POLICY PAPER

FINANCING THE HEALTH CARE SYSTEM IN ROMANIA

Priorities and Financial Proposals

- *Working Paper* -

Bucharest 2013

List of Acronyms:

AMCHAM – American Chamber of Commerce in Romania
EC - European Commission
EU – European Union
GDP – Gross Domestic Product
HTA- Health Technology Assessment
ICL – International Common Label
IMF – International Monetary Fund
LAWG – Local American Working Group - Pharma
MoH – Ministry of Health
NHIH – National Health Insurance House
NUSHIF –National Unique Social Health Insurance Fund
OCDE – Organisation for Economic Co-operation and development
UIIS – Unique Integrated Information System
WHO – World Health Organization
WB – World Bank

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1. Introduction

This report is the result of a joint effort between **LAWG** and **AmCham** and proposes to improve the population health status by means of promoting and supporting investments in the health care system.

The scope of this report is to set forth an executive summary with focus on viable solutions for financing the health care system. These solutions follow various research and analysis papers produced in recent years which have been validated and forwarded by experts in this field.

Through this joint report, LAWG and AmCham aim to highlight the main features of health care funding in Romania and to present possible future directions having as scope to boost health care financing and to ensure efficient resource utilisation. The report also emphasizes the importance of investing in innovation and prevention, and advocates the increasing role of ensuring data transparency with respect to the decision making process in implementing public health care policy.

The report integrates conclusions and recommendations compiled from studies conducted in recent years at LAWG's and AmCham's initiative, namely:

- Information Paper *Explaining AmCham EU's Position on Investment in Healthcare,* by the American Chamber of Commerce to the European Union, December 2011;
- Policy Brief *Incomes and expenditures of the health care system* - a brief comparative analysis of the alternatives for reform, conducted by EFOR for LAWG, May 2012;
- Study "*Compensated medicines policy in Romania 2008 - 2013,*" produced by Mind Research & Rating for LAWG, October 2013.

Additional analyses and recommendations from other studies and reports conducted in recent years by institutions and experts in this field (WHO and OECD) have also been considered.

2. Issue Overview: Financing the Healthcare System

Health care financing is a key factor in determining the population health status. The low level of allocated funding and the inefficient use of resources are reflected upon health indicators which place Romania much below EU averages.

Romania should make the effort to increase the magnitude of funds allocated to the health care system, to invest in innovation and to streamline costs. It is equally important to find an optimal balance between public expenditures and innovation stimulus.

2.1 Funding Levels Point Toward the Population Health Status

Health indicators place Romania below EU averages on the main issues reflecting over the population health status:

- **Life expectancy at birth** is 73.83 years, compared to 80.13 years as is, on average, in the EU (2010);
- **The mortality rate** is 948 per 100,000 inhabitants, as compared to 603 per 100,000 inhabitants in the EU (2010);
- **Infant mortality** in Romania is twice as large (9.79/1000 live births) as the EU average (4.04/1000 live births) in 2010[1].

One of the main factors which affect these results consists of the health care system itself and, more specifically, of the investments in health, as emphasised by the following considerations:

- **The funding level influences the main policy decisions in this area:** Romania holds the lowest price in Europe for medicines along with the lowest reference pricing on therapeutic areas, and features long payment periods, followed by the introduction of the Clawback tax, and exhibits limitations on prescriptions for medicine - all of which lead to limited public access to treatments.
- **The remuneration of health professionals inevitably leads to restrictions on patients' equal access to healthcare** due to staff shortages. Medical staff wages (physicians, medical specialists, nurses, etc.) are much below other European countries, fact confirmed by unprecedented exodus of medical staff from Romania[2].

2.2 The Healthcare System is Underfunded and Investments in Innovation are Minimal

- Healthcare expenditures in Romania account for only 5% of the GDP (see Figure 2), which has been documented as being the smallest figure at UE level[3]. The percentage of health expenses from total public expenditures

[1] WHO database: http://www.euro.who.int/en/data-and-evidence/databases

[2] In the last seven years, more than 20,000 physicians have left the country, according to the Romanian College of Physicians;

[3] WHO database: http://apps.who.int/nha/database/DataExplorerRegime.aspx;

remained constant in recent years around the figure of 10%[4], indicating an affordable level of resources for health by the public budget in the current fiscal frame.

