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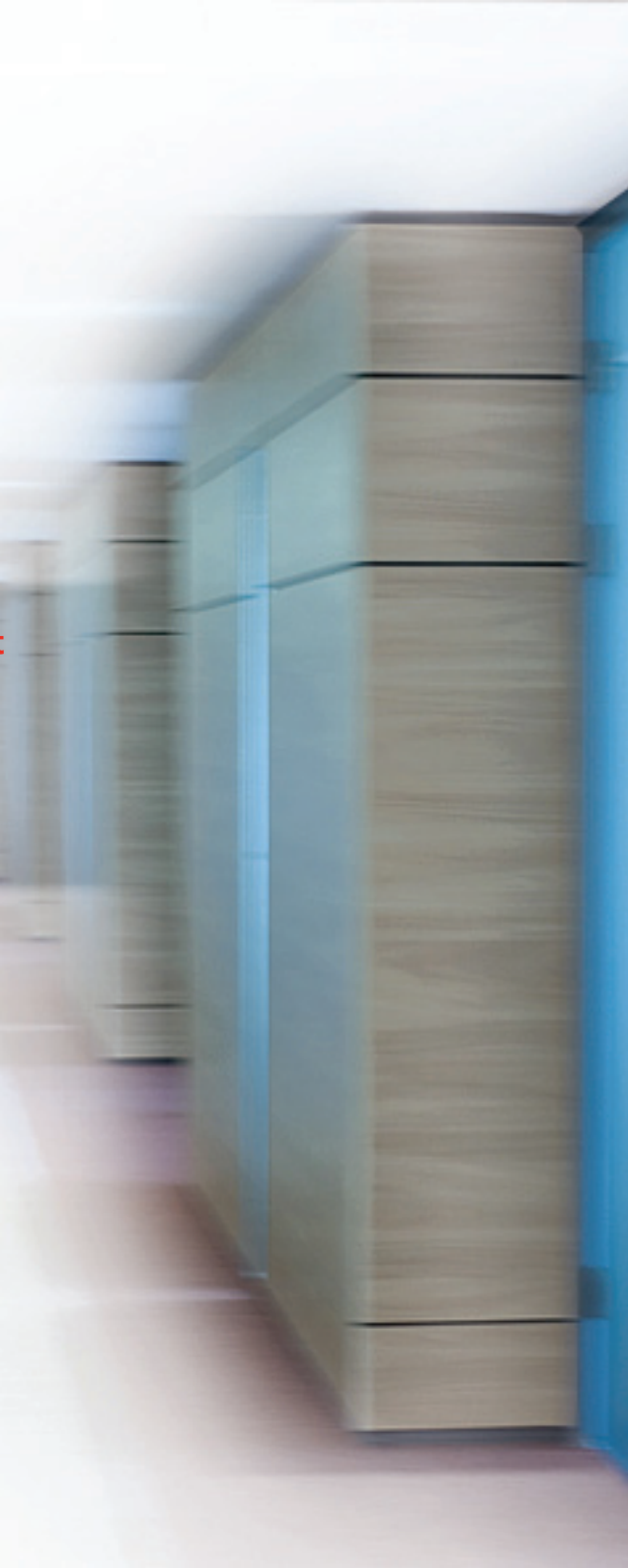
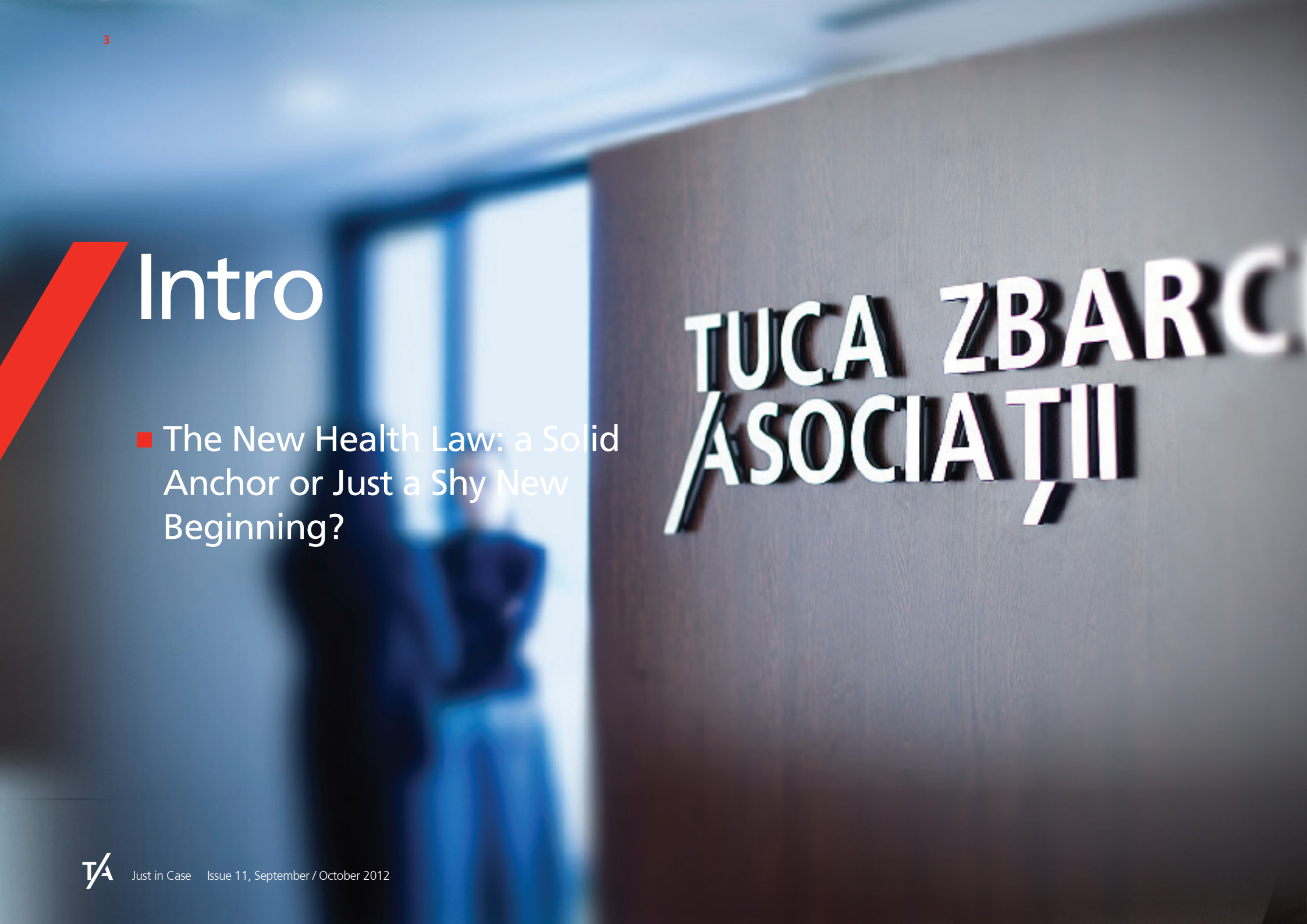


Intro

- The New Health Law: a Solid Anchor or Just a Shy New Beginning?



