Risk-sharing, individual price agreements and reference pricing – recent developments in Polish pharmaceutical policy

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After a long period of stagnancy in pricing and reimbursement policy, the profound changes have occurred in the second half of 2011 and beginning of 2012 in Poland, after introduction of the Reimbursement Law. One of the most important novelties was introduction of risk-sharing and individual price agreements between pharmaceutical industry and the Minister of Health. Reference pricing has been used in Poland for 20 years and recent reforms have strengthened its role. Mutual exchange of specialist knowledge and experiences from the field of pharmaceutical pricing and reimbursement among countries, which have similar economies and similar health care systems, is strongly required in the era of financial austerities.

INTRODUCTION

The health care financing in Poland, after switching from Semashko model, has become grounded on the compulsory health insurance, starting from 1999. Almost all citizens (approximately 38 million) have become insured – initially under auspices of the 17 sickness funds and starting from 2003 until nowadays – within framework of the centralized National Health Fund (NHF). The total expenditure on health in Poland was about 7,0% of GDP in 2010 (compared to 7,8% in Hungary; 7,5% in Czech Republic; 9,0% in Slovak Republic and 9,5% being the OECD average). Public expenditures on health constituted 71,7% of total expenditures on health in 2010 in Poland (compared to 64,8%; 83,8%; 64,5% and 72,2% respectively). Total expenditure on pharmaceuticals and other medical non-durables, measured as percentage of total expenditure on health in Poland equaled 22,7% in 2010 (compared to 33,6%; 19,9%; 26,4% and 16,6% respectively). Total expenditure on pharmaceuticals and other medical non-durables in 2010, measured per capita in USD purchasing power parity, was 314,8 in Poland (compared to USD 538,4; USD 374,7; USD 554,2 and USD 496,0 respectively) [1].

Brief comparisons of data presented above, show that the total expenditure on health (% of GDP) in Poland was relatively low. In the same time, the share of public payer in total expenditures on health was close to the OECD average and differences among selected countries of the Central European region were significant. The pharmaceutical expenditure (% of total health expenditure) in Poland was above the OECD average. The drug expenditures calculated per capita were quite low – not only in comparison with the OECD average but also with other countries of the Visegrad Group. Traditionally, provision of pharmaceuticals financed from public sources has been an area of strong tensions, resulting from constant imbalance between limited possibilities and unsaturated needs. This provides an important, although not one and only explanation, why the rational pharmaceutical pricing and reimbursement policy of the state has been always strongly needed.

The statutory payer for pharmaceuticals used in public health care in Poland is the NHF, however responsibility for pharmaceutical policy is being held by the Minister of Health (MoH). This responsibility embraces also the pharmaceutical pricing and reimbursement policy, which has been extensively reformed after introduction of a new legal act, called the Reimbursement Law [2].

REFORM OF PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICY IN POLAND

There was a long period of stagnancy in pharmaceutical pricing and reimbursement policy in Poland, taking into considerations numerous initiatives in other European countries. The profound changes have occurred in the second half of 2011 and beginning of 2012. Virtually all areas of policy have been completely reformed according to the Reimbursement Law. One of the most important reasons of the aforementioned changes in drug policy in Poland, besides many other well-documented calls for change, verbalized in various ways on span of recent years by experts and some politicians, was the need to comply with the Transparency Directive of the European Union [3, 4]. This directive was implemented only partially during a period of eight years after accession of Poland to the European Union.

Legal regulations on setting level of reimbursement and patient co-payment to drugs in Poland were modified by the Reimbursement Law. New categorization of reimbursed products was introduced, not only pertaining to drugs and medical devices but also to a new category of products, labeled as food products for special dietary use. The criteria of setting co-payment levels and making reimbursement decisions, as well as the rules of setting official and fixed prices of drugs were precisely defined. The position, role and responsibility of the expert group involved in price negotiations between the Ministry of Health and the pharmaceutical industry, called the Economic Commission, was defined. Strong emphasis has been put onto transparency of the whole process of price negotiations. The Reimbursement Law has also changed the rules of cooperation between out-patient pharmacies and the NHF – contracting based on more strict requirements is now in place. Also the contracts between

