

THE POLICY OF REIMBURSED MEDICINES

IN ROMANIA 2008-2013



2 INTRODUCTION**3 THE HEALTH OF ROMANIA'S POPULATION**

4 RECENT DEVELOPMENTS IN THE ROMANIAN HEALTH INDICATORS

6 THE EUROPEAN LEGISLATION WITH CONSEQUENCES ON THE NATIONAL POLICIES IN TERMS OF MEDICAL SERVICES AND MEDICINES

6 THE DIRECTIVE NO. 105/89 OF THE EUROPEAN ECONOMIC EU ON THE TRANSPARENCY OF THE MEASURES THAT GOVERN THE PRICING OF THE MEDICINES FOR HUMAN USE AND THEIR INCLUSION IN THE SCOPE OF APPLICATION OF THE NATIONAL HEALTH INSURANCE SYSTEM

7 THE IMPLEMENTATION OF THE DIRECTIVE 105/89, THE ASSESSMENT AND THE AMENDMENTS PROPOSED DURING 2010-2013

9 DIRECTIVE 2011/24/EU ON PATIENTS' RIGHTS IN CASE OF CROSS-BORDER HEALTH SERVICES

10 THE REGULATORY FRAMEWORK AND PRACTICES IN ROMANIA ON PRICING AND MEDICINE REIMBURSEMENT

10 PRICING

11 DRUG COMPENSATION UNDER THE HEALTH INSURANCE SYSTEM WITHIN THE PERIOD 2008 - 2013

12 THE 2013 NEW PROCEDURES FOR APPROVAL OF MEDICAL TECHNOLOGIES

14 IMPACT ASSESSMENT OF UPDATING THE LIST WITH REIMBURSED MEDICINES

15 THE DESCRIPTION OF FRAMEWORK ANALYSIS

19 RESULTS

21 ROMANIANS' ACCESS TO MEDICINES. INFORMATION AND POINT OF VIEW

21 THE INFORMATION IN THE AUDIO-VIDEO

24 THE INFORMATION IN THE WRITTEN MEDIA

25 THE PUBLIC'S POINT OF VIEW

26 CONCLUSIONS AND REFLECTIONS**29 BIBLIOGRAPHICAL REFERENCES**

Abstract

The current study intends to analyse the reimbursement policy of medicines issued based on medical prescription in the health insurance system in Romania over the past 5 years. The access to effective medical technologies and services has a significant influence on the population's health and its contribution to economic growth. Romania has taken steps to control the health care costs since the economic crisis started. One of the most affected sectors was the drug reimbursement system for the people insured through the health system. Among other things Romania has not made any decisions related to the list of reimbursed medicines ever since the end of 2008. This goes against the European stipulations in this sector and may have limited the Romanian patients' access to more effective treatments in comparison to patients from other countries of the EU.

Since 2013 Romania has a new framework for the health technology assessment, based on which the applications for the inclusion to the list of medicines for the insured with or without personal contribution, will be analysed. This framework is tailored to the diversity of the new medical technologies, as well as to the need of a rational use of the limited resources of the health insurance system.

The cost for updating the reimbursed medicines list, assessed using a specially created calculation model, is not prohibitive. According to the hypotheses used for the market penetration level, the budgetary effort during the first three years following the updating could vary between 2.3% and 5.2% from the FNUASS budget assigned for medicines during 2013. Instead, the economic impact cumulated on the long run might rise up to approximately 0.5% of the gross domestic product (GDP) (estimated for 2013), by increasing the degree of population participation to the economic activity. Therefore, the Romanian society has a lot to gain by investing now in the new therapies, especially because most Romanians (82.5%) consider that innovative medicines are important and very important for the improvement of the population's health.

Abbreviations:

AEM – EMA	European Medicines Agency
ANT – NTA	National Transplant Agency
APP – MA	Marketing Authorisation
CANAMED	National Price Register for Medicines for Human Use
CNAS – NHIF	National Health Insurance Fund
FMI – IMF	International Monetary Fund
FNUASS – NSHIF	National Social Health Insurance Fund
INS – NSI	National Statistical Institute
MS – MH	Ministry of Health
INSP – NPHI	National Public Health Institute
OMS – WHO	World Health Organisation
RCP – SPC	Summary of Product Characteristics
UE – EU	European Union
UETM – HTAU	Health Technology Assessment Unit

Introduction

The data published at European level show that the values of the most important indicators of the Romanians' health are below the EU average. This state is influenced by a complex of factors, namely the health system. In terms of the health system, the performance is determined by the quality, availability and accessibility of medical technologies and services.

Considering the past four years, the economic crisis has affected the government revenues, including the health insurance contributions paid to the National Social Health Insurance Fund (NSHIF). The response from the authorities was to implement a comprehensive program of rationalization of expenditures, especially in the areas of hospital care and reimbursed medicines consumption. During this period, the efforts were focused on the control of resources, supply and consumption. Instead, the quality, diversification and increase of access to health services have been left behind. In this sense, one of the most affected sectors was the price reimbursement of medicines issued based on medical prescription within the social health insurance system.

The reimbursement decision of medicines' price is the result of a complex of factors, technical, financial and political. The assessment is based on criteria of clinical efficacy, safety in use, impact on the patient's quality of life, health policies and budgetary impact. In addition to these, there's the social and economic framework. Acknowledging the diverse national peculiarities, the European Union grants the member states the freedom to make decisions, but tries to standardize certain procedural aspects, meant to ensure the free movement of goods and services within the common market. One of the objectives of the EU involvement is to guarantee equal treatment for patients and providers throughout the Union. For example, EU regulations harmonized the deadlines by which the national public authorities should decide upon the inclusion / non-inclusion of medicines in the list of reimbursed products.

Romania has not made any decisions in terms of the inclusion in the list of reimbursed medicines since the end of 2008. Furthermore, a series of

public policy decisions, determined by budgetary considerations, have limited the access to medicines for the entire population: minimum European price, reference by therapeutic groups, delayed payment of suppliers, claw-back tax, prescription limitation etc. All these measures tend to deprive the Romanian patients of the benefits of new therapies, some with the potential to save lives.

The development of health services and ensuring equal treatment for Romanian citizens involves a set of measures with consequences on the entire health system. Updating the list with reimbursed medicines is a necessary step. In order to meet the needs of the actors involved in the assessment of the health technologies, the current study aims (i) to assess the European and national policies in terms of compensation the price of medicines, (ii) to quantify both the additional financial effort of the health insurance budget, as well as the economic benefits that new therapies proposed for compensation might have and (iii) to show the Romanians' point of view towards this subject.

In the first chapter we make an analysis of the health of Romanians and the recent development of the relevant indicators compared to other member states. The used statistics come from Eurostat databases and the World Health Organization.

In the second chapter we assess the EU regulations that have an impact on the health policies in Romania, focusing on the pricing decisions, medicines' value compensation within the health insurance systems and the compensation of cross-border healthcare. The shortcomings found in the implementation process and the amendments recently proposed by the European Commission are also highlighted.

In the third chapter we look at national regulations on pricing, compensation and health technology assessment. The compliance with the European directives is also assessed. Starting with 2013, Romania has a new framework for health technology assessment based on the multi-criteria decisional analysis that will be used for the decision of inclusion / non-inclusion in the list of reimbursed medicines of the approximately 170 molecules / new indications on the waiting list.

In the fourth chapter the budgetary and economic impact of updating the list of reimbursed medicines with the new pending molecules / indications is quantified. For each of them we estimated the target group, the cost of standard therapy, the cost of the new proposed therapy, the effectiveness of the standard and the newly proposed therapies. While assessing the incremental cost, a gradual penetration was proposed for the new molecules at the estimated target groups, taking into account

the budgetary constraints, from an average of 15% in the first year, and up to 35% in the third year. The economic impact of updating the list of reimbursed medicines was quantified based on future treatment effectiveness compared to the standard one. The effectiveness indicators for each condition were translated into years of active life, which materialize into normal contribution to the economic activity, equivalent to the GDP per capita.

In the fifth chapter the reflection in the mass media of the health system issues is showcased, including the policy on reimbursed medicines. Romanians' views in terms of the innovative medicines and the access to them are highlighted.

Finally, the conclusions and reflections chapter selects the key findings and provides options to finance the additional cost of updating the list of reimbursed medicines.

The health of Romania's population

From the Eurostat and the World Health Organization databases we see a detailed picture of the differences between the health of Romanians and the European average.¹

Although life expectancy at birth has had a steadily increasing tendency over the last 5 years (73.8 years in 2010 compared to 71.6 in 2000), the difference between Romania and the EU average is more than 6 years (80 years in 2010) and the gap increased between 1990 and 2010. Over a lifetime, a Romanian citizen recovers on average between 1 and 2.5 years of life so that the life expectancy at 45 years is of 31.4 years in Romania compared to the EU average of 36.5 years and at 65 years is of 15.8 years in Romania, compared to the EU average of 19.4 years. These indicators show an excess infant mortality (0-1 years) and excess mortality of the active adults (up to age of 65) in comparison to the EU average.

In Romania, the standardized general mortality rate is of 948 per 100.000 inhabitants (2010) compared to 603/100.000 inhabitants, the EU average (2010). The infant mortality in 2010 in Romania was double (9.8 / 1.000 live new-borns) compared to the EU average (4/1.000 live new-borns in 2010). Overall, the mortality before the age of 5 is 11.7 / 1.000 live new-borns in Romania (2010), compared to 4.9 / 1.000 live new-borns, the EU average (2010). On the other hand, the reduction of life expectancy by death before the age of 65 was of 7 years in Romania (2010) compared to 4.4 years, the EU average (2010).

¹The databases are available at the following websites http://epp.eurostat.ec.europa.eu/portal/page/portal/health/public_health/data_public_health/database and <http://www.euro.who.int/en/what-we-do/data-and-evidence/databases/european-health-for-all-database-hfa-db2>, accessed during the months March - June 2013.

The information presented in this chapter come from the above mentioned sources.