- The main assets allocated to health care are from public sources and public health insurances, whereas private health insurances are practically absent.
- Since 2008, the situation of NUSHIF has been worsening constantly as a result of the economic crisis and consequent measures (abolition of restrictions on the consumption of subsidised medicines and decreased rates of contribution to health insurance), a situation that has reached explosive levels between 2010 and 2011 - when the claims accumulated by the system reached 6.6 billion LEI, more than double as compared to 2007[5];
- Under pressures from commitments to international bodies [6] focused around the payment of ariars in the healthcare system, the Romanian authorities decided to implement legislative frameworks so as to finance the resulting deficit via the pharmaceutical industry, while introducing the Clawback tax, through which the drug manufacturers must cover the entire excess budget for the allocated consumption of medicines;
- The list of subsidised medicines has not been updated since 2008, and has thus caused restrictions to patients' access to innovative treatments, mostly life-saving.

If for countries with advanced health systems more money does not necessarily imply better results, in countries such as Romania the first step should involve the allocation of funds to health care, followed by the optimisation of costs[7].

Investing in innovation is also essential for improving the population health status. However, it is also important to find the right balance between efficient public expenditures and effective innovation stimulus.

3. Types of Incomes and Expenditures in the Healthcare System

Romania's incomes from the health care system are mainly public. Private sources of direct payments entail a very low percentage, whilst private insurance is practically absent.

Most expenditures are from NUSHIF sources, where hospital assistance accounts for the largest percentage of the total fund expenditures.

Prevention, primary care and ambulatory treatments must be given priority in the allocation of funding to relieve NUSHIF from very high costs associated with hospital care.

[4] Efor, *Incomes and expenditures of healthcare system*, Policy brief no.7, 2012, pg. 22;
[5] Efor, *Incomes and expenditures of healthcare system*, Policy brief no.7, 2012, pg. 21;
[6] Standby Agreement 2009 - 2011, concluded by Romania with the IMF, European Commission and World Bank.
[7] AmCham EU, *Explaining AmCham EU's Position on Investment in Healthcare*, december 2011;

3.1 Incomes in the Healthcare System are Mainly from Public Sources

Although the total amount of resources allocated to healthcare is the highest spent by our country in this sector[8], there are many shortcomings loom large. Only half of the resources earmarked for health care are generated by the compulsory insurance contribution. Private payments - at 20% - are rather low by EU standards. As a result, the subsidies to the NUSHIF are getting higher to prevent the accumulation of arrears and the default on payments to suppliers.

Therefore, in 2013 the contribution of the public sector exceeds 4% of GDP, thanks to increased allocations to NUSHIF from the state budget aimed at clearing overdue payments to drug suppliers[9].

The main public income streams arise from compulsory health insurances paid by employers and employees / pensioners /authorised freelancers. Vice taxes and Clawback taxes are then added to this figure. Furthermore, the health care system collects grants from the state budget, which is then used to counterbalance NUSHIF shortfalls.

The private incomes mostly come from direct payments, including co-payments or full payment rates for services. The contribution of private health insurance to revenue generation is extremely low and is therefore insignificant.

Figure 1: The weight of main sources of revenues to Romanian health system, 2012 - 2013

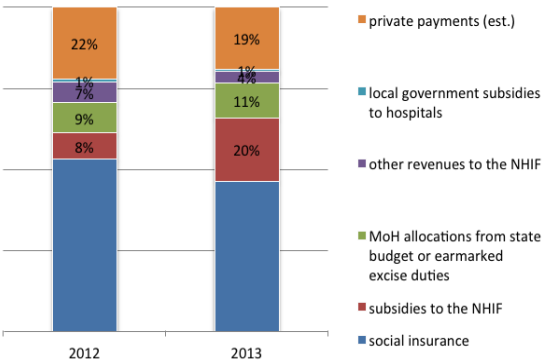
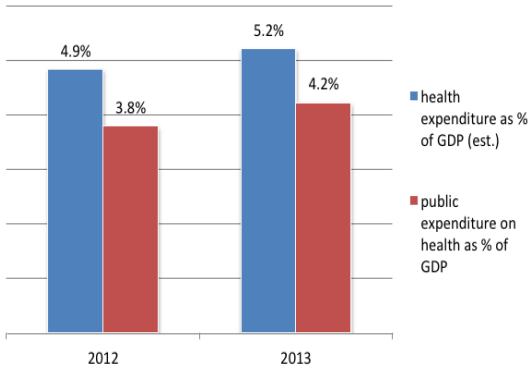