physicians and the NHF, authorizing physicians to prescribe prescriptions which are reimbursed by the NHF, contain more precisely defined rules of collaboration now. It has to be mentioned that changes in rules of contracting triggered the strong wave of protests in first months of 2012, lead by some professional organizations of physicians, including the Main Chamber of Physicians. As a result, the MoH had to modify these rules. Due to conflict related to practical implementation of modified contracting, the president of the NHF was later dismissed by the MoH. The role of the Agency for Health Technology Assessment in Poland (AHTAPol), as well as the role of health technology assessment (HTA) in decision-making processes in pharmaceutical reimbursement has also been strengthened by the Reimbursement Law. The key institutions, which are currently involved in pharmaceutical pricing and reimbursement in Poland are presented in Figure 1.

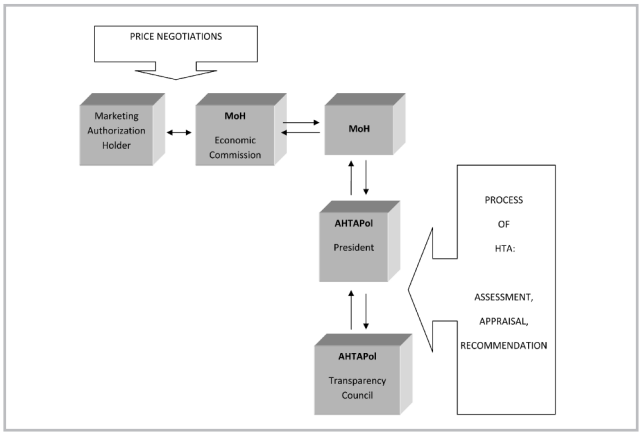

Figure 1.
Key institutions involved in pharmaceutical pricing and reimbursement policy in Poland, after reform in 2011 (MoH: Ministry of Health; AHTAPol: Agency for Health Technology Assessment in Poland)

INDIVIDUAL PRICE AGREEMENTS AND RISK-SHARING

Individual agreements on drug prices, negotiated between the marketing authorization holders (MAH; pharmaceutical industry) and the public authorities have become increasingly popular within recent years in Europe [5]. They have been often labeled as risk-sharing agreements (RSA), since they are supposed to diminish risk of payer. This risk is inherently linked to uncontrolled introduction of a new drug into the public reimbursement, especially in case of a drug with big market growth potential. The undisputable benefit of RSA for a pharmaceutical company is an entry into the reimbursement system, which usually translates into sharply increasing revenues from expanding sales.

Introduction of RSA between pharmaceutical industry and the MoH was one of the greatest novelties of the Reimbursement Law. In fact, risk-sharing under the new law has two forms. The first one has taken shape of the obligatory risk-sharing, not requiring any special or individual agreements; it is associated with general statutory 50% payback. This payback is due after exceeding the fixed yearly budget, which the NHF reserves for reimbursement of all pharmaceuticals. The drug budget is equal to 17% of the total yearly NHF budget on all health care services. This form of risk-sharing is binding for all pharmaceutical companies, unless individual contracts related to various voluntary forms of risk-sharing have been agreed. The individual RSA could be related to making the MAH's income dependent on expected health outcomes. They could be also related to making official price of a drug dependent on such conditions as: delivering a drug at negotiated and reduced price; volume of sales of a given drug; partial payback of reimbursement received from the NHF. Setting other conditions of reimbursement, enhancing availability of health services or lowering costs of health services are among other possible foundations of risk-sharing between the MAH and the MoH.

After a few months of functioning, it is too early yet to assess RSA as the completely new tool in pharmaceutical pricing and reimbursement policy in Poland. Nevertheless, at this point of time, it is clear that some important issues have to be addressed. What is nature of a particular RSA – who is really risking what? Where is borderline between risk-sharing and price-hiding? Is risk-sharing a good remedy for various problems resulting from parallel trade of pharmaceuticals? How will confidentiality of RSA impact possibilities of robust scientific analyses of risk-sharing and its impact on health care system? How do analytical capabilities of the MoH and the MAH compare one to another? How to manage an increasing administrative burden which is being brought by RSA to the NHF? How to utilize potential advantages which RSA could provide for increasing overall efficiency of a national health care system? How to utilize growing international experiences, gathered by various countries within this area?