The causes of infant and early childhood mortality are many, but most of them (over 80%, according to NSI) may be efficiently amended through preventive interventions (immunization especially for diseases that can cause pneumonia/bronchopneumonia) and effective and timely treatment of the residual diseases. The causes for excess mortality in the active adult population are mainly represented by chronic diseases (cardiovascular disease, cancer, diabetes, chronic respiratory diseases and digestive diseases). These can be improved or even eliminated through various interventions, such as (i) prevention (the HPV vaccine), (ii) early active diagnosis (for cancer of the cervix, breast, and colon), (iii) change in lifestyle and (iv) timely access to an optimal therapy that would heal, improve the quality of life and / or, where appropriate, assure survival.

Romanians' lifestyle doesn't favour their health. The standardized mortality rate by deaths caused by alcohol consumption has double values in Romania (108/100.000 inhabitants in 2010) compared to the EU average (59/100.000 inhabitants in 2010).

The standardized mortality rate associated to tobacco consumption in Romania was of 427.7/100.000 inhabitants in 2010, while the EU average was of 190/100.000 inhabitants in 2010.

The hypotheses that could explain the high values of these indicators in Romania compared to EU average refer to both the inefficiency of the legislative measures and the lack of promotion of a healthy lifestyle and of the preventive interventions for diseases caused by alcohol and tobacco.

In addition, the standardized mortality rate by drug side effects for people aged between 0-64 in Romania was of 0.07/100.000 inhabitants in 2010 and having a sustained upward tendency during recent years, compared to the EU average (0.0 /100.000 inhabitants in 2010).

The explanations for the values of this indicator may be the use of medicines with a low safety threshold and major side effects that cannot be effectively monitored, but also poor education of the prescribing physician, the attending physician and the patient's in terms of monitoring and reporting the adverse reactions.

Recent developments in the Romanian health indicators

The tendencies in the health of a population have multiple causes. The most important factors can include: economic status, lifestyle, socio-cultural conditions and health services. The latter influence health through quality, availability and accessibility of the offer. In this framework, the medicines are one of the factors with consequences on health.

As shown in the previous section, the health imbalances between the Romanians and the average values of the European Union persist. The tendencies recorded between 2004 - 2008 have

marked a visible convergence. As of 2009 the rate at which Romania was recovering the differences has significantly decreased, especially for certain indicators (see Figures 1 - 4)².

²The statistic data in this section come from the „Health for All” database of the World Health Organisation, <http://www.euro.who.int/en/what-we-do/data-and-evidence/databases/european-health-for-all-database-hfa-db2>, accessed in June 2013.

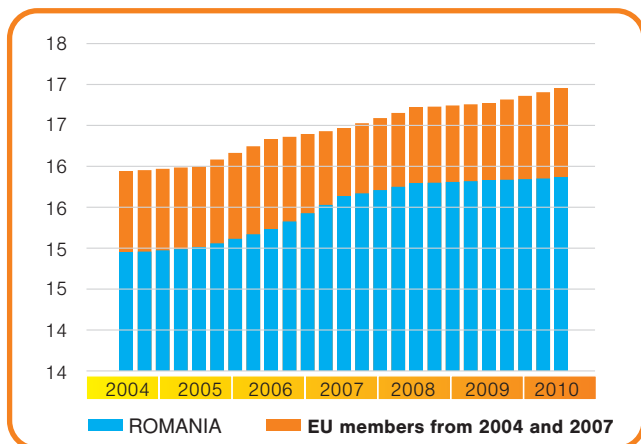


Figure 1

Figure 1: life expectancy at the age of 65 (years)

Figure 2: standardised mortality rate (deaths at 100.000 inhabitants)

Source: WHO, the „Health for all” database

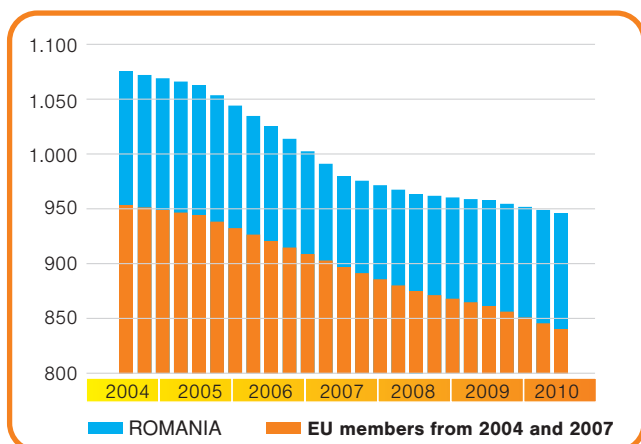


Figure 2

Two therapeutic sectors where the access to services and cutting-edge technologies influence patient survival or healing are the chronic liver and respiratory system diseases. In both cases, the values recorded in our country during the past seven years have regressed; while the other new EU Member States have reported improvements (see Figures 3 and 4). An important explanation of these tendencies is the insufficient access to efficient services and therapies.

Figure 3: mortality associated with cirrhosis and chronic liver diseases (deaths at 100.000 inhabitants)

Figure 4: mortality associated with diseases of the respiratory system (deaths at 100.000 inhabitants)

Source: WHO, the „Health for all” database

Without being able to establish a direct cause, we notice the coincidence of this deterioration with various processes affecting the Romanian society: the economic crisis, the reduction of the available income in households, the rationalization of public expenses on health, the limited access to new medical technologies, including by freezing the list of reimbursed medicines.

Figures 1-4 reflect the tendencies of some health indicators in Romania, compared to the average of the new EU member states since 2004.

Those indicators which show a deterioration of the convergence tendencies were selected influenced by quality and access to medical services and technologies.

After the period 2006 - 2008 when the evolution of life expectancy at the age of 65 and the lower standardized mortality rate showed better values than the average of the new Member States, since 2009 there has been a reduction of the rhythm for our country (Figures 1 and 2).

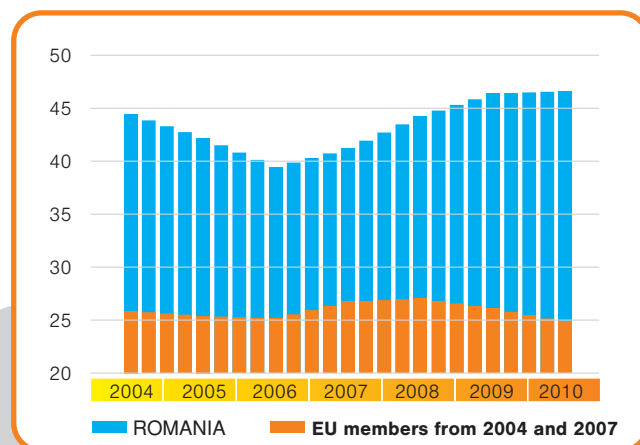


Figure 3

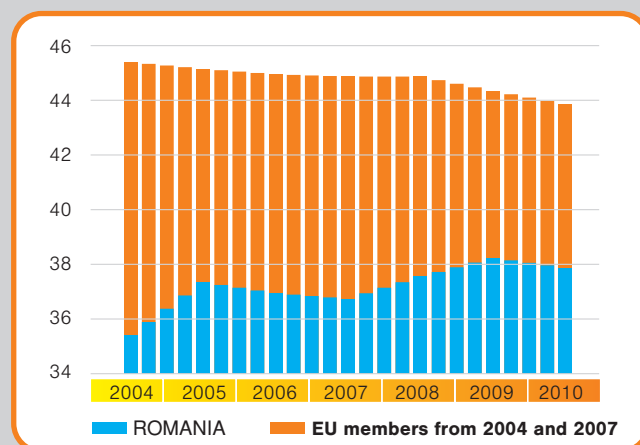


Figure 4

The European legislation with consequences on the national policies in terms of medical services and medicines

The European Union's member states have the exclusive jurisdiction to regulate and organize their own health systems. In terms of medicines, their freedom to control the demand or the consumption, to set maximum prices or to condition the compensation is not restricted. However, the rules of the common market and ensuring the free movement of goods and services have led the European Commission to adopt a common set of rules applicable to all Member States. Out of these, the most important refer to (i) authorizing the marketing of the medicines, (ii) the drug pricing procedures and approving their compensation, and (iii) cross-border medical services. For the object of this study, the last two above mentioned areas of EU regulation are relevant and will be analysed in detail.

The Directive no. 105/89 of the European Economic EU on the transparency of the measures that govern the pricing of the medicines for human use and their inclusion in the scope of application of the national health insurance system.

The Directive's aim is to ensure that the drug pricing or compensation measures, as part of health insurance systems, do not discriminate based on the origin of the products. This seeks to ensure that the differences made by the member states between medicines are based on objective and verifiable criteria.

In order to control public expenses on medicines, all Member States implemented methods to limit both the supply and the demand for medicines within the health insurance systems. In order for this not to obstruct the intra-EU trade, the European Commission has imposed a series of conditions aimed to ensure the transparency of the decisions for pricing and inclusion in the drug compensation list.

Thus, the member states lay down their own rules to approve the prices (see below Romania's case) that any holder of a marketing authorization (MA) must observe. However, the length of the pricing procedures cannot exceed 90 days since the file submission. An exception is the situation when the responsible public authorities request additional information and the 90 days period resumes from the date of their delivery. If the pricing decision is not notified within 90 days, the product can be

marketed at the level proposed by the owner of the MA. Any rejection decision must be based on objective and verifiable criteria and the applicant must be informed on the available appeal options.

In case a member state decides to freeze the drug prices (general or for certain categories) it is required to annually review this decision in order to determine whether the macro-economic conditions that led to it are maintained. In this framework, certain medicines can receive exemptions from the freezing decision if the reasons and need are justified.

The applicable measures in case of inclusion in the lists of reimbursed medicines within the health insurance systems are comparable to those of pricing. The member states are free to impose requirements, conditions and constraints according to their own economic and social condition. They also establish the content of the files and the assessment criteria for the applications. They are made public and are presented to the European Commission.

The approval procedures should not exceed 90 days since the submission. If further information is needed, the deadline restarts when that information is provided by the MA holder.

Any decision not to include or exclude the medicines to/ from the lists must be based on objective and verifiable criteria, on expert opinions and the applicant is informed on the available appeal options.

Therefore, under normal conditions, the procedures for pricing and for inclusion / non-inclusion in the list of reimbursed medicines should not exceed 180 days. Moreover, the rules underlying the decisions must be made public,

applied indiscriminately and communicated to the European Commission. The decisions are justified on objective criteria and are publicly communicated.