Figure 2: Total health spending as % of GDP



Source: Efor, Incomes and Expenditures in the Health Care System (2012), updated data for 2012 and 2013 (est.)

3.2 Healthcare-related expenditures are Mainly Driven by NUSHIF. Hospital Assistance Holds a very High Percentage of Total Expenditures

[8] The amount estimated for 2013 will exceed 32 bilion lei (7.4 billion euro);

[9] For implementing the Directive 2011/7/UE of the European Parliament and of the Council of 16 February 2011 on combating late payment in commercial transactions;

Most of the resources spent for healthcare in Romania are managed by the NHIH, namely 70%. Ministry of Health (MoH) own spending goes up to 11%, while private spending hovers around 20%[10].

Figure 3. The spending on healthcare by payer

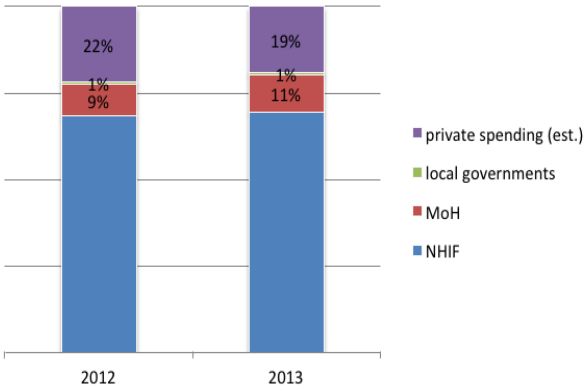
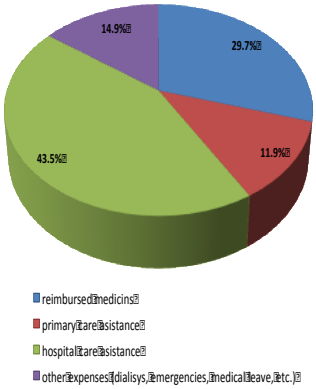


Figure 4: The NUSHIF spendings, average data for 2005 - 2013



Source: Efor, Incomes and Expenditures in the Health Care System (2012), updated data for 2012 and 2013 (est.)

By comparison, in other European countries, the weight of private insurance is at least a few percentages of all spending. For Romania, the development of such a mechanism would not only add to the scarce resources, but would relieve significant pressure from the NUSHIF.

Regarding the structure of NUSHIF for 2015- 2013, the hospital assistance holds a quite large weight of the total expenditure: 43.5% (see Figure 4). The expenditure with medicines increases in 2013 due to the allocated amounts for reducing the payment terms for the suppliers.

This distribution, with a large weight of hospital assistance, is quite atypical in comparison to other health systems in the EU. To optimise resources, primary care and ambulatory treatments should be augmented. Increasing the magnitude of such services would defend NUSHIF against very high outflows on hospital care, which in many cases may not even be necessary.

3.2.1 The Ways of Financing the Reimbursed Medicines Are More and More Complexe

The institutional structure facilitating drug subsidisation is highly complex in nature, as relationships between different participants within the system have become more challenging and more significant in scale.

The reimbursed medicines are allocated to patients based through three main systems:

[10] Efor, *Incomes and expenditures of healthcare system*, Policy brief no.7,2012, pg. 23, updated data for 2012 and 2013 (est.)

