„Pay-back" mechanism in the Polish reimbursement system - analysis and appraisal

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ABSTRACT

The text of this review has been based on a diploma thesis, prepared by Mr Borys Podgorny under the supervision of Dr Iwona Skrzekowska-Baran, as part of the XXII Edition of the Advanced Management Training in Pharmacoeconomics, HTA, Pharma Marketing and Law of the Warsaw University Of Technology Business School. The presented review has employed a detailed analysis of appropriate provisions of the Reimbursement Act, while benefiting from the practical experience of the authors, regarding the implementation of the Act and the practical application of its principles.

The results of the conducted analysis indicate a number of significant drawbacks in the current version of the pay-back mechanism, which either prevent any correct calculation of the amounts to be paid back or which may become a breeding ground for disputes and conflicts with marketing authorisation holders, as regards the administrative and legal aspects of the process. In consequence, should the pay-back mechanism remain an integral part of the Polish reimbursement system, it will need urgent legislative amendments to ensure its effective management and, first of all, to streamline the calculation of reimbursable amounts, based on available and verifiable data. Above all, however, it seems still reasonable and appropriate to ask about the sensibleness of and reasons for further existence of such a solution in the Polish legal system, where other legal mechanisms successfully execute the systemic goals in terms of reducing the payer's expenses.

BACKGROUND

In spite of more than two years since the implementation of the new reimbursement system in Poland, some of its elements and mechanisms still raise serious controversies and arouse conflicting feelings.A reflection of this situation may be found in the works on amendment of the reimbursement provisions, which have, for some time, been underway at the ministerial level.

A controversial area, often avoided in discussions on the reimbursement system, is the mechanism of the, so-called, pay-back, i.e., a statutory, common obligation, assuming the payback of a reimbursed amount in total or in part if the actual reimbursement expenses exceed the fixed annual budget.

The high complexity of this regulation raises reasonable disputes, regarding a number of substantive issues, such as the range of products, taken into account in the calculation of the amounts to be returned or the conditions to be met to trigger the mechanism for appropriate actions.

In this context, as well as in the absence of any broader examination of the pay-back mechanism in available literature, it seems highly advisable to analyse the assumptions of this solution. This review is an attempt of a systematic and complex approach towards payback-related issues. A starting point of this analysis, as well as its scope, are determined by the existing legislative framework, since nowadays, any implementation of solutions, which would sharply diverge form the (relatively new) regulations, laid down in the actual Reimbursement Act, can hardly be expected.

ANALYSIS

The principle of solution

The 'pay-back' term started to enter wider circulation in 2010, being first used by the persons, involved in the reimbursement issues in Poland, simultaneously with the publication of the reimbursement act project, drafted in its first version and has, since then, at once become one of the symbols associated with the new legislation. Unfortunately, more in the context of risks and uncertainties, carried by the new regulations for the pharmaceutical market.

This term has been introduced not so much in the Act itself but more in its explanatory memorandum. While giving reasons for the implementation of the mechanism, it has been indicated that „the problem of considerable and unforeseeable increase in the expenses for reimbursement, incurred in the course of the financial year, was long ago recognised in other countries of the European Union. "Particular countries have, during the last ten years, been introducing various solutions to prevent and tackle the problem, which – in the majority of cases – are based on the payback of any excessively reimbursed amounts by marketing authorisation holders after the end of financial year. In this context, it has been considered necessary to implement a mechanism in Poland which would allow „sharing the risk of the National Health Fund, associated with the inclusion of subsequent products in the reimbursement scheme, with the industry" [1], referring to the solutions used in France, Portugal, Italy, Belgium and Hungary.

Taking into consideration the final legislative provisions, this pay-back solution "tailored to the Polish reality", has been based on the following two fundamental assumptions:

1) A statutory definition of the total budget for reimbursement – at a rigid level for the years 2012-2014 – or in statutorily defined intervals, starting from the year 2015,

2) A statutory, obligatory mechanism of financial participation by the entities (reimbursement applicants) which have been awarded with positive reimbursement decisions. This participation shall be equivalent to the amount, paid by the public payer above the original plan of reimbursement expenditure (calculated according to mechanisms provided for in the law).