In addition, the Directive also stipulated the establishment of an Advisory Committee made up of representatives of the Commission and the member states to assess the aspects of its implementation.

Implementation of the Directive 105/89, its assessment and the amendments proposed during 2010-2013

The Directive 105/89 has never been amended. Meanwhile, the domestic market conditions have evolved and the expenses control measures as well. The tendencies have also been admitted by the European Commission, which commissioned and published a series of analyses of the EU pharmaceutical market³. Among the main change factors affecting the applicability of the Directive, the review reports invoke the diversification of the innovative medicines and proliferation of the generic ones. Both put pressure on the health insurance budgets, which push the national authorities to take different measures in order to control the offer, consumption and prices.

The most commonly used instruments are:

- external price reference systems;
- methods of health technology assessment and benchmarks for the inclusion / non-inclusion in the compensation lists;
- use of multiple compensation lists and issue of partial approvals;
- partially reimbursed prices by internal referencing in groups considered therapeutically equivalent medicines;
- claw-back mechanisms;
- incentives for doctors to prescribe cheaper medicines;
- market controlled access by cost-volume, cost-volume-outcome mechanisms, risk sharing, etc.;
- public procurements for the selection of reimbursed medicines for certain therapeutic sectors;

In addition to these control mechanisms, the member states register delays in decision making for pricing or for inclusion in the compensation lists. Thus, they violate the stipulations of the directive, as confirmed by the European Court of Justice. Statistics show that the delays vary from several months to several years⁴. Among the methods commonly used by the member states to delay decisions we mention:

- repeated requests for additional information, which cause the recalculation of the 90 days period;
- requests for specific information for the marketing authorizing procedure, namely quality, safety, clinical effectiveness, bio-similarity, bio-equivalence;
- the fragmentation of the decision-making process between multiple institutions or administrative levels;
- delayed publication in the official journals or postponing the entry into force.

³Communication From The Commission To The European Parliament, the council, the european economic and social Committee and the committee of the regions Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector, Bruxelles, 2008, available at http://ec.europa.eu/health/human-use/package_en.htm

European Commission, Pharmaceutical Sector Inquiry (Final report), Bruxelles, 2009, available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

⁴„Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council”, Bruxelles, 2012, available at: [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0030\(51\):FIN:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0030(51):FIN:EN:PDF) or at: http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/transparency/index_en.htm

Failure to comply with the terms set out in Directive 105/89 takes a toll on the manufacturers of both the innovative medicines and the generic ones. For the former, the actual period of protection and exclusivity is reduced and the revenues diminished, which discourages future research and development activities. For the generic ones, the delay to the market entry and to the compensation lists is considered as discrimination and lessens the potential for rationalization of public expenses on health. Ultimately, the patients are those who are most affected by restricting the access to efficient and affordable treatment.

The expenses control mechanisms and the delay of the decisions also determined certain marketing strategies of the MA holders. They prefer to submit the pricing and compensation requests first in states with the highest prices and afterwards in those where the levels are lower⁵. Consequently, the European patients find themselves on not having equal access to treatments.

Under these circumstances, the European Commission produced a draft directive aimed at replacing the existing one⁶. The aim of the new act is to eliminate delays and other barriers to the access of medicines on the member states' markets. Also, additional protection mechanisms are proposed to the holders of MA and transparency. The Commission adopted the new proposals in March 2012, and is now running the legislative procedure in the European Parliament. In the course of 2013 the final approval is expected, and the Directive will be implemented no later than the end of 2014.

The main novelties of the proposal, as amended during the negotiations within the European Parliament and the EU Council include:

- reducing the pricing and the inclusion in the compensation lists for the generic medicines whose original product has already been approved from 90 days to 30 days;
- the decision deadlines include all the necessary analysis procedures, including the assessment of health technologies; however, in case of additional information, the deadlines are resumed at the same time with their supply by the holders of MA;
- the approval deadlines are suspended during the negotiations;
- the applications for inclusion in the compensation drug lists can be recorded at any time;
- the additional information required by the authorities cannot be specific to the marketing authorization or related to intellectual property rights;
- the promoting or control measures for the prescription of certain products must be based on objective and verifiable criteria, which are made public;
- their manufacturers or representatives may enter into informal negotiations with the authorities before obtaining the marketing authorization;
- the voluntary agreements for controlled access on the market and the procedures for centralized public procurement of the reimbursed medicines for ambulatory treatment are not covered by the regulatory transparency directive;
- the member states may set up independent administrative bodies for solving complaints and allegations of violations of the rules and / or the terms of pricing or inclusion in the compensation list;
- the civil society and associations of patients and consumers' consultation is mandatory before adopting or amending the internal rules on pricing and inclusion in the compensation lists;
- the member states shall annually communicate to the European Commission and to the public reports on the applications received, the decision deadlines for them and the reasons for delays, if necessary.

⁵Idem.

⁶The text is available at

http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/transparency/index_en.htm

The web page was accessed in June 2013.

The draft directive maintains at 90 days the applicable deadlines for pricing and inclusion in the compensation lists for innovative medicines. Overall, the procedures may not exceed 180 days for innovative medicines and 60 days for the generic ones. It also maintains the obligation to justify any rejecting / exclusion decision and to indicate the appeal options.

The new directive on the transparency of the decisions regarding drug access on national markets in the EU is a step forward compared to the act in force. There are stronger premises that the member states will reduce the delays of decision making. However, the MA holders have no guarantee in this respect and neither the guarantee to recover the damages. The independent administrative bodies, which could assess the complaints of violations of the rules and decide punitive measures against the responsible public authorities, are not binding. Therefore, in some member states the current appeal procedures, which often proved slow and inefficient, will remain the same.

A final remark in this sense is the favourable treatment for generic and bio-similar medicines. The reduction of the decision deadlines and the explicit prohibitions on the information that may be requested during deliberations for these, simplify their access to the markets where the original products have already been approved.

Directive 2011/24/EU on patients' rights in case of cross-border health services

In the same framework of the unique market and the free movement of goods and services, the European Union has issued Directive 2011/24, with the deadline for transposition on October 25, 2013, which establishes the procedures for discount/reimbursement of the medical services received by the citizens of member states in other member states. The main condition for reimbursement is that the respective service be included in the basic package of health services that the insured in the state of residence benefit from. In addition, the reimbursement is made up to the limit value that would have been covered by the national health insurance system.

The potential significance of the Directive 24 is major because it creates equal access to treatment between Romanian patients and those from other member states. However, the entry into force of the Directive does not automatically produce a massive reimbursement demand of cross-border medical services because it allows other member states to impose restrictions. In approving the reimbursement / repayment, they may apply the same conditions, eligibility criteria and administrative procedures as if the service was provided on national territory. In addition, the

member states may establish prior authorization requirements for the reimbursement of certain cross-border services. Any such limitations, as well as the types of services must be notified to the European Commission and made public.

The reimbursement control measures for cross-border services can be justified only if they aim to "ensure a sufficient, permanent and balanced supply of services in that member state or whether they aim to limit the costs and prevent inefficient use of available human and material resources"⁷. The conditions or prior approvals shall be considered as discrimination or barriers to the free movement of patients, goods and services when the medical care cannot be timely provided in the member state of residence based on the objective patient health and its probable course.

In terms of the prescriptions, any member state has to supply medicines indicated for patients in another member state, if they are licensed on both national markets. In addition, the therapies prescribed in other member states must continue in the states of residence, and they have the obligation to issue the respective product or equipment.

⁷Art. 3 of Directive 2011/24/EU in terms of patients' rights in case of cross-border health services.

Ultimately, the Directive 2011/24 establishes a network of cooperation and exchange of information on the evaluation of the medical technologies. The network is voluntary and is made up of representatives of the public authorities responsible in the member states. The results of its work will not be subjected to taxes in the member states, which retain the right to regulate the provision and financing of medical services in the national territory.

Although the Directive marks a major development for the European market of medical services, we do not expect their impact on social security budgets to be important. Member States shall maintain sufficient means to control the demand for cross-border medical services, especially for financial reasons. In any case, the limits of the reimbursement / repayment makes them inaccessible to a large majority of citizens from poorer states such as Romania, as the reference value is the one used in the national social security system. Thus, the patients will pay the difference up to the total cost of the medical service when it is more expensive than in the state of residence.

The regulatory framework and practices in Romania on pricing and medicine reimbursement

Romania's regulations on drug pricing and inclusion in the compensation lists comply with the letter of the provisions of Directive 89/105. However, the spirit of the implementation is not in line with the EU values. Romania is among the EU countries that record the longest delays in the decision-making process on drug compensation covered by the health insurance system⁸. Furthermore, external reference pricing ensures Romania has minimum prices as compared to the EU level. The consequences are negative for patients, who have been deprived of efficient or even life-saving treatments for about five years. Instead, the managers of the health insurance system think they have been saving on drug costs, but in fact they have been sacrificing the health of the insured people, and forfeiting economic benefits and reduced future costs of medical services.

Pricing

The pricing procedures for prescription medicines ensure the lowest prices in Europe for Romania, both for innovative and generic medicines⁹. For the former, the price level must be lower or equal with the lowest price of the same drug from a list of 12 Member States. As regards generic medicines, the highest price that may be proposed is 65% of the

price of the corresponding innovative drug in Romania. If the level is even lower in the comparison countries, then such lower value is used. In case of biosimilar medicines, the algorithm is similar to that for generic medicines, but the maximum percentage rises to 80% of the reference biological drug.

⁸According to the European Commission, „Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council”, Bruxelles, 2012.

⁹Ministry of Health Order no. 75/2009 for the approval of Regulations in terms of pricing to medicines for human use

According to the legal provisions, the prices shall be approved for periods of one year and updated when there are changes in the prices of the equivalent medicines in the comparison countries. With regards to the decision-making procedures, Health Minister Order no. 75/2009 implements the provisions of Directive 105/89: the decisions shall be made within 90 days and, failing that, merchants can sell the products at the prices they proposed.

Drug compensation under the health insurance system within the period 2008 - 2013

In 2008, through MH Order no. 318/2008¹⁰, the criteria for the inclusion of medicines on the compensation list used in the Romanian health insurance system have been revised.