- **Medicines with and without personal contribution delivered in outpatient treatment (ambulatory care).** The allocation of funds for medicines is managed by NHIH, through which different county structures close a number of deals with open-circuit pharmacies – which then reimburse their monthly expenses.
- **Medicines delivered through national health programs (public and curative).** Financing national health programs will take place using the following patterns: (i) from MoH, the state budget and from its own funds dedicated to public national health programs; (ii) from the NUSHIF for curative health programs; (iii) from other sources, including donations and sponsorships received according to law enforcements.
- Medicines designed for hospital treatment purposes, and which are financed by NUSHIF.

4. Increasing the Healthcare Financing by Improving Sources and by Stimulating their Efficient Use

The health care system needs further resources to ensure patient access to treatments through increased service quality. As such, the population health status can improve by:

- Increasing government incomes for health care;
- Augmenting the resource pool allocated to the health care system.

4.1 Boosting Government Revenues for Healthcare

The contributions system should be revised by the Government to bring fairness, to eliminate undeclared work, to increase collection rates and to correlate this with the level of economic growth. At the same time, the State must substitute for the obligation to pay contributions for social protected categories of persons by transferring relevant amounts accounting for exemptions into the NUSHIF budget, in a clear and transparent manner.

4.1.1 The Contributions System should be Revised

Today, health insurance rates are differentiated among categories of people. Many such persons are exempted from payment, and therefore current collection rates are far from satisfying the need to finance from NUSHIF sources.

On such basis, we believe that the entire taxation system for contributions should be revised by the Government, in order to:

- Bring equity among various categories of tax payers and include other categories of persons exempted from payment in the tax basis, while ensuring social protection for those who are in real need;
- Discourage the current practice of illegal labour or that of hiring unauthorized workers or personnel under forms leading to the avoidance of employer contribution (5.2%) to NUSHIF;

- Ensure a fair, end-to-end collection process among those who must contribute to the system.

Romania has a rate of 10.7% for health insurance contributions which grants the country the lowest rank within the EU. The decrease in contribution from 2007 (12.5%) to 2009 (10.7%) overlapped with the economic crisis in subsequent years and had led to a major NUSHIF shortage. As a result, subsidies were allocated from the state budget. In 2011, Romania has resumed growth by 2.5% and we anticipate a sustainable recovery to be achieved over the period between 2013 and 2014, when growth forecasts would account for 2-3% annually. As such, Government strategy for setting contribution rates should account for the economic evolution forecast targeting the 2012-2014 fiscal period.

4.1.2 Ensuring the Allocation of State Budget Subsidies for Persons Exempted from Payment, in a Measurable, Predictable and Transparent Manner

Health legislation validates the categories of beneficiaries of basic health service packages which are exempted from paying compulsory insurance. Social security and state budgets are expected to fully compensate for these exemptions, at least until 2012. However, the most important compensation types (relating to the pensioners, children, pupils and students) have not even occurred due to the lack of legal provisions.

The state budget is now subjected to significant cash outflows in order to cover NUSHIF deficits. The predictability and transparency of the process could be facilitated through compensations relating to health insurance for children attending compulsory education institutions, for pupils in upper secondary education and for students, which would all account for 5.5% of the minimum wage.

4.2 The Effective Use of Resources within a Better Performing System

The efficient use of allocated resources can be achieved by redefining relationships between funders, service providers and patients. Based on the health reform, the private sector must secure a significant role by introducing private health insurance and by promoting basic packages of health services. Concurrently, information management for patient-related medical data will contribute to the judicious allocation of resources. We also appreciate authorities' intention in prioritizing prevention strategies designed to facilitate the development of medical services in outpatient regimes.

4.2.1 Insured Citizens will Benefit from the Participation of Private Companies to the Healthcare System

The official percentage of private expenditures in the Romanian health care sector is below European averages, and accounts for about a fifth of total costs. As such, voluntary health insurance represents only a fraction, while direct payments

represent the main value generating source.

Private sector participation to the health insurance market is necessary, as this would:

- bring additional revenue inflows into the system so as to cover services outside the basic package;
- determine private and public providers to respect high quality standards;
- lead to lower prices for medical services.

Given the early stage of the private insurance market and the pressing demand to supplement system resources, we recommend to stimulate voluntary insurance.