Pre-conditions for pay-back system implementation

The Reimbursement Act defines one, basic condition which, when fulfilled, triggers a whole series of obligatory steps, tests and calculations, used to calculate the amount to be returned for a given reimbursed products (commonly referred to as "pay-back"). This condition is the overrun of the total reimbursement budget, „in the course of the National Health Fund's financial plan implementation" in part assigned to funding of medicinal products, foodstuffs intended for particular nutritional uses and medical products dispensed at pharmacies against prescriptions.

The possibility to verify the fulfilment of the above-mentioned condition should obviously be determined by the existence of a clearly defined reference point, with which the expenses, incurred during a given year, will be compared (the Plan vs. the Execution). The Plan should then be a fixed figure, rigidly defined (e.g., in results of the voted and approved financial plan of the National Health Fund) and evaluated in time, as needed.

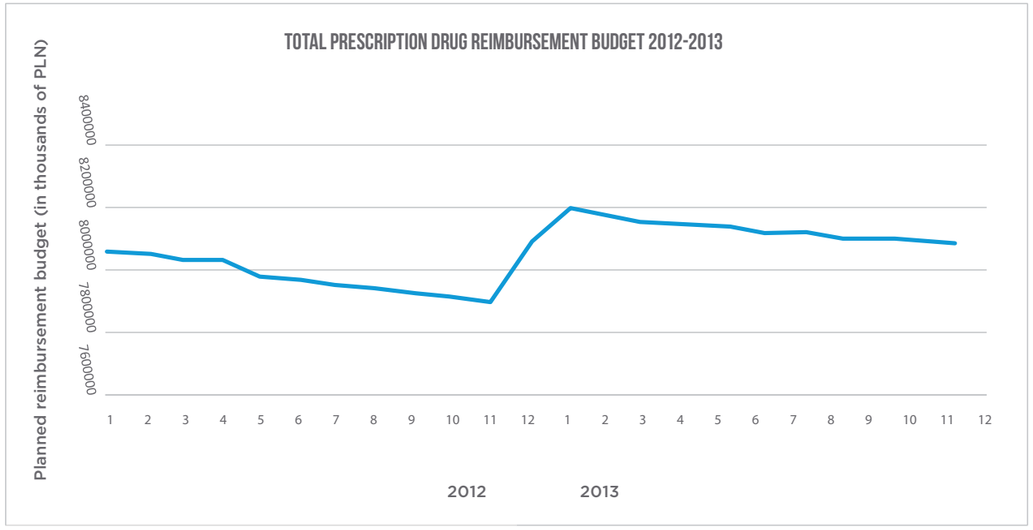
Interpretation difficulties begin already with this condition. Here not only does the legislator use a rather unclear and imprecise term of budget overrun „in the course of implementation of the National Health Fund's plan", but, furthermore, it emerges that the term of total budget for reimbursement in its part of funding the products, dispensed at pharmacy against prescription, has not been clearly defined, either. It is so, as – even if the Reimbursement Act indicates provisions, determining the level of the total budget for reimbursement [2], the implementing rules do not rigidly determine a division of the planned expenses in line with particular budget components, what means that no accurate, partial plans are made for the reimbursement of particular sectors, such as the products available at pharmacy, the products available from drug programmes or from the catalogue of chemotherapy agents. In consequence, pursuant to periodical communications, published by the Economic-Financial Department of the National Health Fund, the height of the planned total budget for the reimbursement of prescribed products is characterised by a rather high volatility, what is well illustrated by the table below.

THE 'PAY-BACK' TERM STARTED TO ENTER WIDER CIRCULATION IN 2010, BEING FIRST USED BY THE PERSONS, INVOLVED IN THE REIMBURSEMENT ISSUES IN POLAND, SIMULTANEOUSLY WITH THE PUBLICATION OF THE REIMBURSEMENT ACT PROJECT, DRAFTED IN ITS FIRST VERSION AND HAS, SINCE THEN, AT ONCE BECOME ONE OF THE SYMBOLS ASSOCIATED WITH THE NEW LEGISLATION

The presented illustration indicates that, with no clear reference point in the actual legislative system, it is difficult (or even impossible) to assess from the point of view of the the reimburse-