The list was substantially updated at the middle of the year, based on new criteria and requirements. This would be the last substantial change for the following five years. By the middle of 2013, only 17 new molecules or indications have been added - of which 12 in 2009, usually following public health events (for instance the avian flu epidemic).

The lack of the decisions regarding the inclusion or non-inclusion of new molecules or indications on the subsidy list over the past 5 years represents a breach of the Directive 105/89. MH Order no. 318/2008 provided for the annual updating of the list "in accordance with the governmental health and budget policies", although compliance with the letter of the directive would have required at least two such actions per year. Meanwhile, over 100 requests have been submitted which have not been granted so far, for fear that it would trigger an uncontrolled rise in NSHIF (National Social Health Insurance Fund) expenses for reimbursed medicines.

Order no. 318/2008 established criteria for rapid assessment of the requests for inclusion. Thus, when a new drug or indication had been reimbursed in at least three EU countries and had proved better clinical efficacy or safety than the standard therapy, it would be included in the list. If

its efficacy or safety was similar to those of the standard therapy, but the proposed price was lower, the decision would also be favourable. Although proofs in terms of efficacy and safety, costs and cost effectiveness were required, the impact calculation was concise, which attracted subsequent criticism and probably fuelled the reluctance towards updating the list in the following years¹¹. In consequence, the debate has been deviated from the reasons of non-inclusion of new molecules on the compensation list and the breach of the provisions of Directive 105/89 towards the need to change the criteria and requirements and to establish a new assessment system for the medical technologies, which would ensure a more rational use of NSHIF limited resources.

In terms of procedural matters, Order no. 318/2008 complied with the EU requirements. The decisions had to be communicated within 90 days from filing the applications or from filling in the documents. After the assessment of the files by the relevant commissions under the Ministry of Health, the inclusion or non-inclusion in the compensation list was proposed by the Therapeutic Strategy Commission. Its decision had to be validated (or invalidated) by the National Transparency Commission, which would draw up the final lists and would forward them to the Minister of Health. The Latter would forward them to the Government for approval.

¹⁰Order no. 318/2008 for the approval of criteria in terms of the inclusion, non-inclusion or exclusion of medicines in/from the List with international common names of the medicines that the insurants benefit from, with or without the personal contribution, of the documentation that had to be submitted by the applicants in order to include a drug in this list and of the working procedure of the Therapeutic Strategy Commission.

¹¹See the report NICE International, Technical Assistance in Reviewing the Content and Listing Processes for the Romanian Basic Package of Health Services and Technologies, 2012.

The 2013 new procedures for approval of medical technologies

After five years during which the list of reimbursed medicines under the health insurance system had not been updated and the assessment criteria had been accused of being too flexible¹², a new medical technology assessment system was approved in June 2013¹³.

The assessment criteria are similar to the 2008 ones but the institutional framework, the proofs required, the assessment methodology and the budgetary impact are much more complex. The procedures used in the assessment of medical technologies are different for the innovative, biosimilar and generic medicines. For the first category, the level of complexity is high, whilst for the other, the proof that they have been reimbursed in a minimum number of EU countries is sufficient.

For the innovative medicines, the criteria refer to their reimbursement status in the EU countries, the relative clinical efficacy, the relative safety and the results in relation to patients. Each criterion shall be awarded a score, depending of the level of performance, which shall be proved, among others, through "studies with the highest level of evidence". The maximum possible score is 10 points, and the minimum needed for inclusion in the compensation list is 6 points.

In terms of the reimbursement situation in the EU, the main references are France and UK, through the assessments performed by Haute Autorite de Sante, National Institute of Clinical Excellence, Scottish Medicines Consortium and All Wales Strategy Medicines Group. For the other three criteria, multiple-criteria decision analysis shall be used, following the model created by the EVIDEM Collaboration¹⁴. Such method of assessment attempts to consider all the effects generated by a medical technology.

For biosimilar or generic medicines whose originator is not present on the Romanian market, it is sufficient to prove that they are reimbursed in 50% of the EU member states where they are commercialised¹⁵.

Obviously, the new assessment procedures are better fit for the diversity and the high level of complexity of the new medical technologies, as well as for the need for a rational use of the health insurance system limited resources.

In this framework, it is important that the high level of complexity of the assessment does not prevent compliance with the deadlines for decision making or the access to subsidy of more expensive medical technologies with proven efficacy.

According to Order no. 724/2013, the reimbursed drug list under the Romanian insurance system will be updated twice a year, as it is also requested by the provisions of Directive no. 105/89. Marketing authorisation holders are required to draft a file for each indication of the drug, which shall be submitted in the first two weeks of each month.

The institutional framework of the new medical technology assessment system is complex. It involves the Health Technology Assessment Unit under the Ministry of Health (HTAU), the specialist committees and the National Commission for the Coordination of the Specialist Committees. As regards the latter, a part of its members are responsible for the assessment of the medical technologies, and others for the settlement of litigation.

¹²Idem.

¹³ Through Minister of Health Order no.724/2013 for the approval of the criteria for health technology assessment, of the documentation to be submitted by applicants, of the methodological instruments used in the assessment process and of the assessment methodology for the inclusion, extension of indications or non-inclusion of medicines in the List of non-proprietary names corresponding to prescription medicines of benefit to patients with or without personal contribution. As early as the second part of 2012, a first draft for an intermediate assessment system for medical technologies had been prepared according to the recommendations of NICE International report.

¹⁴ See www.evidem.org

¹⁵ Consequently, it would sufficient if they were reimbursed in just two Member States of a total of four for which a pricing decision has been obtained.

HTAU has multiple analysis tasks, including the following: assessment reports on France and UK medical technologies; efficacy, relative safety and results reported by patients; methodological quality of the documentation; budgetary impact; draft therapeutic protocols prepared by specialist committees. The committees, in their turn, assess the efficacy, the relative safety and results reported by patients and the methodological quality of the documentation. The scores awarded by the HTAU and the committees have equal weight. Following the inclusion in the compensation list, the committees update the therapeutic protocols.

The members of the National Commission for the Coordination of the Specialist Committees tasked with the assessment of the medical technologies draw up a summary of the proofs of intervention and propose inclusion/non-inclusion of new medicines or indications in the compensation list. In cases of dispute, the Litigation Commission makes a decision within ten days from its setting up. If it is not satisfied, the holder of the marketing authorisation may bring a legal action before an administrative court.

Once the complete documentation has been submitted, the assessment procedure will last between 55 and 60 days, according to the provisions of Order no. 724/2013. Where additional documents are requested, time limits will be suspended until such documents have been provided. The Order does not provide for a time limit for the Government Decision approving the updated list.

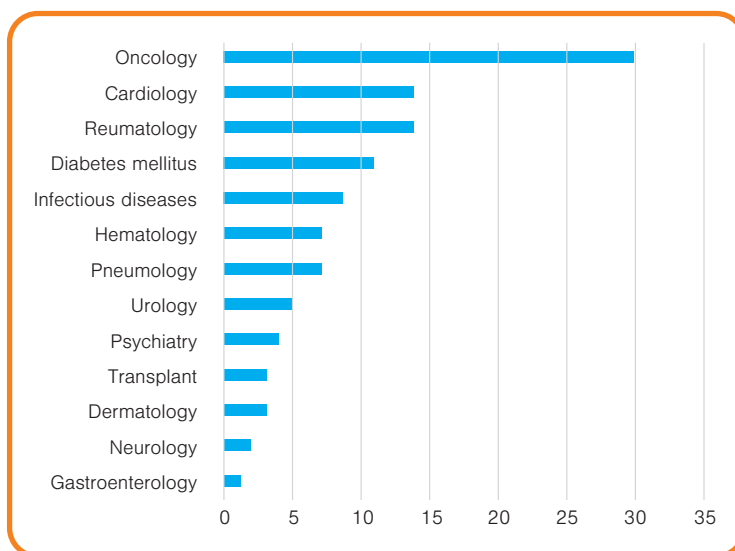
Given the high number of new molecules and indications awaiting inclusion in the compensation list, as well as the complexity of the documentation and the assessment criteria, the compliance with the deadlines undertaken for the first batch of requests, submitted between June 11 and 25, is a difficult task. In this stage, there are good intentions, but the results are still to be seen. However, if the updating of the reimbursed drug list under the Romanian health insurance system is postponed again, the trust gained by the authorities through Order no.724/2013 could dissipate.

Impact assessment of updating the list

Currently, around 170 new molecules/indications await inclusion on the list of reimbursed medicines¹⁶. According to the new assessment procedures, their inclusion or non-inclusion will depend upon the result of the evaluation of their status in other European countries, their therapeutic benefits, the safety in use and their impact on patients. Undoubtedly, the budgetary impact will also have significant contribution to the decision. The additional costs for NSHIF following the updating of the reimbursed drug list must be recognized and solutions must be identified in order to finance such cost. At the same time, it is important to show that the budgetary impact is not unilateral: apart from the immediate costs, the patients' health will improve, there will be economic benefits and a future drop in the cost of the medical services, which currently is significantly higher in Romania. So, the decision to compensate new molecules/indications should not be viewed from a narrow perspective in terms of time and analysis; rather, it should be assessed at least in the medium term, allowing the benefits of the new therapies to take effect.

In this section, we would like to assess the economic impact and the additional cost for the health insurance budget which would be generated by a potential inclusion of 110 new molecules/indications on the list of reimbursed medicines, for which statistical data is available as regards the number of people eligible for the treatment and the related unit costs. The 110 molecules cover a total of 13 therapeutic sectors with high social impact (morbidity, disabilities and mortality). As it can be noticed from figure 5, the most refer to oncology, followed by cardiology, rheumatology and diabetes.

Figure 5: The distribution of molecules/new indications on therapeutic sectors



¹⁶In June 2013, a number of 167 files have been submitted to the Ministry of Health for assessment of new molecules and indications. Most of them targeted oncology (33), followed by those for diabetes (16), rheumatology (15) and cardiology (14).

The description of framework analysis

The assessment of the incremental costs generated by the molecules and the new indications was carried out during a period of 3 years, assuming a gradual increase of their rate of penetration, from one year to another. The market share coverage was estimated differently, separately for each case, according to the classification in two categories, thus:

(i) for the molecules/indications that stand for a therapeutic sector in the health insurance system from Romania, a higher penetration rate was assumed;

(ii) for the molecules/indications that diversify/extend a therapeutic sector in the health insurance system from Romania, a more reduced penetration rate was assumed.

