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Hot, Long Summer in Pharma Market

Hot, Long Summer in Pharma Market

A hot summer laid on the pharma market, with new political, business or legal issues added to the chronical issues still unsettled and put significant pressure on all market players, either medicine and medical services suppliers or beneficiaries.

As usual, the heart of the matter is the poor funding in the medical sector in general and in the medicine market in particular. The limited funding is of real concern in any State, even the European Commission is looking for measures to allow patients in Member States the access to reimbursable treatments. However, besides its health budget *per capita* significantly lower than the EU average, distinctively Romania has no coherent and correlated health policies to tackle the health system dysfunctionalities, including the access to proper medication. Moreover, the unpredictable, restrictive legislation adopted in disregard of a transparent decision-making process has negative impact on the local pharma market, in which the much-needed stability and medium- and long-term strategies are no more than a utopia.

A succinct radiography of the pharma market in this summer revealed the absence of actual solutions to the traditional issues of the pharma market, and the adoption of measures for controlling the medicines' exodus. Nevertheless, such measures lead to tensions between medicine manufacturers and distributors.

In this context, the most unpredictable and non-transparent tax burden in Romania i.e., the clawback tax imposed on the marketing authorisation holders, remains an obstacle to the development of the pharma market and to patients' access to treatment. As a result, some essential medicines - including the cheapest ones - disappear, whilst innovative therapies are blocked from entering the market; introduced in 2011 as a temporary measure for a time of crisis, the clawback tax became permanent and proved an unsustainable burden, as the medicine manufacturers must pay for roughly 20% (and this percentage is steadily rising) of the reimbursable medicine budget (i.e., the full overrun of the approved budget) whilst the authorities refuse to increase the amount of such budget.

Unfortunately, what can be predicted about the clawback tax is that its rate will increase in the next quarters, and that, despite various promises and declarations, the governmental authorities did not prove firm intentions to amend its legal regime so as to regulate a sustainable and transparent tax burden. At most, minor changes like freezing the percentage of the tax at a specific level and exclusion of the cheapest products from scope of clawback might be implemented in the future, if the voice of the industry and patients' associations (timidly endorsed by >

the members of the Romanian Parliament's Health Commissions) will be listened by the Ministry of Finance and Government as well.

At its turn, the price policy has a number of severe consequences on the pharma industry, which are borne by the end beneficiary, the patient. At this point, Romania has some of the lowest prices for prescription-based medicines (and the lowest net prices i.e., the cost the State incurs for the reimbursed products), but the regulatory authorities imposed an additional 35% reduction of the prices for the innovative medicines whose generic correspondent of which have been priced by Ministry of Health; the level of prices thus generated is below the European minimum level and may not be supported by the international manufacturers of innovative medicines for various reasons, including the creation of a spiralling drop of the prices in the other European States which, directly or indirectly, reference their national price to medicines to the ones approved in Romania.

The Ministry of Health alleges that, further to the local regulation of two price catalogues, the European States would take as a reference the level of the prices in Romania's Public Catalogue (where the maximum price equals to the arithmetic average of the lowest three European prices), and not the prices in Canamed (at most equal to the lowest European price, possibly also aligned to the generic/biosimilar reference price– thus additionally decreased by 35% /20%). But of course, no one can guarantee that this contrivance will be effective, as it has no mandatory effects for any of said States.

In early summer, it was supplementary confirmed that regardless of its negative consequences, such decrease in medicine prices is rather non-negotiable, as an element assumed under the current governing coalition's programme.

As far as the patients are concerned, in theory the price drop should have been a beneficial or at least a neutral measure; and yet, due to the extremely low prices in Romania, the cheapest essential medicines (financially unsustainable in the context of the clawback tax) and the most innovative therapies - which are the subject of parallel export to EU countries that have considerably higher prices - disappear from the market.

As a rule, parallel trade is a legal phenomenon perfectly justified from an economic perspective, and it is one of the EU market's pillars; special attention should be paid to the parallel trade of medicines (which are not mere commodities, at least as they have regulated prices and limited production capacities), which may affect the patients' safety. The Romanian authorities have gradually become aware of the Romanian distributors' ample parallel exports, and have recently adopted measures for reporting and controlling the effects of the phenomenon; still, some of such measures are contradictory, and the authorities do not intervene at the level of the causes. In this context, the Ministry of Health imposed rules for creating minimum monthly stocks of medicines subject to reimbursement, which are applicable to distributors, as well as obligations for marketing authorization holders, to ensure the minimum monthly turnover of same medicines as well as to cover the justified orders addressed by the pharmacies.

However, there are some deficiencies as no sufficient details are provided in respect of some key terms (e.g., definition or qualification of the "need of the public health"), or some mechanisms for balancing obligations between manufacturers and distributors; consequently, these measures generated significant tensions between the two categories of market players, which will be further arbitrated by the authorities having a very broad power of interpretation, in lack of precise legal benchmarks. Hence, this summer we expect the authorities to adopt solutions that will be objected by the pharmaceutical companies involved.