Table 1. Payback graph

		PLANNED PRESCRIPTION DRUG REIMBURSEMENT BUDGET IN 2013	EXECUTION	EXECUTION IN ASCENDING ORDER	TOTAL BUDGET
2012	1	8 090 926,00	422 160,45	422 160,45	
	2	8 084 926,00	531 771,18	953 931,63	
	3	8 062 002,00	610 377,57	1 564 309,20	
	4	8 061 995,00	582 700,45	2 147 009,65	
	5	8 003 755,00	576 383,54	2 723 393,19	**10 445 819,00**
	6	7 995 895,00	647 856,48	3 371 249,67	**10 445 819,00**
	7	7 974 787,00	518 610,89	3 889 860,56	**10 445 819,00**
	8	7 965 608,00	553 812,13	4 443 672,69	
	9	7 946 745,00	551 801,10	4 995 473,79	
	10	7 936 385,00	645 959,25	5 641 433,04	
	11	7 918 885,00	598 713,28	6 240 146,32	
	12	8 121 004,00	607 601,39	6 847 747,71	
2013	1	8 243 247,00	599 556,77	599 556,77	
	2	8 211 247,00	582 273,79	1 181 830,56	
	3	8 191 097,00	603 147,69	1 784 978,25	
	4	8 187 597,00	607 477,33	2 392 455,58	
	5	8 182 147,00	569 549,21	2 962 004,79	
	6	8 159 247,00	582 959,76	3 544 964,55	
	7	8 159 247,00	591 496,59	4 136 461,14	
	8	8 142 942,00	555 952,26	4 692 413,40	
	9	8 137 242,00	582 470,32	5 274 883,72	**10 901 083,00**
	10	8 134 742,00	666 854,53	5 941 738,25	
	11	8 123 142,00	598 104,81	6 539 843,06	
		-324 362,00			



ment applicant, i.e., the potential back payer, if the preliminary condition for the calculation of the exceeded amount is met during a given year. The system is also susceptible to errors or frauds, since – with the lack of annual measurements and of the budget amount – determined in advance – a risk cannot be excluded that, in result of provisional "shifts" among particular budget components or the Provincial Departments of the National Health Fund, the plan for a given month is exceeded (e.g., in result of a temporary budget underestimation), while in the annual approach, a surplus of means may be accounted by the National Health Fund. In terms of the regulation in its actual version, even in such a situation, it should be mandatory to precisely calculate both the exceeded amount and the pay-back amount in particular limit groups [3]. On the contrary, the actual system demonstrates high far-reaching volatility and unpredictability in effect of inaccuracy in the legislative solutions, what may in future be a source of disputes and conflicts, regarding correct calculations of pay-back amounts and their height.

The mechanism of calculation of exceeded amounts in particular limit groups

Assuming that – regardless of the above-mentioned controversies – the preliminary condition for pay-back determination is regarded as met for a given reference period, another legislative mechanism will be activated on the pathway, leading to pay-back amount calculation. Namely, the amount of exceeded reimbursement will be calculated for a given limit group. The proportion of reimbursement applicant's share in the exceeded reimbursement in a given limit group will be determined in further sequence.

At this moment, the legislator has decided to abandon the analysis of exceeded amounts at the level of the entire reimbursement budget (total or in its part, dedicated to the reimbursement of prescribed medicinal products) and proceed with further analyses of exceeded amounts in particular limit groups. Such a solution leads to a peculiar observation – the exceeded amounts and the pay-back amounts at limit group level are calculated without any reference to the exceeded amounts at the whole budget level. In other words, in an extreme situation, the exceeding by 1 PLN of the entire reimbursement budget in its part for medicinal products, available at pharmacies, will trigger the whole mechanism of calculating the exceeded amounts for the involved limit groups, i.e., in general, those for which the reimbursement expensed have increased vs. the plan.

At the same time, a situation may not be excluded (while being fully in line with the system assumption) in which the summed up exceeded amounts per individual reimbursement applicant will exceed the total exceeded amount in the whole budget. It should also be added that limit groups are defined in conformity with Art. 15 of the Reimbursement Act, also for the products in the following categories of reimbursement availability: "used in drug programme: and "used for chemotherapy", what suggests that the amounts of exceeding the reimbursement plan in limit groups are also calculated for these products and, consequently, the pay-back amounts as well.