As it can be noticed in table 1, in case of a molecule that belongs to a therapeutic sector where the current alternative is optimal supportive care or placebo, 40% of the target group of identified patients will have access to the new therapy during the first year since the medicines have been included in the list of the reimbursed medicines. In the two following years, the value shall evolve gradually to 60%. In terms of the molecules committed to some therapeutic sectors with existent standard treatment, only 10% of the eligible patients will have access to a new therapy, the value increasing step by step up to 30% in the third year since the reimbursed drug list has been updated.

Table 1: The penetration rate assumed for molecules/new indications during the first 3 years from their entry in the compensation list

Category / Year	YEAR 1	YEAR 2	YEAR 3
The first in the therapeutic sector	40%	50%	60%
Extends the therapeutic sector	10%	20%	30%

The molecules that are currently on the waiting list have been segmented according to affections, depending on the ICD code of the disease (the international classification of the disease). In case more molecules are available for a certain affection, a market share was assumed equally divided between each of them, included in the penetration rates provided in table 1.

For each type of affection where there are molecules/new indications subject for approval, the incremental cost was calculated as a difference between the cost of the future treatment¹⁷ and the cost of the standard treatment. The cost with the hospitalization does not influence the cost, as we assumed this one will be left unchanged in case of future treatment. It is obvious that, the costs with the hospitalization will be reduced for certain

molecules (fewer days with the hospitalization); in default of relevant information that should allow the quantification of these costs, the hypothesis of keeping unchanged the hospitalization cost shall remain the only viable option.

The starting point in estimating the costs is represented by the eligible target population for the treatment on each affection. As there are no relevant statistical data at the national level for the target group of patients that might benefit from each type of new treatment, more means of estimating the cohort have been used, simultaneously, respectively data provided by the international specialty literature, incidence data at the national level, the number of cases discharged in one year from the hospitals from Romania or the experts opinion.

¹⁷If more molecules /new indications are available for the same affection, the average of their costs was used.

The unit costs (per patient) of the standard and future treatment have been taken over according to the price data of the reference medicines from the current lists of the reimbursed medicines and from CANAMED (the National Price Register for Medicines for Human Use). The standard treatment

administered in case of a new affection has been taken over for the most part of the cases from the RCP of the new molecules (active comparator), but we noticed also cases when standard therapy was not even mentioned (and in these cases optimal supportive care or placebo was used).

Efficacy indicator	Therapeutic sector
Successfully treated patients	Infectious diseases, Dermatology, Gastroenterology, Hematology, Urology, Neurology, Pneumology, Psychiatry, Rheumatology, Transplant
Avoided deaths	Cardiology, Hyperglycemia
Prolongation of survival	Oncology

Table 2: The treatments efficacy measure with the new molecules or indications

The economic impact of updating the reimbursed drug list was quantified starting from the effectiveness of the future treatment compared to the standard one (Figure 6). The efficacy data have been taken over from the RCP's medicines. In most of the cases, the efficacy of a treatment was measured as (i) the improvement of a symptomatology or of some biological constancies (the number of patients successfully treated) but also (ii) as deaths avoided (cardiology and diabetes) or (iii) the survival period (cancer).

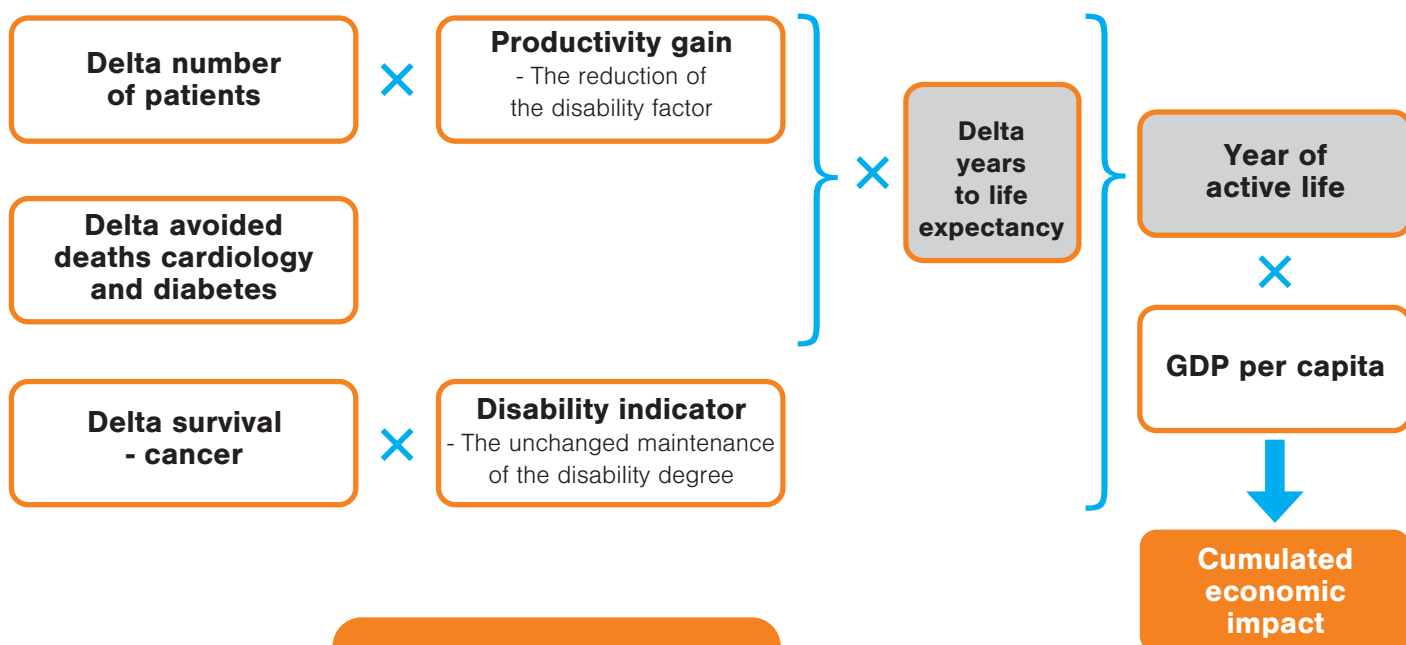


Figure 6: The economic impact assessment algorithm of the molecules/new indications vs. standard treatment

The efficacy indicators on each affection have been translated in active years. They have been quantified taking into account the productivity gain¹⁸ as a result of the reduction in terms of the degree of disability, the average age of the patients and the average life expectancy. The degree of disability has been quantified through a coefficient calculated by OMS¹⁹, that varies between 0 (perfect health) and 1 (total disability, equivalent with death).

The active years account for the average period of time in which a perfectly healthy person (with a 0 disability coefficient) brings his contribution to the economic activity, irrespective of age, in terms of offer (through work and/or capital) and/or demand (through consumption and/or investments). The contribution brought to the economic activity was quantified through GDP average per capita, estimated for the period of time up to the life expectancy limit in Romania.

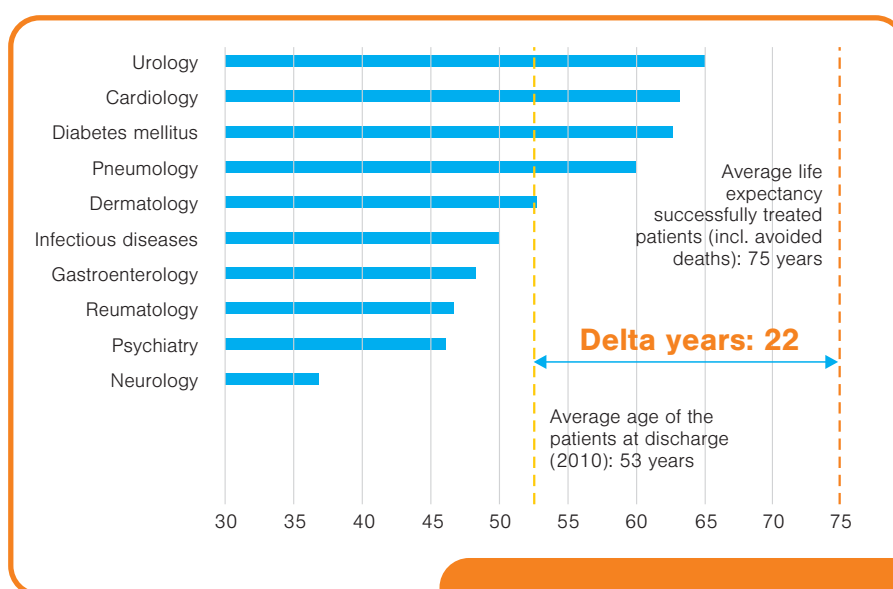


Figure 7: The distribution on affections of the average age of the patients at discharge (2010)

Figure 7 shows the average age of the patients's discharge from the hospitals from România in 2010 by categories of affections. At an aggregate level, the average age of the patients was 53 years, that, cumulated with the average life expectancy of 75 years, results in 22 additional years of life in case of successfully treated patients.