4.2.2 Ongoing Reforms Must Continue

Health care reform is a permanent subject on the public agenda. Since 2008, a consistent number of proposals for reform have been forwarded by different institutions with appropriate expertise, whose recommendations we share broadly. We appreciate the fact that their implementation has commenced in recent years, following the recommendations of the IMF and those of the EU.

We believe that further debates on health care reforms should follow strategic directions accounting for more efficient fund allocation.

4.2.3 Reforming the Basic Package of Health Services is a Must

Reforming the basic package of health services is the keystone in the development of the social health insurance system in Romania. The basic package should include services that can be financed with incomes generated through NUSHIF, which would rebalance expenditure needs and resource availability; the scale of these latter components was severely unbalanced due to the economic crisis and to the measures, which eliminated barriers to the consumption of medicines and medical services.

As Romanians were accustomed to enjoying a quasi-universal health care service pool, a sustained information campaign to stimulate interest for voluntary health insurance becomes impending.

4.2.4 The Role and Scale of Investments in Primary Health Care Must Increase

In Romania, the percentage of health insurance-related costs allocated to primary health care accounts for only 12-13%[11].

Reforms taking place in recent years, including service fares provided by GPs have risen to 50%. The figure is fully accurate, but requires further actions, such as:

- Allocating more money for prevention services;
- Encouraging family physicians and other specialists to provide additional

[11] Efor, *Incomes and expenditures of healthcare system*, Policy brief no.7, 2012, pg. 61;

services;
- Improving health services in rural areas, so that, if necessary, patients in these areas will not require hospital services directly or relocate to emergency units.
- Developing the community social assistance system.

4.2.5 Computer Management of Medical Data for Patients, Treatments, Medical Services and Medicines

NHIH projects on electronic health cards, electronic prescriptions and electronic patient records are welcome. However, we recommend the NHIH to develop an ability to analyse and synthesise information flows in order to obtain progress in the quality of services and use of resources, and to make these available through its website while increasing transparency at institutional levels.

5. Improuving the Patients'Access to Innovation

Investing in innovation is a key element for improving population health. Medical innovation increases the life expectancy of the population and significantly reduces mortality rates caused by important chronic diseases.

To allow patient access to innovative medicines in real time, the Romanian authorities are required to:

- ***Update the list of subsidized medicines biannually, as required by legislation, in a regular, predictable, transparent and impartial manner based on HTA principles;***
- ***Perform permanent updates of medical guidelines and prescription protocols;***
- ***Enforce special regulations for biosimilar medicines to ensure patient safety;***
- ***Promote measures to encourage investments in innovation, including temporary claw-back tax readjustments so as to diminish the impact on***

5.1 Medical Innovation is a Key Element in Improving the Population Health Status

Life expectancy in the EU countries had increased over a span of six years since 1980, when it was 73.63 years and has reached the level of 80.13 years in 2010. The average value in EU for the 2010 was 77.16 years for men and 83.02 years for women[12].

Medical innovation is a key element in improving population health while this reflects significant improvements in life expectancy. In the early 20th century, there were no drugs to treat illnesses like diabetes or cancer. Today diabetes is a manageable condition due to modern treatments, while mortality caused by breast cancer has declined significantly due to screening prevention and the availability of better treatments.

[12] WHO database: http://www.euro.who.int/en/data-and-evidence/databases

5.2 Romanian Patients' Access to Innovative Medicines has been Restricted since 2008

Over the last years, Romanian patients' access to innovative medicines has been obstructed; moreover, the list of subsidised medicines has not been updated since 2008. Thus, patients do not have access to the latest scientific developments in the field, such as minimally invasive therapies and life-saving drugs.

Beyond the major health benefits of new drugs, further care should be set forth to reduce costs in the health care system by changing the evaluation criteria, such as the inclusion of cost analyses from the perspective of the entire population. New technologies enable patients to return to work, to increase work capacity, to reduce the length of hospitalisation, to reduce side effects and to save lives. All these aspects are incurred in short term and long term costs for both the health care system and the national budget.