REFERENCE PRICING

The reference pricing has been introduced in Poland in the mid-nineties of the XX-th century, soon after its first European application in Germany, which took place in 1989 [6]. The criteria of establishing reference groups of reimbursed pharmaceuticals were also reformed by the Reimbursement Law. Both international and internal referencing has been used in Poland. The Economic Commission, which negotiates drug prices on behalf of the MoH (see Figure 1) takes into consideration (among many other criteria, not related directly to price of a drug), prices in all countries of the European Union and the European Free Trade Association. The internal referencing is associated with establishing groups of drugs, which have the same reference price (i.e. price establishing base for reimbursement). These drugs need to have the same indications or clinical uses in which they are reimbursed, as well as similar effectiveness. It is possible to create a separate reference group for a drug which shows some level of innovation. In such case either a mode of application of a drug or its pharmaceutical form should substantially enhance current out-

comes of treatment or they should bring new therapeutic effects. Currently there are about 360 reference groups of drugs used in out-patient therapy.

After 20 years of using reference pricing in Poland, the future use of this solution of pricing and reimbursement policy has been secured and strengthened by the Reimbursement Law. There are some arguments that reference pricing could potentially impact pharmaceutical innovation in a negative way [7]. Quoting other arguments, drug prices cannot be identically low in all countries of Europe, since only one country can have the lowest price [8]. Taking into consideration all arguments, the reference pricing should be used wisely and it should not remain the only tool within national pricing and reimbursement policy. The recent reform in Poland seems to follow this line of reasoning.

CONCLUSIONS

After many stagnant years, the Reimbursement Law brings important changes in Polish pharmaceutical pricing and reimbursement policy. The risk-sharing becomes a promising tool, but experience with using it, after half a year only, is too short for performing complete assessments. The position of reference pricing has been strengthened and processes related to setting drug prices have been elaborated. The international price comparisons remain the key element of price negotiations. Robust analyses and careful monitoring of policy changes, drawing from international experiences and mutual exchange of specialist knowledge among countries, which have similar economies and similar health care systems, are strongly required – especially now, in the era of financial austerities.

BIBLIOGRAPHY

[1] OECD: OECD.StatExtracts (http://stats.oecd.org/Index.aspx?DataSetCode=SHA), 2012, date of visit: 07.08.2012

[2] Ustawa z dnia 12 maja 2011 r. o refundacji leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych (The Reimbursement Law), Dz. U. z dnia 13 czerwca 2011 r. (in Polish)

[3] EEC, Transparency Directive 89/105/EEC, Transparency of measures relating to pricing and reimbursement of medicinal products

[4] Ministerstwo Zdrowia (the Ministry of Health), „Założenia zmian w systemie refundacji leków" („Guidelines for changes in the system of pharmaceutical reimbursement"), Ministerstwo Zdrowia, Warszawa, 15 września 2005r, 2-25 (in Polish)

[5] Adamski J et al. „Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers" BMC Health Services Research, 2012, 10: 153

[6] Bochenek T, Kozierkiewicz A, "Ceny i refundacja leków" („Pricing and reimbursement of pharmaceuticals"), Termedia Wydawnictwa Medyczne, Poznań, 2009, 13-95 (in Polish)

[7] Ioannides–Demos L, Ibrahim J, McNeil J, "Reference-based pricing schemes", Pharmacoeconomics, 2002, 20 (9), 577-591

[8] Kalo Z, "Pricing and reimbursement of pharmaceuticals in Central-Eastern European coutries", VI-th National Training and Conference on Health Economics: Health Economics, growing importance in scarcity, META – Hungarian Health Economics Association, 20.06.2012-21.06.2012, Budapest, Hungary (conference materials)

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