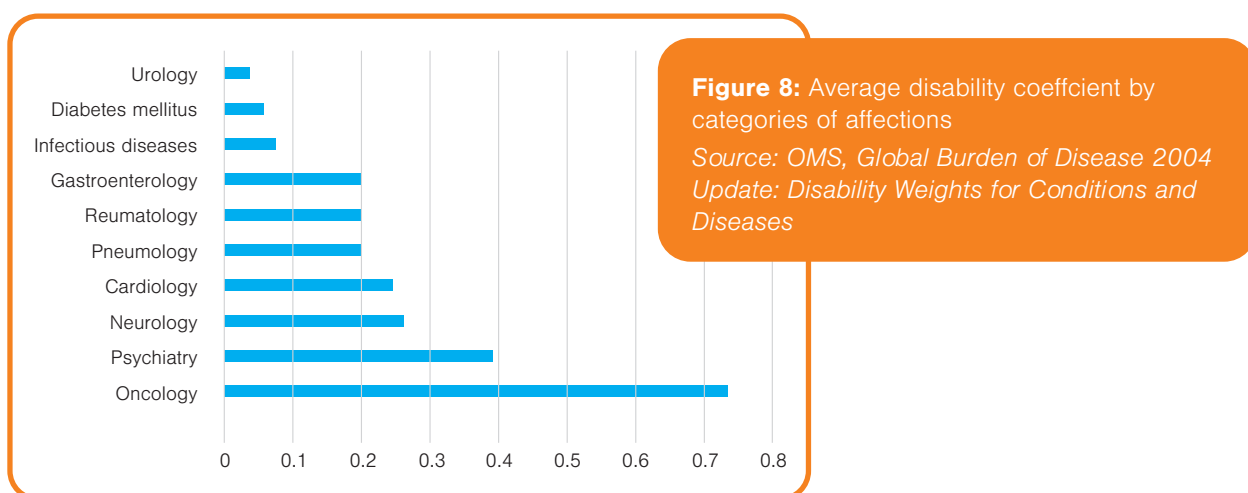
In order to obtain active years of life gained in case of treatment with molecules/new indications, compared to the standard treatment, the average life expectancy of the additional patients successfully treated must be balanced with the productivity gain resulted from the reduction of the disability coefficient. The hypothesis considered the base for this reasoning is that a patient who suffers from a certain affection brings his contribution to the economic activity in inverse proportion with the disability coefficient, and the successfully treatment of that affection shall determine the gradual return to 0 of the disability coefficient.

¹⁸ In case of molecules whose efficacy is measured by a number of survival months (for example at cancer) we assumed there is no productivity gain (the disability coefficient shall be left unchanged).

¹⁹ OMS, Global Burden of Disease 2004 Update: Disability Weights for Conditions and Diseases, 2004, available at http://www.who.int/healthinfo/global_burden_disease/GBD2004_DisabilityWeights.pdf, accessed in May-June 2013.

For example, a patient who suffers from hepatitis C has a disability coefficient of 0.075 (Figure 8). Therefore, the successful treatment (the reduction of disease symptomatology) shall increase its productivity by 7.5% per year, and the economy shall gain 1.65 years of active life for each cured patient (respectively 0.075×22 years on average till the life expectancy).

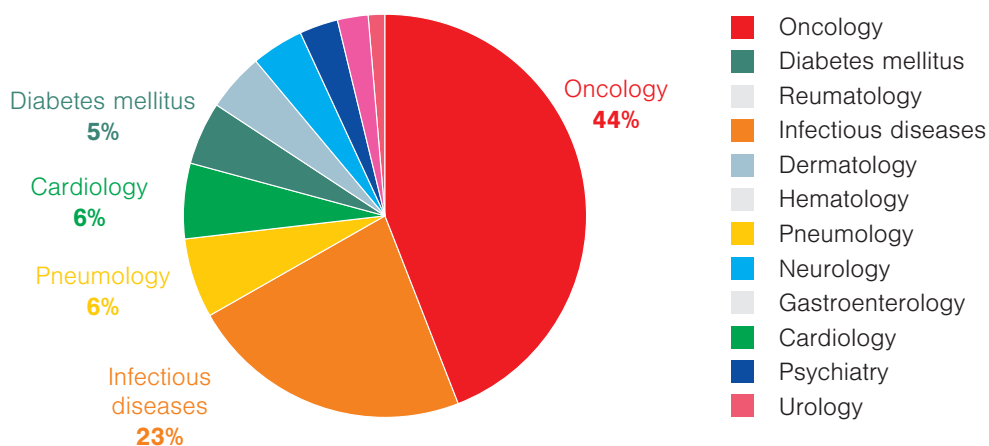
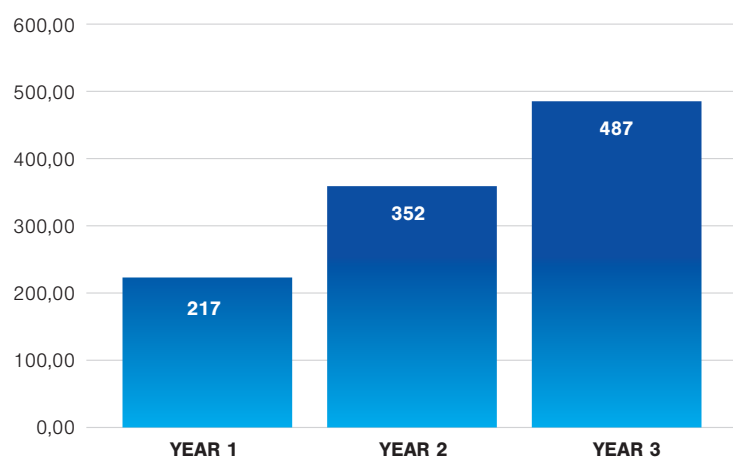
In case of patients with oncologic diseases targeted by the new molecules, the successful treatment shall determine a prolongation of life expectancy with 6 months on average compared to the standard treatment. Consequently, we assumed that the successfully treated patients will not record an increase of productivity (the disability coefficient shall be left unchanged, at 0,73 on average). In the current situation, the number of active years of life gained will depend on the number of survival months.



Implementing the methodology described above, the additional budgetary effort that should be provided by NSHIF following the inclusion of the molecules/new indications in the reimbursed medicines list varies, according to the penetration rate assumed²⁰, between 217 million lei, in the first year from compensation, and 487 million lei in the 3rd year, respectively between 2.3% and 5.2% from NSHIF budget allocated to the medicines in 2013. The data are showed in figure 9.

Figure 9: The cost of updating the reimbursed drug list (million lei)

Figure 10: The cost structure of updating the reimbursed drug list by categories of affections



The highest weights in the additional costs are owned by five main therapeutic sectors: oncology, infectious diseases, pneumology, cardiology and hyperglycemia, a hierarchy compared to the current structure of the expenses with medicines of NSHIF (see figure 10).

The update of the reimbursed drug list with the molecules/new indications that are included on the waiting list might generate in the long run an economic impact of approximately 0.5% of GDP. The positive impact comes from the increase of public participation to the economic activity, as a result of the disability degree reduction (higher productivity) at a higher number of patients compared to the effects of maintaining the standard treatment, that is currently available.

²⁰ See table 1.

Table 3 shows the incremental impact synthesis of the new therapies, quantified in years of active life. Their economic value was determined by the multiplication with average GDP per capita in the years left to the life expectancy limit.

Efficacy indicator	YEAR 1	YEAR 2	YEAR 3
Years of active life gained future vs standard treatment			
Years of life gained related to the successfully treated patients	20.174	40.347	60.521
Years of life gained related to the deaths avoided	5.625	9.717	13.810
Years of life gained related to the prolongation of survival	297	428	560
Delta years of active life – Total	26.096	50.492	74.891
Average GDP per capita in the following 22 years (lei)	44.075		
The total economic impact in the long term²¹ (billions lei)	1,15	2,22	3,30

Table 3: The economic impact of updating the reimbursed drug list

²¹Stands for the economic impact in the long term (till the average life expectancy of the patients ~ about 22 years) that determined the treatment of exigible patients with new molecules (assuming the penetration rates from Table 1) during the years 1, 2 and 3, calculated as Delta years of active life x GDP per capita.

Romanians' access to medicines. Information and point of view

The healthcare system stands for a frequent topic of debate in the public area. The point of view of the population in terms of different policies or components of the system are influenced by the messages transmitted through the means of information in mass. We shall assess in this chapter how these means reflect the topics related to the healthcare system, as well as public's opinion on the reimbursed medicines.

The information in the audio-video

The radio and the television are the main media that provide information to Romanian people, including information related to the healthcare system as a whole and the access to medicines in particular.

In terms of the audio-video sector, the daily media is dominated by news and materials that speak about the crisis from the system being treated in all its aspects. The articles that treat the Romanians' access to medicines, appeared during the period January 2011 – July 2012 can be classified, according to content, exposition and information approach, in three big categories: issues, causes and solutions.

The first category includes the articles that show the state of things, the event that generates the news: the lack or the disappearance of some medicines from the market, the production or import interruption, the limited access of the Romanian patients to state-of-the-art medicines, the rise of some pharmaceutical products, the shut-down in issuing some free or reimbursed medicines. The tone used by the televisions in presenting the news from this category varies between neutral to alarmist.

Let's look at few examples:

- "Agitation in pharmacies: people consider to lay up algocalmin and analgesic provisions. The news that in short term certain analgesics will be able to be bought only based on a receipt incited the people". (PRO TV, January 19, 2011);
- "The treatments for the diabetes and cancer patients might become a luxury. Although they are included in the national health programmes, they will be able to be found harder and harder. The pharmacies didn't get money for medicines for almost a year, and the suppliers refuse to continue the supplies until they pay their debts". (Antena 3, January 26, 2011);
- "The Romanian patients shall be left without the medicines and treatments that keep them alive". (Antena 3, February 15, 2011);
- "Millions of Romanians might be deprived of the access to treatment. Not less than two million of generic medicines for all the affections might disappear from the market". (Realitatea TV, February 24, 2011)
- "The "claw-back" tax deprives the Romanians of 30% of the free and reimbursed medicines". (PRO TV, October 5, 2011)

- "Hundreds of pharmacies, especially those from the rural area, went bankrupt or are in insolvency. Others are already closed". (Realitatea Tv, October 7, 2011)
- "The patients must prepare more money when going to the pharmacy. Hundreds of medicines have been considered unprofitable and have been removed by the companies from the reimbursed medicines list". (PRO TV, July 17, 2012)

Although these events are also heard on the radio, still less catastrophically, the preferred tone is the neutral one.

A frequently met subcategory in the news on radio is represented by the studies that reflect the health state of the Romanians. We find out that, in Romania, "the drug consumption is four times smaller than at the European level", but "the Romanians tend to use large amounts of antibiotics", ranking first on the continent in this sector. Other counter-performances that can be periodically heard on the radio:

- Romania ranks third in the world in terms of mortality from causes of cardiovascular diseases;
- Romania ranks third in Europe in terms of child obesity number;
- 73.4% of Romanians didn't go to the doctor because they didn't have money;
- Romania ranks first in the European Union in terms of morbidity tuberculosis;
- A million of Romanians suffer from chronic obstructive bronchopneumonia;
- Romania allocates the smallest budget from Europe for the treatment of haemophilia;
- A quarter of the population became overweight in the last year.