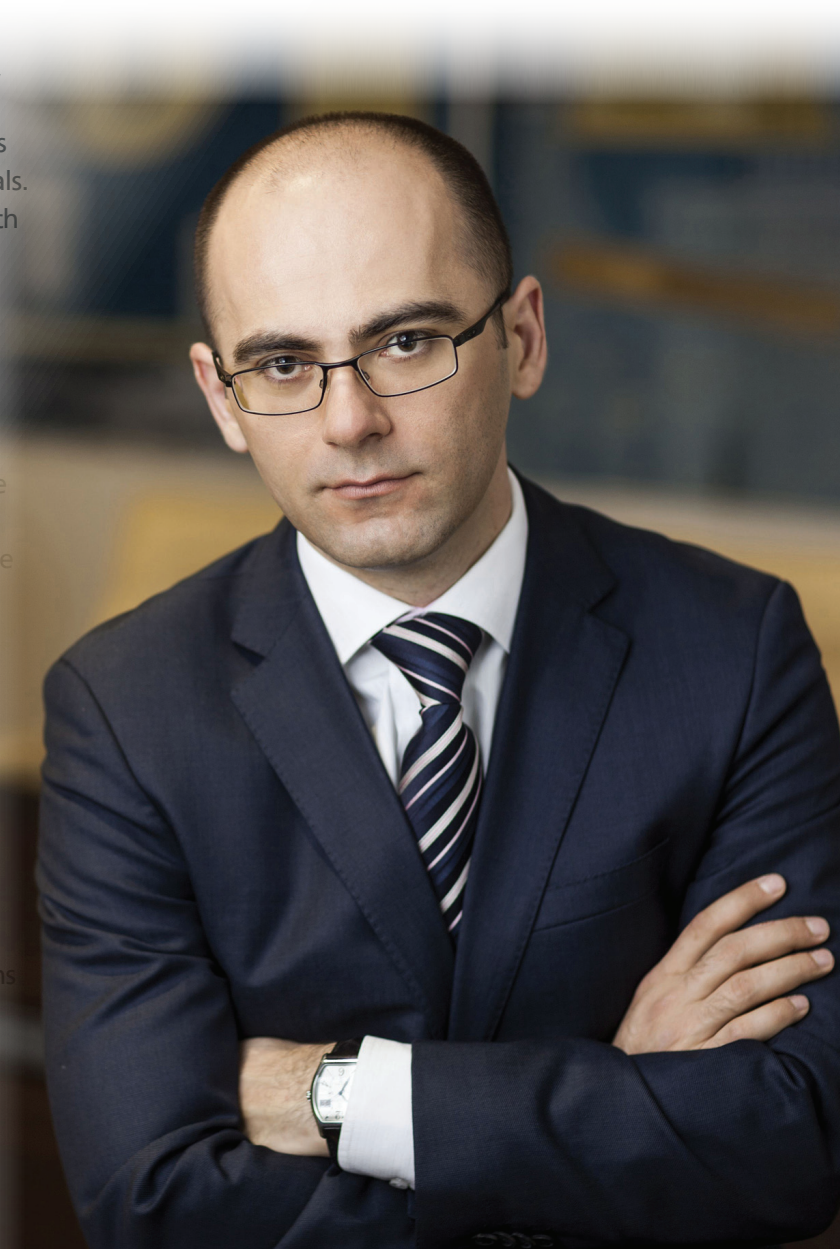
The New Health Law: a Solid Anchor or Just a Shy New Beginning?

With a healthcare budget below 4% of the GDP and an extremely low level of social health insurance tax, Romania must build a new system to finance and organize public healthcare, which balances the increasing need for medical services and drugs and the financial resources allocated. Basically, this is the challenge that the new law on the organization and operation of the Romanian healthcare system (the New Health Law) must face. The draft law, which was put up for public consultation in July 2012, should soon be either debated in Parliament or approved by the Government, and is expected to come into force at the beginning of 2013.

Ambitious Project, Innovative Principles

Judging by the magnitude of the reform and vital importance of the regulation, the New Health Law could be, along with the New Civil Code, one of the most significant organic laws enacted in Romania. Of course, to qualify for that description, the New Health Law must be accompanied by complementary and secondary legislation, so as to represent a consistent, operational and effective legislative package. The draft enactment sets out innovative rules and principles, designed, inter alia, to substantially change the health insurance system, increase the collection basis of the insurance fund and reorganize hospitals.

The ambitious reorganization of the health insurance system, inspired by the Dutch and Belgian models, envisages the end of the monopoly of the National Health Insurance House (which will become the National Mandatory Health Insurance Regulatory Authority, ANRAOS), the reorganization and consolidation of the existing health insurance houses into approximately 8 to 10 mutual health insurance companies, private insurance companies being allowed to penetrate the system, stimulating competition among insurers and hospitals, the autonomous management and administration of the National Mandatory Health Insurance Fund, structuring the insurance system according to packages of medical services (basic, social, minimal and optional packages) and the general institution of co-payment for any healthcare services included in the basic package. Social health insurance contributions will be collected by the National Agency for Fiscal Administration (ANAF) and transferred to ANRAOS, with 92% of the funds being>



allocated to the health insurers for the payment of health services included in the basic package, according to the agreements executed with ANRAOS and insurers' actual performances. Under the rules provided by the Health Law and the Framework Agreement enacted by the State, new private insurers would administer and manage the health services market, in line with the principles of competition and insurers' freedom to make decisions.

Management of hospitals, meanwhile, would follow the European trends which encourage self-government, managerial and financial autonomy. Hospitals may become public, private or public with private activity structures and would undergo an accreditation procedure, according to the standards stipulated by the competent authority.

Material Details and Legal Instruments of Implementation: Still an Unknown Quantity

As it stands, the New Health Law is an innovative set of general rules meant to change the existing concepts in the Romanian medical system and health insurance. From the dual perspective of lawyers and potential beneficiaries of the effects of such an enactment, we notice however that essential elements, which are vital for the proper operation of the new system and to ensure patients' access to appropriate medical services and medication, are subsequently left to be regulated under separate laws or secondary legislation.