Until now, updates on subsidised medicine lists were largely opaque and unpredictable. Additionally, these neglected critical considerations such as price, cost-effectiveness and budget impact[13]. Starting with 2013, new impartial and quantifiable criteria were approved. The addition of new medicines to the existing subsidised schemes is based on an interim evaluation of new medical technologies (inter HTA)[14], applied to both innovative drugs and bio similar medicines.

Updating the pending list of drugs would imply a budgetary effort of between 2.3% and 5.2 % of the FNUASS medicines budget allocated in 2013 over a span of three years. However, long-term economic impact is expected to reach 0.5% of the GDP (estimated in 2013), by increasing population participation to economic activities. Consequently, the Romanian society would greatly benefit from by investing in new therapies, specifically because Romanians (82.5 %) are confident that innovative medicines are important and very important in improving the population health status[15].

Since the institutional framework has been set-up and the law began implementation, further questions about the time when patients will fully benefit from effective access to new therapies remain political decision matters.

5.3 Biosimilar Medicines Require Specific Regulatory Frameworks in order to Ensure Patient Safety

A Biosimilar is a product that is similar to the biologic original without being considered identical. A biosimilar is not a generic original biologic product, as biologics feature highly complex molecules whose exact reproduction may be impossible.

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[13] NICE International, *Technical Assistance in Reviwing the Context and Listing Process for the Romanian Basic Package of Health Services and Technologis*, 2012

[14] The system was introduced following the agreement signed with the FMI, -EU- WB assumed by the Government;

[15] Mind Research&Rating, *Compensated medicines policy in Romania 2008 - 2013,* 2013, pg. 6

Further to acknowledging these differences among Biosimilars, the European Medicines Agency issued a specific set of guidelines to obtain marketing authorisation. Moreover, the EC admitted the differences between generics and biosimilars and has consequently required specific traceability records for the former module. Such stipulations led to additional cross-border care directives postulating the need to for prescriptions on biologic drugs and to also mention the relevant brand names.

Romania observed the European trend and included in the legislation the requirement for both an INN and brand prescription. Moreover, biosimilars have to go through a simplified HTA pathway.

In order to ensure patient access to safe biologic drugs, Romania must enforce a certain set of basic principles:

- **Automatic substitution of biologics is currently not possible.** Biologics and biosimilars are not as closely linked to one another as opposed to the relationship between conventional medicines and their generics. This is the reason for which automatic substitution for one medicine with its generic version by a pharmacist without consent from the prescribing physician is not considered to be appropriate for biologics.
- **Government authorities should closely monitor biosimilars in the long run.** Once approved for patient use, all biosimilars should be placed under long-term observation by regulators and physicians to monitor potential occurrences of side effects during regular usage, following the model enforced in the case of innovative medicines.
- **Each Biosimilar product must feature a unique label.** Biosimilars and biologics are dissimilar enough to be marketed under distinct brand names. This would allow physicians and patients to acknowledge that (1) a biosimilar is not an exact copy of the medicine and (2) prescriptions and further instructions should be consulted before use. In addition, different labels will help determine potential differences in the efficacy/safety profile of the biosimilar drug.

5.4 Clawback Tax Inhibits Investments in Innovative Medicines

In its current state, the clawback tax sets a massive tax burden on drugs manufacturers. It covers the expenditure deficit for medicines included in the national health programs, medicines with and without personal contribution which are delivered in ambulatory, as well as for the medicines used in hospital treatment and dialysis program. The impact of the Clawback tax on the drug supply may not be yet visible, but its perpetuation or tightening will definitely cause the withdrawal of key suppliers in the Romanian market, including other negative effects on the business environment.

Therefore, we believe that a stable level of drug consumption along with appropriate cost control measures in the context of a resumed economic growth, would enable

the Government to withdraw the clawback tax or to alter sales benchmarks to reduce impact.

