k EUR (0.3% of total value of sales).

In the beginning of 2012, as a result of price negotiations and new regulations on wholesale and retail margins, retail prices of anastrozole and letrozole were reduced on average by 11%. All drugs were placed in one reference group and the reimbursement limit was set along with the new rules at 4.85 PLN (1.21 EUR) per DDD (135.9 PLN, 34.0 EUR per package of anastrozole and 145.6 PLN, 36.4 EUR per package of letrozole). The drug setting the limit, Aromek (letrozole), was the cheapest in the whole group, so it was the only brand for which there was no co-payment (covering around 15% of DDDs sales). For all other products above-the-limit co-payment ranged from 5.8 PLN (1.5 EUR) up to 129.4 PLN (32.4 EUR) per package.

Figure 5. Prices and sales volume of Aromek (letrozole) in 2012-2014



The second half of 2012 brought further price reductions and changes in the reimbursement limit. By the end of 2012 it was at the level of 2.79 PLN (0.70 EUR) per DDD – 43% lower than at the beginning of 2012. NHF costs were clearly reduced during this 12 months. However, after listing counterpart exemestane and making it the limit drug, patients' co-payment doubled and did not lower until January 2013.

Conclusions

The new reimbursement law resulted in substantial savings in costs of drugs. The success is however relative, as costs of drugs were partially shifted towards patients.

References

1. IKAR pro – interactive reimbursement database. http://ikarpro.pl
2. Ustawa z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych. Dz.U. 2011 nr 122 poz. 696