Although there is little time remaining until its proposed debate and approval by Parliament, the New Health Law fails to stipulate the actual content of the basic package of health services to be granted to insured patients, the rules and criteria of the technological healthcare assessment, the effective legal instruments through which hospitals will be able to organize themselves and operate as per the regulated legal forms, and operational details of the legal and financial circuit ANRAOS – insurer – medicines or medical devices supplier – healthcare service provider – patient.

Save for a mere mention that they would still be financed from the State budget, the draft law does not clarify the status and functioning of the national health programs by which the prevention and treatment of the most deleterious diseases are ensured.

From a financial standpoint, whereas a Romanian patient benefits from an average of roughly EUR 200 per year for healthcare, while the level of social contributions to the healthcare budget remain the same, it is objectively questionable to what extent the new system, including complementary and facultative health insurance, will be able to ensure the proper financing of healthcare needs instead of passing the deficit from the State budget to private entities.

A Bet for the Future

In view of the above, it appears that the New Health Law cannot change per se the paradigm of the current healthcare system, but merely sets its premises. In our opinion, the actual conception and regulation work does not end upon submission of the draft New Health Law to Parliament – this should be just the beginning. Otherwise, the ambitious principles of the New Health Law and planned healthcare system would remain ineffective.

It is therefore the duty of the authorities, along with all relevant stakeholders and with the support of healthcare, economics, insurance and legal experts, to identify and regulate as soon as possible the necessary mechanisms and instruments for implementation and operation, so the outcome for healthcare is successful. Last but not least, decision-makers must understand and objectively demonstrate that healthcare should no longer be seen as an ordinary expense, but as one of the main investments for the benefit of the people.

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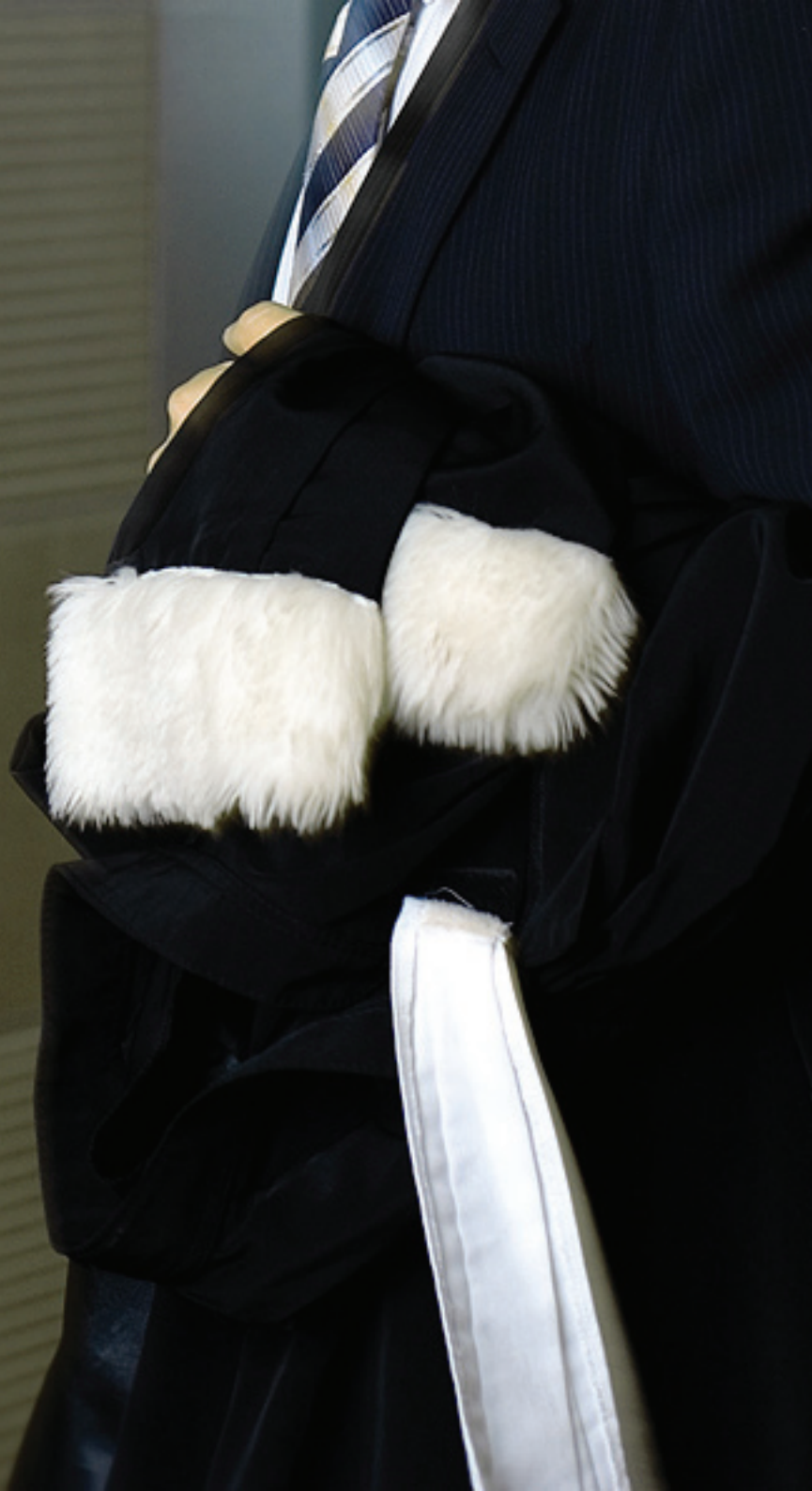
Case by Case

- They Agreed to Disagree: Why Context Matters in Cartel Assessment



They Agreed to Disagree: Why Context Matters in Cartel Assessment

Case Study: Pharmaceutical Wholesalers' Boycott of the Ministry of Health

In 2008, the EUR/RON exchange rate had gone wild, the Ministry of Health froze the rate for imported prescription drugs despite its legal obligation to reflect the market movements, and the drug importers were left in severe distress. As dialog with the Ministry of Health proved fruitless, a public form of boycott by jointly cutting supplies for one day was concocted by the wholesalers as a "statement" that was difficult to ignore.

Many saw the boycott as a legitimate exceptio non adimpleti contractus: the Ministry of Health had failed to comply with its obligations under the public procurement agreements to adjust the price according to the fluctuations in the RON/EUR exchange rate and so importers cut supplies.