Champions at diseases and poverty, the Romanians are kept far from the cutting-edge treatments, highlights the press, stating that many years shall pass until our governors decide to take steps in order to introduce the new discoveries on the reimbursed medicines list. The reimbursed drug list hasn't been updated since 2008, state the journalists.

During the period July 2012 – July 2013, the press materials that refer to the rights of the Romanian patients to treatments and modern medicines, as the other European citizens benefit from them, become quite frequent in this sector. The preelectoral environment as well as the new political players, whose public statements inspire optimism bring their contribution to this situation. The necessity of updating the reimbursed drug list with innovative molecules is often debated. The gap between the patients from Romania and those of other European countries in terms of the access to cutting-edge medicines is reflected in a legitimate way.

Subsequently, as some of the authorities' promises in terms of a situation improvement did not materialize, the Romanian patients' drama and the system counter-performances proliferated through titles such as:

„Cheap health, sick population: Romania spends the least in Europe for health”
(Antena 3 – November 6, 2012);

”The patients hospitalized in the infectious disease hospital, forced to buy their medicines”
(Realitatea TV – November 7, 2012);

”The woman who did not let herself beaten by the system. The teacher Adela Rogojinaru, suffering from cancer, buys medicines with the money gathered by her students”
(Antena 3 – November 4, 2012);

The elections at the end of 2012 brought new promises for the patients: "Starting with 2013, after many years, the pensions will be indexed, and the medicines will be reimbursed with 90 % for those who have pensions under lei 1.000”, assures the minister of Labour
(www.stirileprotv.ro – November 10, 2012).

Moreover, during the same period preceding the elections, the press broadcasted the announcement of the responsible persons from the Ministry of Health in terms of starting the assessment for 150 cutting-edge medicines, in order to introduce them in the list of reimbursed medicines.

The year 2013 brought clarifications after the elections, but also a little bit of caution from the part of the authorities from healthcare system in expressing their opinion in terms of updating the reimbursed medicines list. In this case, the press continued to show peoples' necessities who are suffering, who hope for cutting-edge treatments, underlining at the same time the players' promises.

The second category of information, which is important as weight taking the entire studied sector as a whole, is the one that includes causes of deficiencies and also identified blockages. In this framework, it is shown, from different angles, the relationship between the Ministry of Health/the health insurance funds – the medicines producers – suppliers – pharmacists – physicians. The most important point of debate is represented by the public money and how it is managed.

Thus, the representatives of the pharmaceutical industry complain about delays in the reimbursement periods, identifying in this way a main cause of the blockages. The Ministry of Health, the governors in general, call for the lack of funds, but also the shortcomings of a system whose recovery depends, actually, on the efficiency of the same players. In all this „dialogue of the deaf”, the beneficiary's voice, that of the citizen, can hardly be heard.

The third category of news includes the proposals and advanced solutions in order to defuse the existing crises. By far, the highest share is held by the claw-back tax establishment and the discussions on this topic. According to the drug producers such a tax thought to cover the difference between the reimbursed medicines that the state affirms it can no longer support could have a devastating impact on the market of pharmaceuticals, and the patients' access to treatment could be limited.

The proposals addressed to the Government are highlighted at this point, options intended to provide predictability in the business plan and avoid syncope in terms of patients' access to medicines. On the other hand, the governmental factors, that consider the claw-back tax as a sort of

panacea that could heal an underfinanced system, promise to hinder the production of arrears, that will guarantee the existence of medicines in pharmacies, "at fair prices" and assured through transparent procedures.

The information in the written media

The drug market problems are largely reflected in the newspapers too. Compared to the audiovisual media, in the written press the frequency of the opinion articles is larger, as well as the interviews with the actors involved. The causes of the system's crisis, but also the possible solutions, are

presented in an explicit way in the print area, depending on the space allocated to the materials. The alarm signals, compressed in titles and subtitles, have a strong resonance. Here are some examples:

"The Romanian pharmaceutical system can collapse every second if drug manufacturers would quit crediting the market"

(Financiarul, March 23, 2011);

"Romanians, the lowest access to medicines in the EU"

(Cronica Română, March 15, 2011);

"The lowest rate of compensation in Europe"

(România Liberă, March 14, 2011);

"No expensive medicines for cancer, tuberculosis and diabetes"

(Evenimentul Zilei, August 8, 2011).

The claw-back tax is largely debated, with a quality addition to the audio-visual, the parties involved having the opportunity to explain more clearly what this initiative involves.

Almost without exception, the topics on the radio, TV or newspapers can be found in the online. Well represented on the internet and much more accessible to the interested public are the local or regional news. But according to the principle "Internet bears anything" the quality of information

sometimes is unsatisfactory. This drawback of the internet is, in turn, signaled even by the EU officials: "(...) the patients face a growing volume of information from different sources and is often difficult for them to identify reliable information about medicines. The growing use of the Internet in recent years makes the need for clear information even more important. Online information on medicines must be accurate and reliable"²².

²²Press release of European Commission on the theme of revised propositions which clarifies the information that the profile industry may put at public's disposal in terms of the medicines released only based on medical prescription.

http://ec.europa.eu/romania/news/111011_medicamente_ro.htm, November 2011

The public's point of view

So, Romanians have multiple sources of information in terms of medicines. In order to determine in what way the information released was received and how it influences the opinion and behavior of consumers, we resort to a IMAS survey data, carried out during the period August 9 -14, 2012, on a representative sample of 1036 people.²³

According to the survey, 88.6 % of respondents had bought medicines in the past five years for them or anyone else; of them, 28% said had bought for serious conditions such as hepatitis, cancer, diabetes. Only 12.8% of the medicines for serious conditions purchased were free and 75.7% - reimbursed. Almost everyone with severe conditions (98.6 %) say that they have bought medicines from Romania

Only one Romanian of five (19.5%) knows the medicines classification in innovative (original) and generic, knowing what each concept means separately. Most of the respondents (80.5 %) say they do not know these terms. However, Romanians recognize the importance of the cutting-edge medicines and say that they would like to benefit from them:

- Most of them (45.4 %) say they would prefer to buy innovative medicines, 17.1% - generic, for 30.3% this matter is not important;
- 46.2 % believe that it is better to treat themselves with innovative medicines, 16% with generic medicines, for 28.7% this matter is not important;
- 77.2% of the respondents consider important to buy innovative medicines, only 21.5 % state the opposite;
- 88.5 % of the subjects stated that for serious diseases such as hepatitis, cancer, diabetes and others, they should be able to choose the cutting-edge medicines.

Although mass-media broadcasted many materials that the list of reimbursed medicines was "frozen" since 2008, the awareness of the population on this issue is quite low. According to IMAS study, only 6.2% of respondents claim to know when the reimbursed list was updated, however most of them offered a wrong answer:

only 12.6% of them know that the list has not been updated since 2008, the majority (42.3%) believes that it was updated in 2012.

The subjects are informed that the last update was made in 2008 and are asked how often do they think that the list of free and reimbursed medicines should be updated. Most say that these changes should be made at least once a year (23.7% - once in 6 months, 34.2 % - once a year), 4.1% -every two years, 23.6 % - whenever a new drug appears, 14.4 % - do not know.

Asked whether they would be willing to pay full price for cheap medicines instead of compensation of expensive medicines, IMAS 56.9% of respondents answered affirmatively, while the rest rejected the idea. Among those who would be willing to pay 34.1 % would pay out of their pockets 5 lei in addition, while 35.6 % agreed to pay between 5 and 9.99 lei for a cheap drug. Only 18.3% - would pay between 10 and 19.99 lei, 7.9% - 20 lei or more, and 4.1% - do not know.

Finally, the great majority of Romanians (82.5 %) consider that cutting-edge medicines are the least important for improving the health of the population. Few people believe them to be unimportant (4.5 %) or totally unimportant (1.1%), while 11.9 % do not know what to say.

²³Romnibus carried out by IMAS Marketing & Sondaje, August 2012.

Conclusions and reflections

Statistics show that Romanians live less and are sicker than Europeans. Our country is facing a number of health imbalances that are caused also by the quality, quantity and insufficient access to medical services. In case of the majority of health indicators, Romania occupies the lower half of the ranking of EU member states. The pace of improvement of the results and recovery of the disparity was alert until 2008, but has fallen since the economic crisis.

The European health policies in terms of health evolve and interfere more and more with the sovereignty of the Members States. A new directive on cross-border healthcare services reimbursement must be transposed into national law until October 2013. The European Parliament debates a lay-out project on the transparency in decisions regarding the drug access on the national markets. Our country will have to implement the EU regulations, so as to ensure its citizens equal rights as any other European.

In Romania, the legal framework in terms of drug pricing and drug inclusion in the lists of compensation observes the provisions of Directive 105/89. The spirit of implementation, however, deviates from the EU values. Romania finds itself among the EU countries that have the highest delays in making decisions about drug compensation in the health insurance system²⁴. The last general update of the reimbursed drug list was carried out in 2008. Unfortunately, the health insurance system imagines current savings in the drug expenses, but sacrifices the health of taxpayers, economic benefits and discounts of the future health care costs.

Since mid-2013, Romania has a new framework for the assessment of medical technologies, taken into account when analyzing the requests for inclusion in the list the medicines that the insured might benefit from, with or without personal contribution²⁵. The assessment criteria, the institutional framework, the required evidences, the

methodology of analysis and forecast of the budgetary impact makes new system much more complex than the one used in the past.

It is better adapted to the diversity of new medical technologies, and also to the need for rational use of limited resources of the health insurance system. However, it is important that the high level of complexity of the assessment not to become an obstacle in observing the deadlines for making decisions or for the access to compensation of some more expensive medical technologies, but with proven efficacy.

Using a specially designed calculation model, we estimated incremental costs and benefits of updating the list of reimbursed medicines. The budgetary impact is not one-sided: apart from the immediate costs, the health of patients shall improve, economic benefits and future reductions in expenses on medical services shall be found, that are superior to Romanian society. Therefore, the decision to compensate new molecules/indications should not be viewed from a narrow perspective of time and analysis, but assessed at least in the medium term so that the benefits of new therapies to make their effects felt.