5.5 Recommendations Concerning Patients' Access to Innovation

- Updating subsidised medicines lists in a regular and predictable fashion and would provide patients with real-time access to innovative treatments;
- Permanent updates on guidelines and prescription protocols would enable patients to gain access to treatment facilities in the shortest possible time;

- Collaborating with the industry on issues involving the developing and implementation of legislation with regards to the introduction of risk-sharing agreements would allow a larger number of patients to have access to new drugs;
- Introducing a full health technology assessment programme (HTA), in line with EU practices aimed at increasing the quality of medicines and access to medical services, such as in the EU, would facilitate the assimilation of added values for drugs when it comes down to pricing and reimbursement;
- Promoting measures to encourage investments in innovation, including clawback tax readjustments would enforce a positive impact upon R&D activities in the pharmaceutical industry without exposing patients to further risks associated with innovative drugs.

6. Prevention is Important for Healthcare

Prevention is regarded as a key public health policy among developed European countries. On such basis, the span of resources allocated to prevention programs is increasing. Romania began to take action in this regard, but most recent developments are not significant.

Current reforms in this field must continue, but additional resources are essential. A coherent funding program will trigger medium and long term results and will decrease the level of occurrence for chronic diseases with high incidence in Romania.

In the current economic climate, long-term aging issues and spread of chronic diseases infer additional issues which most European member states are taking actions against in order to ensure better performing standards for their overall medical systems.

Likewise, institutions such as the WHO, EC and the World Bank have pressured governments to pay particular attention to prevention-related issues; this implies a better control of chronic diseases and a more efficient promotion of healthy living principles. Prevention has started to become a public health policy in developed European countries; as such, resources allocated to prevention programs are increasingly reaching higher standards[16].

[16] France spends for prevention programs over 6% of health budget

This sets a timid loom on the paradigm between thinking and implementing public health policies. The MoH took critical action towards designing and implementing prevention policies while linking funding sources to particular health program types. Therefor, starting with 2012, the prevention and curative national programs were split and there are no overlaps between NHIH and the MoH in terms of financing and development issues. Further provisions on the matter have been considered by the MoH as part of a broader reform program. According to official statements, prevention remains a key element of the proposed reform.

The Ministry of Health took responsibility for the implementation and financing of 13 national health programs during 2013-2014, which aimed at preventing and controlling communicable diseases, including non-communicable one.

Although certain issues regarding the implementation of specific prevention platforms (e.g. screening programs against cervical cancer) remain a matter of public concern, the Ministry of Health is committed to set out coherent and effective health programs. Despite all this, authorities must cope with the limited availability of appropriate resources.

Recommendation for a new prevention strategy:

- Reduce the burden and increase the control of non-communicable disease;
- Ensure an optimal level of health and quality of life in Romania at all stages of the life cycle;
- Effective control of behavioral and environmental risk factors and early detection of disease;
- Focus on preventing the leading causes of death and the factors that underline these causes;
- Prioritize high-impact interventions on healthcare;
- Promote high-value preventive care practices;
- Ensure accountability in the healthcare system;
- Ensure multiannual budgets for public health activities.

The implementation of prevention programs must remain a priority on the health reform agenda. A better and more consistent funding plan for such programs will improve medium and long-term effects and will help reduce the incidence of chronic diseases which currently place Romania at the bottom of European rankings.

(http://www.irdes.fr/), while England spends over 4%
(http://www.healthengland.org/publications/HealthEnglandReportNo4.pdf)

7. Ensuring Transparency in Funding the Healthcare System

The health system is in urgent need for greater transparency on topics involving the publication of information regarding incomes and expenditures in the health system.

This need for publishing data on allocated budgets, medicines consumption and expenditures became stringent taking into consideration that:

- ***The pharmaceutical industry took over the deficit of drug consumption among population (through clawback taxes). Hence the availability of data for calculating and verifying payments is essential.***
- ***The new evaluation system for subsidized medicines to the public system requires access to specific data in the absence of which comparative evaluation on new criteria would not be possible.***

7.1 Transparency in the Healthcare Financing is Highly Limited

Romania faces a serious lack of transparency regarding the publication of financial health indicators. Main institutions such as the Ministry of Health and NHIH publish limited information. If authorities provide supplementary data, new issues arise: either information cannot be compared, either facts strike out as scattered among different sources which makes them difficult to process.