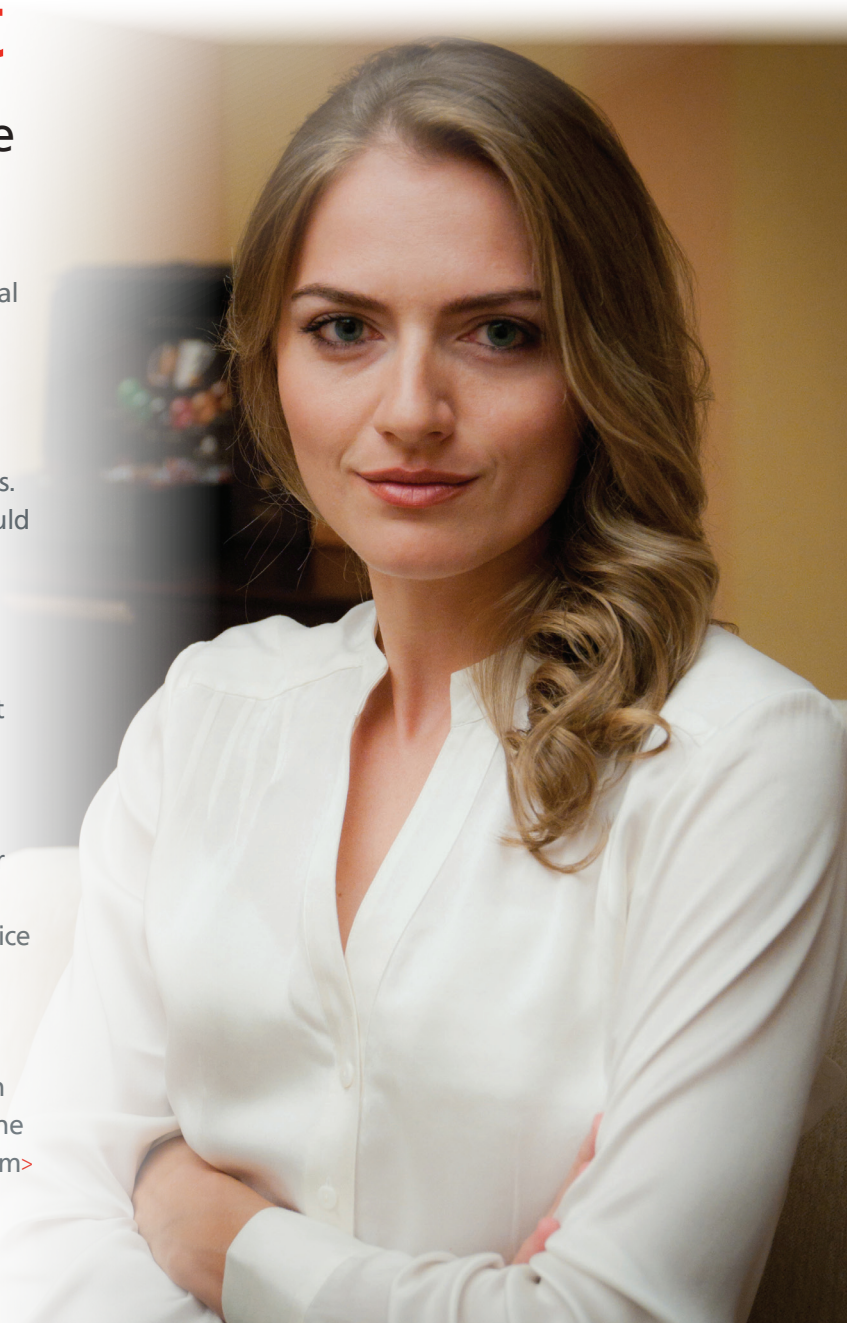
Was that collective action by competitors, however, legitimate from a competition perspective, as competitors should not, in principle, discuss their market moves with each other? Maintaining the uncertainty around your market strategies and not knowing how your competitors will react are core principles protected by competition law as fundamental to healthy competition in the market.

Given the particular circumstances of that case, the RCC seemed to say yes, even competitors can, for one day, jointly protest against illegitimate actions by the authorities. Exceptional circumstances, however, we would add. Most concerted actions by competitors remain banned under the cartel law.

The Background

In Romania, a maximum resale price is set under CaNaMed by the Ministry of Health for prescription medicines irrespective of their origin (domestic or imported). No similar restrictions apply on over-the-counter medicines.

In 2007-2008, the CaNaMed maximum price for the wholesale distribution of imported prescription medicines was set by reference to the maximum CIP manufacturer price in foreign currency and calculated in Romanian currency based on an exchange rate set by the Ministry of Health. Accordingly, the maximum>



wholesale prices were directly linked to the exchange rate set by the Ministry.

Since imported prescription medicines are preponderant on the market, the revenues obtained from sales of such products had a remarkable impact upon wholesalers' market activities and their financial results.

During the period, the gap between the Romanian currency and the main foreign currencies used in the field (EUR, USD, CHF) increased. However, despite warnings from the industry, the Ministry of Health refused to adjust the CaNaMed exchange rate by reference to the market rate as calculated by the National Bank of Romania for the period.

Those circumstances put a significant financial burden on the distributors buying the products in the foreign currency stipulated by their contract with the manufacturer at a market price significantly higher than the "frozen" rate set by the Ministry of Health. The wholesalers were selling imported prescription medicines at a loss, cashing in less than their payment obligation to the manufacturers.

Throughout 2008, wholesale distributors of pharmaceutical products tried, on numerous occasions, to persuade the Ministry to adjust the relevant exchange rate by explaining that the price freeze was not economically sustainable. However, their efforts were in vain, and their parlous financial situation grew worse.

In October 2008, the top wholesale distributors of pharmaceutical products acting on the Romanian market and members of the Association of Medicine Distributors and Importers (ADIM) and the Association of the Romanian Distributors of Medicines (ADMR) agreed to "go on strike" by limiting or halting their deliveries of medicines to hospitals and pharmacies.

Some similar attempts (lasting one-two days) had been undertaken earlier in 2008; however, they were not of the scale of those that occurred in October (which lasted approximately two weeks).

The "strike" was a direct response to the unwavering refusal of the Ministry of Health to update the relevant CaNaMed exchange rate. At that time, the wholesalers, members of ADIM and ADMR, felt that there was no other option but to "go on strike".

The Cartel Investigation

The situation was widely covered in the press, which dubbed it the "medicine crisis". The Romanian Competition Council responded with a threatening press release aimed at "breaking the strike" and opened an investigation into a potential anticompetitive collective boycott infringing Article 5(1) of Romanian Competition Law (Law No. 21/1996) and the corresponding Article 101(1) of the Treaty on the Functioning of the European Union by the wholesalers, members of ADIM and ADMR.

By law, collective boycotts are deemed anticompetitive and sanctioned accordingly by the relevant competition authorities. Currently, Romanian Competition Law provides sanctions ranging from minimum 0.5% up to a maximum of 10% of the turnover (not profits) posted by the undertakings concerned in the year prior to the sanction.