The amount of exceeding the reimbursement plan in a limit group is calculated as the difference between the spent reimbursement amount for a given limit group during a financial year and the planned reimbursement amount in this group. While the first element of the equation does not raise any major controversies, as the reimbursement data in particular limit groups are publicly available, the mechanism of determining the planned reimbursement amounts in particular limit groups requires a broader analysis, as the National Health Fund has not, so far, committed any reimbursement expenditure budgets with breakdown by particular limit groups. Such a requirement does not emerge from the effective legal regulations, either, it is therefore safe to assume that the provisions of the Reimbursement Act do not constitute any new obligation, carried out on an ongoing basis by the National Health Fund and will only be followed when it is necessary to calculate the pay-back amounts. Only then will the reimbursement plans be assigned to particular limit groups.

Following the Reimbursement Act, the planned reimbursement amount is calculated as the

product of the planned reimbursement amount in a given group for the previous year and the total reimbursement budget growth coefficient [4]. Thereby, an artificial and, as it were, automatic mechanism of planned reimbursement calculation in every limit group has been introduced, disregarding not only health and therapeutic trends (e.g., an increased consumption of certain categories of products, justified by epidemiological and/or demographic factors) but also changes in the shape of particular groups. One of the limit groups with foodstuffs for the special nutritional uses may be a good example of dynamic changes which are observed in the limit groups:

NAME	LIMIT GROUP 01.05.2013	LIMIT GROUP 01.05.2014
Neocate Advance	217.7	217.9
Neocate LCP	217.7	217.7
Nutramigen AA	217.7	217.6

Source: The Announcement of the Minister of Health of April 24, 2013 and of April 23, 2014 on the list of reimbursed medicinal products, foodstuffs for special nutritional uses and medical products.

Obviously, any planning of reimbursement amount for 217.7 group, based on the data from May 2013, does not make any sense, as the group was, by decision of the Minister of Health, divided in 2014 into three separate groups. As of today, the regulations do not, unfortunately, provide any answer to the question how to determine the plan for particular limit groups in a situation as the one above (as well as in a reverse situation, i.e., when limit groups are combined), while simplifications of any kind whatsoever, such as building plans per groups on the basis of data from particular products, do not have necessary foundations in the valid legislature.

In each case, the solution, as approved in the Act and concerning the principles of planning reimbursement amounts for particular groups, assumes that some plan already existed for each group in the previous year and this plan will only have to be adjusted by the growth coefficient for the whole reimbursement budget. As it has been indicated, such plans are not built in real time by the National Health Fund, thus the legislator has had to introduce another simplification in order to determine the reference point for the calculation of planned amounts in the limit groups. This simplification is introduced by Art. 73 of the Act which provides that, in order to calculate, for the first time, the exceeded amount, the reimbursement amount for a group, implemented (spent) during the year 2011, will be understood as planned amount of reimbursement for 2011.

Thus assuming purely hypothetically that the exceeded amount will for the first time be calculated for the year 2014, the planned reimbursement level in the limit groups for 2014 will be based on the amount of the real reimbursement in the group in 2011. This solution is for obvious reasons defective and impossible to be implemented, not least for the fact that, in 2011, the term of „limit groups" did not exist in the then effective regulations [5], created by criteria which would have been close to the present ones. Even if one was to admit that the groups of products, being subject to common limits in the year 2011, could be approached as corresponding to the present limit groups, the shape of the groups has undergone (and is still undergoing) such major changes that any attempt of extrapolation of the planned reimbursement amounts for the year 2014 on the basis of data for the year 2011 is doomed to failure, at least for the series of new products, which have been added to the lists since 2012 (including the products with other EAN codes and new product generations) or for the evolution and the shape of the limit groups alone.

Summing up, it seems that the actual principles of planning/calculating reimbursement amounts in the limit groups effectively preclude the calculation of exceeded amounts in particular groups, what may become a serious obstacle to apply the pay-back mechanism in practice. A revision and amendment of these regulations is urgently needed, such that would unequivocally deter-

mine the point of reference (the plan), to which the reimbursement spending during a given reference period, could effectively be compared. It also seems that the concept, which assumes the calculation of exceeded amounts on limit group levels, may be difficult in practice, mainly for the continuous evolution in the shape of the groups, being in a way part of the logic of the Act alone [6].