On issues involving the health insurance system, the NHIH has invested considerably in the procurement of Integrated Information System resources, in an attempt to leverage benefits. But so far, the NUSHIF has not organised a central database for published information on concerns involving: drug consumption for major categories of diseases and number of patients, issued prescriptions for subsidised medication, or the number of putative applications for treatment, or hospitalisation costs per patient.

The national health programs and public health indicators face the same problem. The lack of data centralisation within a unique system makes public access very difficult and sometimes impossible.

We mention the lack of legislation in disclosing information. Due to non-compliance issues or to the insufficient administrative incapacity in collecting, centralising and publishing data, such problems may continue to occur.

7.2 EU Legislation Requires its Member States to Publish Fiscal Year Budget Data in a Systematic and Transparent Manner

The 2011/85/EU Directive sets the minimum requirements for budgetary frameworks for all Member States. The Directive states that *"the availability of fiscal data is crucial to the proper functioning of the budgetary surveillance framework of the Union" (...). An essential element in ensuring the quality of fiscal data is transparency, which must entail regular publication of these data"*[17]. So far, Romania

[17] Directiva 2011/85/EU of 8 November 2011 on requirements for budgetary frameworks of the Member States, paragrapf 4 of the Preamble;

has not reversed this Directive which should be enforced by the 31st of December 2013.

7.3 Solutions for Ensuring an Optimal Transparency in Healthcare Funding

The health system is in urgent need to ensure greater transparency on at least two important aspects:

- **The regular publication of information** on income and expenditure in the health system so that stakeholders will be able to contribute actively, to combat fraud and to rationalise the expenditures.
- **The intensification of consultations with relevant stakeholders** regarding the design and development of policy proposals. As such, health providers will become part of the process, and the implementation would increase in effectiveness.

A security margin on primary information becomes indispensible. Such data should be centralised at national levels and published quarterly so as to facilitate the conduction of analyses on the health sector using:

- Contract values differentiated amongst criteria involving types of assistance, providers and counties of origin;
- Annual cash flows allocated for discounting medical services and drugs within certain reference periods, differentiated by considerations involving counties of origin and types of assistance;
- Discounted cash streams prior to reporting figures in supply contracts, differentiated among types of assistance, supplier, and county of origin;
- Number of supplied medical services differentiated by types of assistance, supplier and county of origin;
- Value of issued prescriptions in primary medicine and outpatient regime, differentiated by types of assistance, supplier and county of origin;
- Value of subsidised and free-of-charge drugs released in outpatient regimes and within national health programs (via pharmacies), differentiated by types of assistance, supplier and county of origin;
- Execution account for public hospitals regardless of their subordination, including debts and outstanding payments;
- Debt balance and outstanding payment on county health houses, differentiated by types of assistance, suppliers and county of origin.

We would like this information to be made available to every person interested in health care. We ask the Ministry of Health to establish clear responsibilities and data flows and to incur severe penalties for those entities which refrain themselves from disclosing transparent information.

8. Conclusions and Recommendations

Authorities' commitment to placing Healthcare at the forefront of priorities should be reflected over the level of allocated financial resources. However, the most important element is to find an optimal balance between efficient public spending and innovation stimulus, so that innovation capability would be secured against temporary financial pressures.

Reforming the health system will certainly require a clear set of priorities as well as an appropriate fund allocation. Considering the current financial challenges within the consolidated European health system, prevention programs and ambulatory treatments must remain a national priority. Adequate funding for such services becomes imminent.

Investments in innovation are another critical element within the context of the health care system. Romania has to change its evaluation perspective on issues covering financing priorities and should consider the medium and long-term benefits, not only short term direct costs. Past experiences in the EU proved that investing and promoting innovation is an essential factor in securing improved health care standards for the population.

We acknowledge the fact that financial resources are limited, but there are alternative solutions and mechanisms to provide additional resources which may trigger more efficient health-related expenditures. All these aspects must be taken into consideration and we ask the Government to analyse and identify the optimal opportunities for investing into the health care system.

Finally, we emphasise the necessity for increasing transparency levels on issues involving health care financing. As always, LAWG and AmCham will continue to promote transparency among the publishing of statistical data and the implementation of public policies in health care.

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