In businesses involving large cash flows (wholesale distribution of pharmaceutical products is one notable example) even a fine set at the minimum threshold triggers a significant financial burden in terms of the absolute final value of the fine.

The collective limitation of production, distribution or sales or any attempts in that direction may be subject to sanctions even if the undertakings involved did not have a direct intention to restrict competition in the market, for instance, in the case of a collective decision to clear market overcapacity.

> " Despite warnings from the industry, the Ministry of Health refused to adjust the CaNaMed exchage rate

Therefore, any similar arrangements would not normally escape the risk of a fine, as they would practically automatically qualify as a breach of antitrust rules.

Nonetheless, in the particular case of the October "strike", the Plenum of the Competition Council carefully considered the circumstances in which the wholesalers reacted and reached a remarkably balanced solution.>

The Conclusion

After hearing the wholesalers' arguments and considering the social impact of the "strike" on the entire market, the State's failure to update the maximum resale price for imported prescription medicines, and the absence of prior similar behaviour, the Plenum of the Competition Council finally concluded that the circumstances in which the "strike" occurred were indeed distressful for the wholesalers and concluded the investigation with no sanctions for the undertakings concerned.

Thus, the rationale of the case prevailed over an automatic application of a set case-law pattern. The circumstances of the "strike" were the key to avoiding the severe consequences of an anticompetitive practice.

> " If faced with a new collective boycott case, the Competition Council is likely to apply severe sanctions to the undertakings involved

Nevertheless, even if, in the particular case of the October "strike", the competition authority did not sanction the wholesalers for stopping or limiting their deliveries of medicines, the rule that collective boycotts are anticompetitive and subject to sanctions remains as valid as ever.

The Romanian Competition Council clearly and publicly indicated that the decision on the October "strike" was made in the context of the great distress of the distributors, circumstances that were fostered by the omission of the Ministry of Health to update the maximum price list and the specifics of the industry. Accordingly, the decision reflected the "exceptional" circumstances of the case, which are unlikely to be repeated.

Therefore, if faced with a new collective boycott case, the Competition Council is likely to apply severe sanctions to the undertakings involved, unless "exceptional" circumstances indicate that deviation from the case-law pattern is required.

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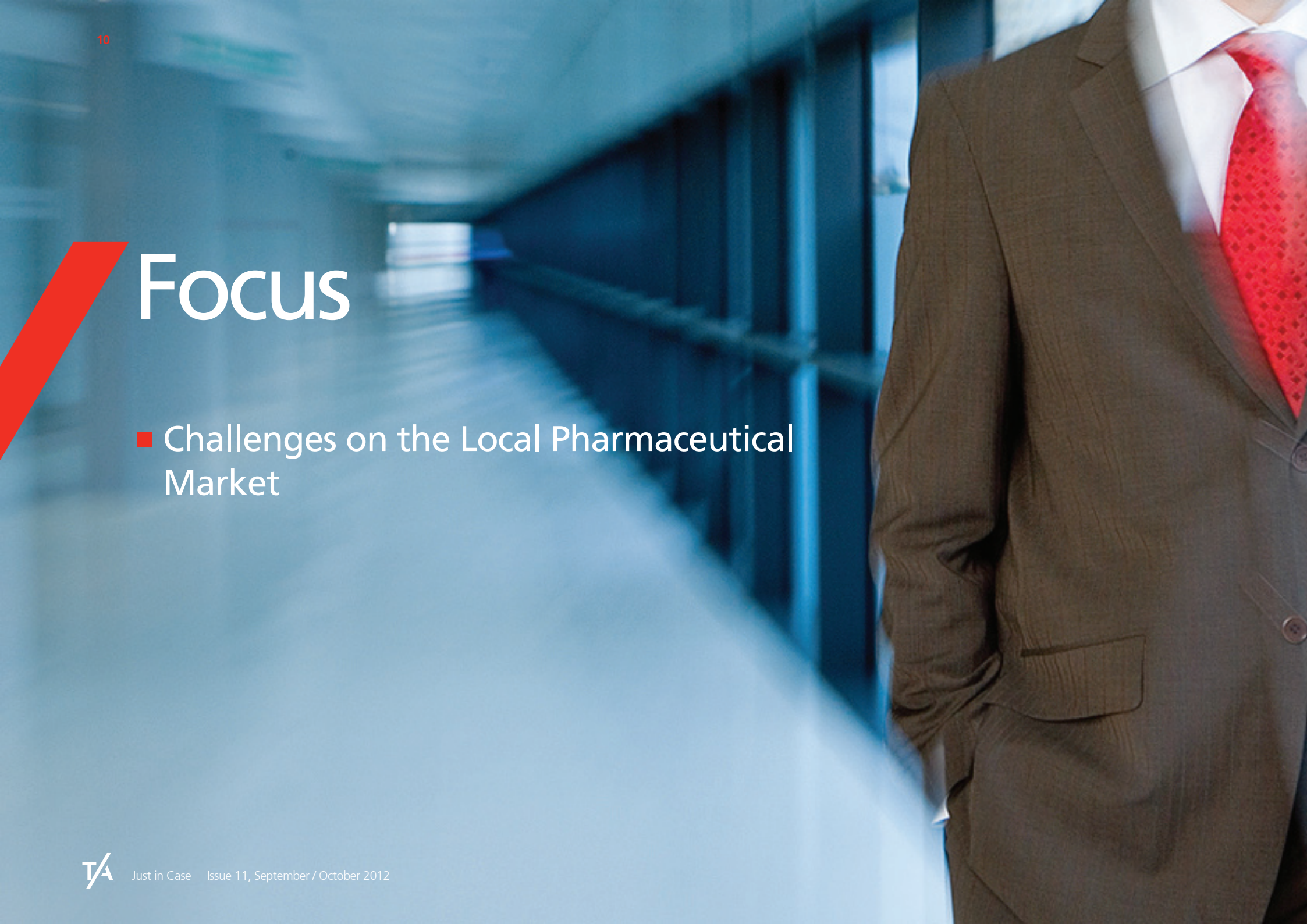
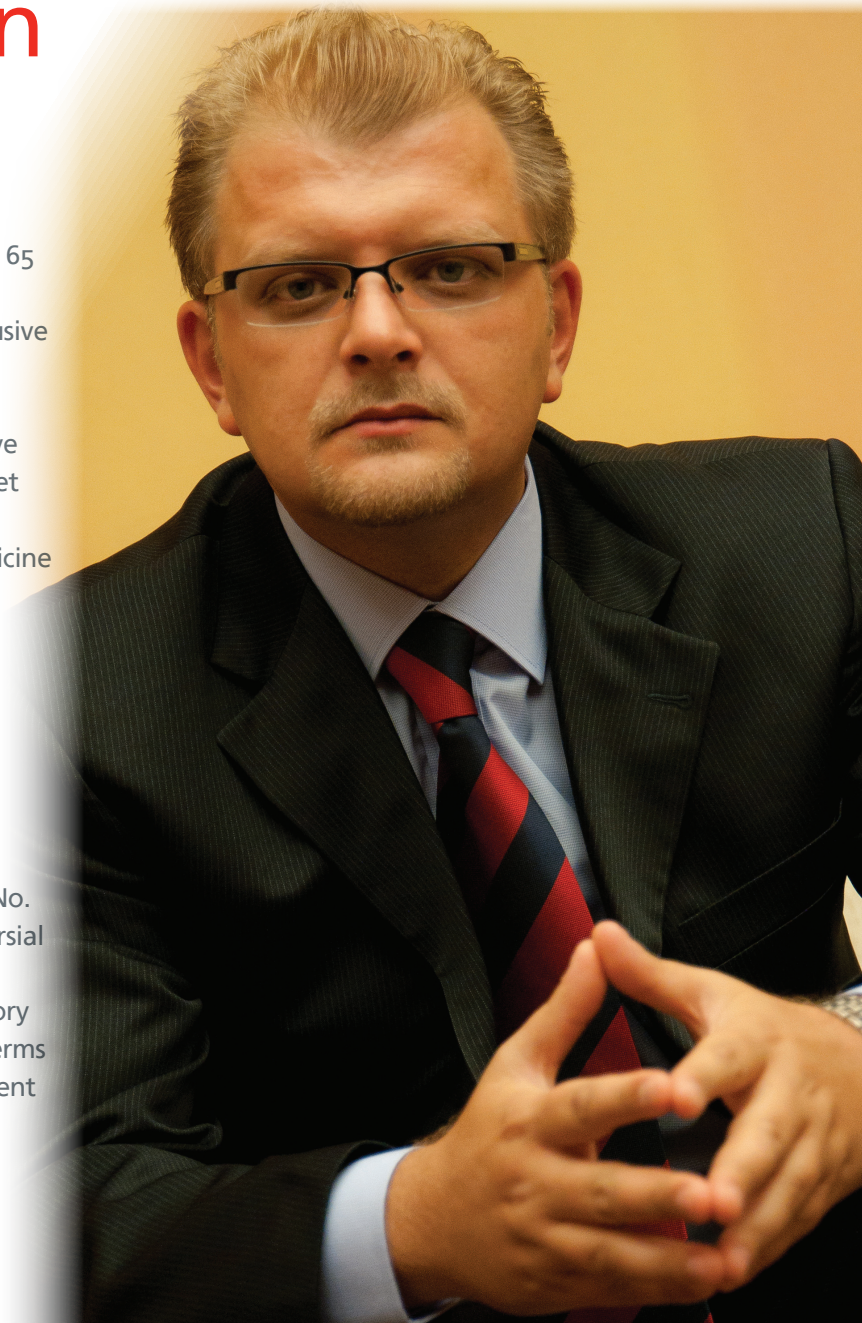
Focus