The mechanism of pay-back amount calculation for individual product

Passing on to the method, by which the reimbursement applicant's share in the total exceeded amount is going to be determined in a single limit group, one should, first of all, indicate that only these applicants participate in the pay-back procedure, for which the dynamics of reimbursement level during a given financial year is either equal or greater from 1 vs. the previous year. Additionally, for the products which were not reimbursed in the previous year, the coefficient of reimbursement level dynamics in a given limit group equals 1. In this way, the products, newly introduced to the group, will always participate in the pay-back process, even if they are characterised by a low market share, while the products with significant, but falling reimbursement amounts, will not be covered by the pay-back system. The products, for which individual risk sharing instruments have been defined, are also excluded from the pay-back system.

Regarding these applicants, which participate in sharing of the exceeded amount in a limit group, the actual participation in the exceeded amount will depend on:

- the share of the reimbursed amount for a given product in the total reimbursement amount in a limit group during financial year (where the calculation of the total reimbursement amount takes into account also the reimbursement value of the products which are excluded from the pay-back, e.g., due to reimbursement drop),
- the proportion of the selling price of a given product to the lowest official selling price of a given product, being the basis for the limit in that limit group in a given financial year (consequently, the more expensive is a product vs. the lowest official price in financial year, the proportionally higher is the pay-back share).

Assuming that the exceeded amount and the share in it have been calculated for a given product, the calculation of correct pay-back amount follows by multiplication of the above-mentioned values by 0.5 coefficient and by "G", an additional adjusting factor.

It is worth emphasising that, in the initial version of the Act, the whole amount of the exceeded reimbursement was to be paid-back by the applicants. Only at the level of works on the Act at the Senate, it was decided to divide the pay-back amount, introducing „the coefficient of risk sharing between the public payer for health care services and the applicant, the medicinal product of which has been awarded by positive reimbursement decision" [7]. This coefficient has, on one hand, assumed the form of pay-back amount adjustment by 0,5 for the payer, while being, on the other hand, completed by an additional formula, marked in the calculation formula by letter „G" [8]. Unfortunately, the explanatory memorandum to the Act does not specify in detail the reasons, justifying the acceptance of particular calculation solutions, including the „risk sharing solutions". Neither are there any detailed calculations or prognoses of budget revenues pursuant to pay-back payments, what may be surprising in case when an instrument of purely financial character is implemented.

DISCUSSION AND CONCLUSIONS

One of the declared (however not always in public) goals of the Reimbursement Act was a limitation of the reimbursement spending and protection of the State budget against an uncontrolled increase of the reimbursement expenditure in the future. In order to achieve the purpose, a number of mechanisms have been incorporated into the Act to impose a number of constraining requirements on the public payer, such the „reference pricing", price negotiations or obligatory price reductions in case when reimbursement applies to the first equivalent of the original reimbursed product or when market exclusivity period expires.

After the two-year effective period of the Reimbursement Act, it should be stated that the above-mentioned, "economic" goal of the Act has been achieved very effectively. It appears from the data of the Ministry of Health that the reimbursement expenditure decreased in the year 2012 alone by PLN 1.96 billion vs. the year 2011 [9].

In the opinion of the Act authors, the pay-back mechanism was to have been another spending reducing solution, playing, at least, the role of a safety-valve in case if reimbursement demonstrated, for any reason, jumping trends. Even if the concept is not entirely unjustified, it has to be admitted that, for today, this particular tool reveals a number of defects. These defects are of such importance that they may either preclude correct calculations of pay-back amounts at all or they may become a source of disputes and conflicts with marketing authorisation holders on administrative-legal grounds. The costs of such legal proceedings (especially when the loser in the game was either the Minister of Health or the National Health Fund) may really overshadow any possible revenues from the pay-back mechanisms [10].