Depending on the assumptions used for market penetration, the costs of updating the compensation drug list must vary between 217 million lei, in the first year from the introduction, and 487 million lei in the third year, respectively between 2.3% and 5.2% from the NSHIF budget allocated for the medicines in 2013.

²⁴According to the European Commission; "Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council", Bruxelles, 2012;

²⁵The Order of the Ministry of Health no. 724/2013 for the approval of the assessment criteria of medical technologies, of the documentation which must be submitted by the applicants, of the methodological instruments used in the assessment process and the assessment methodology in terms of inclusion or non-inclusion, indication's extension or the non-inclusion of the medicines in the List of international common denomination of medicines of which the insured must benefit from, based on medical prescription, with or without personal contribution.

The highest share in additional costs is held by five major therapeutic sectors: oncology, infectious diseases, pneumology, cardiology and diabetes, a hierarchy compared to the current structure of NSHIF expenditure on medicines.

Updating the reimbursed drug list with molecules/new indications pending could generate on long-term a cumulative economic impact of about 0.5 % of GDP (estimated in 2013), by increasing the degree of public participation in economic activity of the population, thanks to the reduction of the disability degree to a higher number of patients, compared to currently available treatments.

Consequently, Romanian society has a lot to gain by investing now in the new therapies. This argument comes as addition to the ethical one, according to which the health system is intended to provide more effective treatments to the patients and reduce their suffering.

The health system is one of the favorite topics of debate in the public sector. Mass-media is according large spaces regarding the Romanians' access to information on medicines, covering both the assembly (the crises and system bottlenecks, underfunding), as well as the particular situations (the disappearance of a specific drug from pharmacies). Usually, the producers' point of view or of their representatives is heard. Much less represented in the media is the opinion of beneficiaries/ consumers of medicines. With rare exceptions (e.g. morphine crisis, cytostatic crisis), the recipients fail to have a large enough media presence, in order to become a pressure factor on decision makers, able to change the status quo.

Although mass-media broadcasted many materials which drew attention to the fact that the list of reimbursed medicines was "frozen" since 2008, the awareness of the population on this issue is quite low. According to the IMAS study used in preparing this report, the great majority of

Romanians (82.5 %) believe that innovative medicines are the least important for the improvement of population's health. However, only 6.2 % of respondents claim to know when the reimbursed list was last updated. Most respondents state that these changes should be made at least once a year (23.7% - once in six months, 34.2 % - once a year), 4.1% -every two years, 23.6 % - whenever a new drug appears, and 14.4 % do not know.

The development of medical services and the provision of equal treatment for all Romanian citizens involve a set of measures, that target the entire health system. The updating of the reimbursed drug list is a step forward. Other steps are also necessary, as already showed in the specialized reports published over the last years²⁶. All qualitative bounces generate incremental costs. In case of updating the reimbursed drug list, they are not prohibitive, accounting for up to 5% of the current expenses with medicines of NSHIF. The long and medium term benefits are instead, important.

The financing of the development of medical services in Romania, including the updating of the reimbursed drug list is a topic that hasn't been agreed on in the public debates and among the decisional factors. The total resources allocated to the Health Department in our country are the smallest in the European Union, respective 5.6% of Gross Domestic Product, as opposed to an average of 9% in EU of Gross Domestic Product²⁷. In terms of these resources, the public expenses with the Health Department don't exceed 4 % of GDP, again one of the smallest values at EU level.

Considering the current legal, fiscal and budgetary framework we consider that financing the development of quality and access to medical services can only come from several sources, namely:

²⁶See the report of the presidential Committee for the analysis and elaboration of policies in the public health department in Romania "A sanitary system focused on citizen's needs", Bucharest 2008; The national strategy of rationalization of the hospitals, approved by the Government Resolution no. 303/2011; The Academic Society from Romania "Crises and reform in the health system. A radiography up to date", Bucharest 2010; World Bank, "Functional analyses. Health sector", Bucharest 2011; Expertforum, "The incomes and expenses of health system. Short comparative analyses of the reform variants", Bucharest 2012; NICE International, "Technical Assistance in Reviewing the Content and Listing Processes for the Romanian Basic Package of Health Services and Technologies", Bucharest, 2012; International Monetary Fund, "Romania: Selected Issues Paper", IMF Country Report No. 12/291, Washington, D.C., 2012; The Romanian Government, "The fiscal-budgetary strategy for the period 2013-2015", Bucharest 2012

²⁷http://epp.eurostat.ec.europa.eu/portal/page/portal/health/public_health/data_public_health/database

- i.** Health contributions;
- ii.** State budget subsidies;
- iii.** Direct payments of the patients;
- iv.** Private health insurances;

In terms of the incremental costs of updating the reimbursed drug list, as they were estimated in this report, there are solutions that we submit to the attention of responsible public authorities. Without trying to substitute to them, we show a series of options and observations that might help during the process of establishing the financing resources of supplementary resources supply:

- i.** The extension from 5.5% to 10.7% of health contribution paid by the certified natural persons and by those that obtain incomes from independent activities might generate additional incomes of over 300 million lei annually;
- ii.** The increase of health contribution with 0.1 percentage points both for employers and for employees would bring a plus of 300 million lei annually, without significantly increasing the cost with the labor force;
- iii.** The increase of efficiency of collecting VAT with 1% compared to the current level would generate additional incomes for the state budget of 500 million lei annually²⁸;
- iv.** The state budget doesn't transfer to NSHIF the equivalent value of the health insurance for the majority of people that benefit freely of this. The quantification of state budget subsidies to NSHIF considering the cost of free health insurance would bring predictability, transparency and would allow NSHIF to plan on the long term the resources use. For example, the compensation of the insurance for students of mandatory secondary- school vocational education and for students with a contribution of 5.5%, calculated at the quantum of minimum wage, would rise to approximately 1.75 million lei annually.

This quantification method of subventions might replace for good the current transfers for covering the NSHIF deficiencies;

v. Of the total sum of 6 billion lei that NSHIF has to recover from the creditors, approximately half come from economic operators with state owned capital²⁹. Their compensation divided by the state budget³⁰ might provide a part of the necessary resources for the development of medical services in Romania;

vi. Without amendments to the regulatory framework of claw-back tax, the producers will be the ones who will cover the additional costs for updating the reimbursed drug list. Such a situation would protect on a short term the social health insurance budget, but might bring prejudice to Romanian patients on a medium term. Romania might risk to become an unattractive market for the producers of innovative medicines, that would postpone of their own initiative the marketing of the cutting-edge and efficient therapies or would withdraw the ones that are currently available.

The decision in terms of the financing sources of updating the list of reimbursed medicines and in a broad sense, of medical services development in our country depends on the fiscal priorities of the Government. Irrespective of the current priorities, in order to build a solid base on medium and long term, that should be for the benefit of the Romanian patients, it is important that the resources generated to NSHIF be directly proportional with the quality and quantity of desired health services, to be transparent, predictable and not a burden for the tax payers.

²⁸According to the Fiscal Council, in the Report for 2011, the degree of efficiency of VAT taxation in Romania in 2009 was of 56%, the lowest value from EU (www.consiliulfiscal.ro).

²⁹Expertforum, "The incomes and expenses of health system. Short comparative analysis of the reform options", Bucharest 2012".

³⁰The collection of NSHIF incomes is the responsibility of National Agency for Tax Administration, that is under the authority of the Ministry of Public Finance.

Bibliographical references

World Bank, "Functional analysis. Health sector", Bucharest 2011

European Commission, Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council, Bruxelles, 2012

European Commission, Communication From The Commission To The European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector", Bruxelles, 2008, available at http://ec.europa.eu/health/human-use/package_en.htm

European Commission, Impact Assessment accompanying the Proposal for a Directive of the European Parliament and of the Council, Bruxelles, 2012, available at [http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0030\(51\):FIN:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0030(51):FIN:EN:PDF)

European Commission, Pharmaceutical Sector Inquiry (Final report), Bruxelles, 2009, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

The Presidential Commission for the analysis and elaboration of policies in the public health department in Romania, A sanitary system focused on citizen's needs, Bucharest 2008

The Fiscal Council, the Report for 2011, Bucharest, 2012, available at www.consiliulfiscal.ro

Eurostat Public Health Database, http://epp.eurostat.ec.europa.eu/portal/page/portal/health/public_health/data_public_health/database

Expertforum, The incomes and expenses of health system. Short comparative analysis of the reform options, Bucharest 2012

The Romanian Government, The fiscal-budgetary strategy for the period 2013-2015, Bucharest 2012

The Romanian Government, The national strategy of rationalizing the hospitals, approved by the Government Resolution no. 303/2011

International Monetary Fund, Romania: Selected Issues Paper, IMF Country Report No. 12/291, Washington, D.C., 2012

NICE International, Technical Assistance in Reviewing the Content and Listing Processes for the Romanian Basic Package of Health Services and Technologies, 2012

Ordinance no. 318/2008 for the approval of the criteria regarding the inclusion, non-inclusion or exclusion of the medicines in/from the List with common international names of the medicines whose beneficiaries are the insured, with or without personal contribution, of the documentation that has to be submitted by the applicants for the inclusion of a drug in this list and of the work procedure of the therapeutic strategy Commission.

The Ministry of Health Ordinance no. 724/2013 for the approval of the assessment criteria of medical technologies, of the documentation that has to be submitted by the applicants, of the methodological instruments used during the assessment process and of the assessment methodology regarding the inclusion, the extension of indications or non-inclusion of the medicines in the List with common international names of the medicines whose beneficiaries are the insured, based on medical prescription, with or without personal contribution.

The Ministry of Health Order no. 75/2009 for the approval of the Regulations in terms of the calculation method of the prices for medicines for human use.

World Health Organisation, Global Burden of Disease 2004 Update: Disability Weights for Conditions and Diseases, 2004, available at http://www.who.int/healthinfo/global_burden_disease/GBD2004_DisabilityWeights.pdf

World Health Organisation, Health for All Database, <http://www.euro.who.int/en/what-we-do/data-and-evidence/databases/european-health-for-all-database-hfa-db2>

The Academic Society from Romania, Crises and reform in the health system. An up-to-date radiography, Bucharest 2010