- Challenges on the Local Pharmaceutical Market



Medicine: Between the Social and the Budgetary, via Legislation

Challenges on the Local Pharmaceutical Market



Premises: Public Healthcare System Obviously Underfinanced

For several years now we have been witnessing the Romanian State's struggle between the "rock" of budgetary restrictions, which are also seen in the healthcare system, and the "hard place" of Romanian citizens' guaranteed and fundamental right to health protection, as set forth under Article 34 of the Constitution. It comes as no surprise that budgetary austerity has continued this year, and the entire healthcare budget allotted to both the Ministry of Health and the National Health Insurance House (CNAS) barely reached a meager 4% of the GDP. From this perspective, Romania ranks last among European States, lagging behind the average of almost 9% allocated by such countries to the healthcare system.

Out of the healthcare budget approved by Law No. 293/2011, medicines paid for from public funds (the National Sole Fund for Health Social Insurance or the Ministry of Health budget) accounted for about a quarter, namely 1% of the GDP (RON 5.7 bn), which corresponds to a medicine consumption of roughly EUR 65 per capita.

Under these circumstances, for the exclusive purpose of striking a budgetary balance between allotted resources and people's treatment needs, the public authorities have imposed on the pharmaceutical market a set of regulatory restrictions and tax burdens, mostly borne by local or international medicine manufacturers.

The Clawback Tax – a Necessary Conceptual Instrument, but a Questionable Regulation from a Legal and Business Perspective

Ever since October 2009, when the Government introduced – through Government Emergency Ordinance (GEO) No. 104/2009 – the first version of this controversial tax, it was noted that both primary and secondary legislation issued by the regulatory authorities were unclear and deficient in terms of the criteria for determination and payment of the new charge.>

The issue of the legitimacy and constitutionality of this special tax – charged only to the pharmaceutical industry – has also been raised, as the funds collected covered various Ministry of Health expenses, including ones without any connection with medicine. Due to said deficiencies, the system regulated under GEO No. 104/2009 met taxpayer resistance and therefore failed to meet its financial targets. Under these circumstances, through GEO No. 77/2011, subsequently amended by GEO No. 110/2011 and GEO No. 17/2012, new clawback mechanisms have been set up. Although clearer in terms of the fiscal procedure to be followed, these mechanisms are still wanting in terms of legitimacy, transparency and predictability of the tax return.

In essence, the system set up under GEO No. 77/2011 and reinstated, with small amendments, by GO No. 17/2012, involves a quarterly tax chargeable to the marketing authorization holder, or local representative thereof, calculated on the basis of (i) data derived from the CNAS's internal records which concern the quarterly consumption of medicines covered by public funds, determined at a national level and respectively per taxpayer and (ii) a benchmark sum representing the quarterly approved budget for medicines. By simplifying the tax calculation formula, it would follow that the value of the medicines consumed through the public system, but not budgeted by the State from the outset, shall be fully charged to the pharmaceutical companies.

A first problematic aspect of the current regulation is the obvious lack of transparency in how the quarterly data communicated by the CNAS to the taxpayer are determined. No mechanism or instrument has been established for the transparent monitoring or auditing of operations for the registration of documents and cash flow at pharmacy, dialysis center or hospital level. These operations are exclusively supervised by the CNAS and on that basis the public authority unilaterally sets the value of the quarterly consumption of medicines communicated to the taxpayer and thus determines the level of the clawback tax due. Therefore, the taxpayer has neither the chance to verify the grounds for and accuracy of the communicated data nor the right to defend against possible errors or abuses by the CNAS. The absence of verifiable and foreseeable data will also prevent the pharmaceutical companies from drafting viable business plans, with a negative impact on pharmaceutical investments.