If, however, the pay-back tool was to remain an integral part of the Polish reimbursement system, urgent legislative changes are needed, which would enable an effective management of the mechanism and, first of all, which would ensure correct and precise calculations of pay-back amounts, based on available and verifiable data. Some changes were partially proposed in the project for the Act amendment of December 18, 2013 [11], however, at their actual stage, they require further processing and final finish. In this situation, the following improvement proposals should receive due consideration:

- a clear, transparent definition of the time point against which the preliminary condition for pay-back calculation could be verified;
- a clear definition of the validity scope for the pay-back mechanism - is the pay-back amount calculated for all limit groups (including the products in drug programmes and in the catalogue of chemotherapies) or for the prescribed products, reimbursed at pharmacies only;
- an implementation of transparent methodology to design a reimbursement plan for limit groups.

Following the Communication of the Economic-Financial Department of the National Health Fund, issued for the period of January-March 2014, the budget for the reimbursement of prescribed products, available at pharmacy, was implemented in 22.69%. In analogous time periods of the years 2012 and 2013, the coefficient was 19.40% and 21.79%, respectively [12]. Thus, even if a clear growing trend in the reimbursement expenditure is observed, still imposing of the obligation to calculate (and pay) the pay-back for the year 2014 is still little probable for the considerable drop in reimbursement during the years 2012-2013 vs. the „reference" year of 2011. Thus, as much time has been left, it would be appropriate to reconsider and implement the required legislative changes to eliminate the actual defects in the structure of the pay-back mechanism. But, first of all, it therefore still seems reasonable to ask about the general sense and reason of the existence of such a solution in the Polish legislative system, if the other legislative mechanisms successfully fulfil the systemic goals of reducing the public payer's expenditure. ■

REFERENCES:

1. Citations from the explanatory memorandum to the Act on the reimbursement of medicinal products, foodstuffs intended for special uses and medical products, forwarded for social consultations in a letter of September 9, 2010
2. See. Art. 3 and Art. 74 of the Reimbursement Act
3. Art. 4 section 8 of the Act, providing that the exceeded amount and the pay-back amount are calculated by the Fund within 30 days from the approval of the financial statement for the previous year, may be regarded as a kind of an „interpretation gate", supporting the verification of the preliminary condition for calculation of exceeded amounts on annual basis. This provision may, however, be interpreted as referring exclusively to the time-point of technical calculation and not to the time-point, constituting the occurrence of the pay-back mechanism
4. Constituting the ratio of the total budget for reimbursement during financial year, decreased by the reserve, mentioned in Art. 3 section 3 of the Act, and of the total budget for reimbursement in the previous year
5. The limit grounds were in that time published in the regulation of the Minister of Health, issued on the basis of Art. 38 section 6 of the Act on providing Healthcare services financed from public funds. The price limits were introduced for the drugs with the same international name or with different international names but revealing the same therapeutic effect
6. For example, the Minister of Health may in certain situations routinely issue decisions, changing limit group definition
7. Resolution of the Senate of May 2, 2011 r., Print No. 4152
8. This coefficient is a ratio (i) of the amount, by which the total budget for the reimbursement of prescribed products is exceeded and (ii) of the sum of exceeded amount in particular limit groups. It may then be assumed that this coefficient is to compensate possible disparities between the total amount of exceeded reimbursement at the total budget level and the summed amount of exceeded reimbursement at the level of the limit groups
9. Source: presentation of the Minister of Health of December 18, 2013 „Summary of the Reimbursement Act". Availabel from: http://www.mz.gov.pl/dla-mediow/konferencje-i-briefing/konferencja-prasowa-ministra-zdrowia-bartosza-arlukowicza-podsumowanie-ustawy-refundacyjnej"
10. It is, among others, indicated in the records from the margin-price dispute, where the main axis of controversy was the legal appropriateness of imposing penalties for some pharmaceutical companies for their alleged exceeding of official prices and margins
11. A draft of September 18, 2013 on amending the Act on the reimbursement of medicinal products, foodstuffs intended for special uses and medical products, as well as of some other acts. Available from: http://www2.mz.gov.pl/wwwfiles/ma_struktura/docs/ustawarefundacja_20130919.pdf"DEF Communications of May 8, 2012, May 7, 2013 and May 6, 2014 - Information on reimbursement amounts, together with the percentage of total reimbursement budget implementation