> " Although clearer in terms of the fiscal pocedure to be followed, the new clawback mechanisms are still wanting in terms of legitimacy, transparency and predictability of the tax return

The value of quarterly medicine sales used to determine the tax uses the reimbursement price, which, in turn, is determined by reference to the maximum retail price of the medicines less the VAT. In other words, the calculation basis includes not only the manufacturer price as perceived by the taxpayer (often reduced by various discounts), but also the maximum level of the margins applied by wholesale distributors and pharmacies. Under these circumstances, the taxation of revenues that do not belong to the taxpayer is not only remiss from a constitutional standpoint but, even more so, an excessive tax burden, which is difficult for medicine manufacturers to bear. As a result they could be forced to resort to dramatic safeguarding solutions (withdrawal from the Romanian market, the elimination from their portfolio or delisting of non-profitable medicines, the cessation of investments in Romania, layoffs, etc.).

Finally, we find that setting the same percentage for the clawback tax for all taxpayers, irrespective of their sale performances, is not fair and does not meet the scope of limiting medicine consumption, as such a move benefits those companies which register high turnovers, from which they may cover the payment of the clawback tax.

A Smothering Set of Regulatory Restrictions on the Pharmaceutical Market

In addition to the clawback tax, various restrictive measures have been imposed during the last few years, whose individual>

and mostly cumulative, effects directly and severely impact medicine manufacturers. Essentially, the main restrictions consist of imposition of extremely long durations for payment of medicines covered by public funds, setting the minimum European level for the approved medicine price (in certain cases, a price even lower than the European minimum) and the refusal to include innovative products on the list of subsidized medicines, in spite of the endorsements and opinions given by competent institutions.

According to the regulations in force, the payment terms for the settlement of the current operations by the CNAS are up to 210 days (30 days for the validation of invoices issued by pharmacies followed by a 180-day settlement term). In practice, the terms reach or even exceed 300 days. It is obvious that, for all undertakings in the medicine distribution chain (manufacturers, wholesale distributors, pharmacies) that are thus crediting the public system, the cash flow and financial resources are globally and severely affected; likewise, during the 300-day term, a medicine manufacturer should pay at least three times the quarterly clawback tax, applied to the value of sold but unpaid for medicines. In such circumstances, the risk of cash flow problems and even insolvency for some undertakings within the distribution chain cannot be disregarded.

In order to avoid or mitigate the economic and social consequences – as insolvency or other dramatic financial measures for the avoidance of insolvency affect both employees in the pharmaceutical industry and patients' access to appropriate medical treatment – the payment terms should be gradually decreased, so as to ensure as soon as possible, preferably before March 2013, the implementation of a maximum 60-day payment term, as required under Directive 2011/7/EU.

Ever since 2009, the manufacturing price of prescription-based medicines is set at the minimum European value, which takes into account the price approved in 12 comparison European countries. Moreover, as regards generic medicines, the law stipulates that the price has to be lower than 65% of the price of the corresponding innovative product. Although apparently beneficial for the budget, the enforcement of this measure has dramatically decreased patients' access to the necessary medication, especially to the expensive and often singular products used in certain therapies, due to the phenomenon of parallel exports.

In general, parallel exports are a foundation of European trade. However, given the specific nature of medicines and the essential role they play in the protection of health – a fundamental constitutional right of Romanian citizens – measures could be identified to limit the exodus of vital medicines, in line with EU functioning principles.

Finally, one last major restriction, which affects patients' legitimate access to new and effective therapies and also puts pressure on medicine manufacturers, is failure to update the subsidized medicines list. During the last four years, 80 new molecules have been endorsed in line with the applicable

> "The risk of cash flow problems and even insolvency for some undertakings within the distribution chain cannot be disregarded

regulations by the Therapeutic Strategy Commission/National Commission of Transparency to be included on the subsidized medicines (INNs) list. However, these medicines were not included on the list, although it should have been updated annually, "according to the Government's healthcare and budgetary policies". Unfortunately, both the patients requiring modern therapies and medicine manufacturers have long been waiting for the "healthcare policies" to allow such new molecules to be covered by the public health system, in line with the recommendations of the competent commissions and actual treatment needs.

Considering the above, it follows that pharmaceutical companies must face a set of restrictive economic measures, which exert constant and high pressure on budgets and business plans. In light of the current budgetary revenues, it is unlikely these measures will be relaxed. However, the>

pharmaceutical industry and the competent authorities should identify a compromise so as to strike a balance between the allotted budgetary resources, a reasonable profitability for pharma companies and patients' continuous and real access to appropriate medical treatment.

Are There Any Solutions?

The answer to this question must be in the affirmative, but it mostly depends on political will. It should be enough if the decision-makers become fully aware that public health is, first of all, an investment and not a subsidiary expense, in the sense that a healthier, properly diagnosed and treated population is the key driving factor in an economy.

Under these circumstances, from the limited stance of the law practitioner, we may identify certain specific measures and targets aimed at harmonizing the interests of the pharmaceutical industry with the State's interests for the benefit of the patients, as follows:

- On the merits, increasing healthcare financing to a reasonable percentage of GDP (6-7% during the next 3 years) concurrent with raising extra-budgetary funds and eliminating/mitigating system square, through fiscal incentives to boost private health insurance, setting cost and efficiency standards in the medical services system and efficiently using the co-payment mechanism, strengthening control over the expenses incurred by healthcare service providers, encouraging prevention and ambulatory care, implementing and using the health card and electronic prescription system, identifying supplementary financing sources for healthcare programs, implementing the healthcare technology assessment, etc.;
- Likewise, the main enactments in the area of healthcare and medicine must comply with the decision-making transparency rules and take into account the standpoints of relevant stakeholders (the business environment, patient associations, prescribing physicians, local authorities, etc.);
- As regards the clawback tax: (i) establishing a sustainable clawback tax, calculated by reference to the manufacturing price of the medicines covered by the public health system and capped at a maximum value, which is thereby foreseeable and objectively sustainable at the same time; (ii) correlating or at least getting the payment terms for the clawback tax closer to the reimbursement deadlines terms provided by the law (this would come naturally should the authorities implement Directive 2011/7/EU); (iii) establishing a transparent mechanism for monitoring/auditing the data centralized by the CNAS on the quarterly/annual consumption of medicines reimbursed from public funds, in line with taxpayers' legitimate right to information and competition principles;
- Eliminating the negative effects of parallel medicine trade, possibly by applying a differentiated price system (increasing the domestic price above the current European minimum, accompanied by a discount granted by the manufacturers on all the products covered by public funds) and strengthening the control of the availability of vital medicines in pharmacies;
- Updating the list of subsidized medicines by including the molecules that have already been endorsed in accordance with the law, accompanied by measures to limit the budgetary impact of this necessary step, e.g., using cost-volume-result agreements, risk sharing or headroom agreements entered into by manufacturers and health authorities, etc. This list must also be updated from time to time with new innovative products, in line with modern, fair and rigorous criteria and mechanisms of healthcare technology assessment to be regulated.

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News and Views

- The Clawback Tax, an Error in Substance or in Form?

The Clawback Tax, an Error in Substance or in Form?

The literal translation of clawback into Romanian is pretty simple. It is a "claw" (the tax) taking "back" (from the beneficiaries) some of the money paid for medicine by public health insurance funds.

This surcharge is one of a kind, as it is not applicable in any other sectors financed from public funds, and joins all the other taxes that pharmaceutical companies must pay, just like the rest of the market players. Certain European States imposed it some time ago, in their attempt to control healthcare expenditure. The formula used in such states is rather simple. Governments estimate the increase in healthcare funding needs, from one year to the next, and if the budget is exceeded, the pharmaceutical industry contributes to the shortfall. If 100 patients were treated this year, and the forecast for the following year is 110 patients (as the population is ageing, diagnosis methods are improving, the range of available therapies is more sophisticated), the State will budget its expenditure for all these patients. If, however, it ends up providing treatment for 115 patients, the balance is covered both by the State and the manufacturers. In other words, the State shares the "excess" expenditure for the five extra patients with the manufacturers. At first, the Government pays for all patients, and afterwards it recovers some of the budget deficit through the clawback tax.

The Romanian clawback tax is unique in Europe, because instead of controlling the annual increase in expenditure, it covers incorrectly funded budget gaps.

Even the aforementioned literal translation is not a true match for the actual situation, since the State charges pharmaceutical companies the tax significantly before (65 days from the end of quarter – according to Government Emergency Ordinance No. 77/2011) it actually pays for the subsidized medicines (within 210 days, according to the applicable Government decision, plus a derogation of 90 additional days allowed by the IMF). We are dealing with a rather uncommon situation, where the State stipulates for its own benefit a considerably longer payment term than the one imposed on the taxpayer, to whom it already owes a lot of money (more than EUR 1.3 bn for subsidized medicines which have not yet been paidfor).

Therefore, this is not an actual clawback, but rather a surcharge on revenues.

Its main problems are unsustainability, unpredictability and unfairness.>

Why Is the Tax Unsustainable?

The value of the tax in the first half of 2012 went up to almost 33% of the manufacturers' revenues obtained through the medicine reimbursement system. This staggering percentage arises from the incorrect funding of medicine consumption. In 2012, a budget of RON 5.7 bn was allocated, i.e. much lower than the 2011 consumption (RON 6.8 bn), disregarding the actual increase of the need for medicines (RON 7.5 bn, as estimated in 2012).

In the first half of 2012, the consumption made public by the National Health Insurance House amounted to RON 3.7 bn. Manufacturers will collect (one year later) RON 2.6 bn of this amount, while the rest shall be allocated to distributors, pharmacies and VAT. The State merely says: "We had RON 2.85 bn available. We accepted an expenditure of RON 3.7 bn, and therefore the tax is RON 850 mn." Hence, the manufacturer pays this amount, representing a 33% tax on the relevant income (0.85 of 2.6), one year before such income is actually collected.

Why Is the Tax Unpredictable?

The sum payable is the mathematical difference between the final expenditure and the allocated budget. Neither of the two sums is controlled by the taxpayer. If you make profit, you know exactly how much you will pay: 16% of the forecasted and calculated profit. Thus, the absolute value of the tax is known early, from the business planning phase. In the case at hand, the budget is drawn up by the Ministry of Finance on the basis of entirely unrealistic assumptions (for 2012, the estimated consumption was 1.1 bn lower than last year's consumption), while the consumption is influenced by patients who want to get healthy. Moreover, fraud and abuses committed within the system are fully covered by medicine manufacturers, which cannot interfere in the State's financial inspection process.

> " The unfairness of the tax also resides in discrimination against the pharmaceutical sector, by applying different operating rules to it than other economic sectors

This lack of predictability has detrimental effects on all pharmaceutical market players. The State is no longer incentivized to finance correctly or to monitor how the money is spent, as somebody else is picking up the tab. Manufacturers (those that survive the 33% income tax in 2012) cannot make business plans for the coming years, as they know neither the budget to be allotted nor the medicine consumption.

Why Is the Tax Unfair?

Manufacturers are also charged for the revenues obtained by other businesses (pharmacies and distributors) and for VAT. The tax is actually calculated for the retail price and is imposed entirely on manufacturers whose sale price is much lower (70% of the final price).

The unfairness of the tax also resides in discrimination against the pharmaceutical sector, by applying different operating rules to it than other economic sectors. It is difficult to grasp why a revenue surcharge would be imposed in relation to medicines (which, in Romania, have the lowest prices in Europe set by law), but not for road construction, of which the same could by no means be said…

What Has the Government Done?

On August 23rd, 2012, it issued an ordinary ordinance (Government Ordinance No. 17/2012) increasing the budget allocated to medicines as of the last quarter of this year, and eliminating VAT from the basis of calculation. Thus, the quarterly budget will increase from RON 1,425 mn, VAT included, to RON 1,515 mn, VAT excluded. This is a step in the right direction, but inadequate to deal with a matter of this magnitude, and it is utterly insufficient if we look forward towards 2013 (as the margins per chain are still charged to the manufacturer, the budget is set still below last year's consumption, etc.).

The same enactment also added a few articles concerning the collection of the clawback tax for the period from Quarter IV 2009 to Quarter III 2011. The question is whether this measure will manage to mitigate>

retroactively the negative consequences of a poorly drafted ordinance (Government Emergency Ordinance No. 104/2009) and its implementation norms which were published rather late (in summer 2010, only to be amended in 2011), and which made things worse rather than better.

Wondering What the Future Looks Like

The most important thing is that the tax should be corrected by Parliament for 2013 and be treated as a temporary measure until Romania manages to move out of last position as regards the ratio of GDP allocated to healthcare (below 4%), to beat the percentage allocated to healthcare by African countries (5.9%) and perhaps even to equal the European average of 8.6%.

In light of the above, the risks hovering over the industry are easy to infer. Therefore, the correct question is not whether the industry will fail in Romania?, but rather when. Beyond the scope of the negative effects on pharmaceutical companies, we can only imagine how distributors, pharmacies and especially patients will suffer too.

The warning signs have caught the eye of the politicians. Most of them have understood the situation, but few have actually done anything to prevent the irreversible downfall of the pharmaceutical supply sector.

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/ **The materials included herein are prepared for the general information of our clients and other interested persons. They are not and should not be regarded as legal advice.**

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