Finally, right after the Ministry of Health adopted said measures for enforcement of the public service obligation, the Romanian Parliament amended Law No. 95/2006, deciding to allow pharmacies to conduct wholesale distribution activities, which is a bizarre measure exponentially multiplying the number of entities authorised to make parallel exports of medicines.

As regards the reimbursable medicines granted to Romanian patients - a traditionally deficient chapter in Romania's medicine policy – we noted that several molecules with favourable decisions within health technology assessment proceedings were included on the list of reimbursable medicines in the year 2017, such list being generally updated on a quarterly basis.

Nevertheless, in regulatory and administrative terms, real obstacles still exist (e.g., many restrictions within the HTA process or related to the execution of cost-volume agreements, significant delays in drafting of therapeutic protocols, etc.), and make difficult the Romanian patients' access to reimbursable >

innovative therapies that are reimbursed for many years in other European countries. The players in the pharma market had therefore a long hot summer, and had to work on reconfiguring their business plans according to the restrictive conditions aforementioned. Unless the authorities' vision changes for the better, most probably the pharma companies will adopt action scenarios including withdrawal/non-launching of products and an increasing number of legal proceedings, initiated in particular at the end of the year and in early 2018, in order to protect their legitimate rights and interests.

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Case by Case

Medicine Producers, You Must Comply with Your Public Service Obligation! But How?

Medicine Producers, You Must Comply with Your Public Service Obligation! But How?

The Ministry of Health has adopted a set of rules for quantifying and monitoring the fulfilment of public service obligation. However, these rules do not solve the causes of the shortage of essential medicines and pose real interpretation issues. Medicine producers have legitimate doubts as to how to appropriately apply such measures.

According to the Romanian authorities' traditional policies, medicine prices (except for non-reimbursed OTCs) were set at the European minimum level. Furthermore, it has been decided that the price of innovative medicines that are no longer protected by a patent should be aligned with the generic/biosimilar reference price (i.e., no more than 65% / 80% of the price of the innovative medicine upon the approval of the first price of the corresponding generic/biosimilar product); this measure has already caused effects on the reimbursement price of relevant innovative medicines and, as of January 2018, it will also impact the official manufacturer, wholesale and retail prices thereof.

The logical consequence was that numerous essential medicines, in particular innovative ones, are now being massively "exported" by wholesale distributors to EU countries where considerably higher prices are charged. As a rule, this parallel trading is lawful, perfectly justified economically, and a pillar of the European Union market, but its effects on Romanian patients are deeply harmful.

The Romanian authorities have become increasingly aware of the magnitude of the parallel exports carried out by Romanian distributors and the shortage of essential medicines on the local market, and have recently adopted measures to report and control the effects of this situation, without, however, dealing with its causes.

At the end of 2016, the Ministry of Health (**MoH**) adopted **Order No. 1345/2016** regulating the obligation to electronically report, on a daily basis, stocks and commercial operations involving medicines subject to reimbursement (i.e., included>

in the national price catalogue – Canamed); this obligation applies to wholesale distributors, importers and producers, as well as pharmacies, and fully came into force at the end of February 2017.

Order No. 269/2017 on the obligation to ensure appropriate and continuous medicine stocks was published on 15 March 2017, aiming to regulate the measures for quantifying and detailing the public service obligations set forth under Law No. 95/2006 on healthcare reform.

Order No. 269/2017 in Short

Essentially, Order No. 269/2017 provides, *inter alia*, as follows:

- Wholesale medicine distributors and marketing authorisation holders/their legal representatives (hereinafter MAHs) must ensure, as regards reimbursable medicines (included in Canamed), the fulfilment of the justified orders issued by pharmacies and healthcare units that have contractual relations with insurance houses (beneficiaries); delivery deadlines to be observed by the wholesalers are very short - 24 / 48 hours;
- The MAH observes its public service obligation by ensuring for each medicine a quantity at least equal to the average monthly turnover (rolling); the average is calculated for the last 3 months of sales, as per the information communicated to the electronic system for reporting the stocks set forth under the aforementioned Order No. 1345/2016;
- In their turn, wholesale distributors must observe their public service obligations by keeping safety (buffer) stocks equal to the monthly average turnover for each distributed medicine, so as to be able to comply with any justified order from the beneficiaries with whom it has contractual relations; distributors must notify the MAH or other wholesale distributors from which they acquired the relevant medicine of the received justified order;
- The decrease of the medicine stock below the monthly average at national level for 7 consecutive days triggers a national alert level launched in said electronic system; the relevant medicine shall be included by the MoH on a special list of products under surveillance (the export of which is temporary banned). Also, if the MoH notices at a wholesale distributor the decrease of the medicine stock for 7 consecutive days, below the monthly average turnover, it will notify the National Agency for Medicines and Medical Devices (the **NAMMD**), which immediately triggers an inspection procedure;
- Exemptions from this public service obligation are strictly limited and concern safety/quality issues relating to a temporary discontinuation in manufacturing the specific medicine.

Although Order No. 269/2017 does not expressly provide so, breaches thereof constitute violations of the public service obligation regulated by Law No. 95/2006, subject to fines of RON 50,000 – 100,000 (applicable to MAHs and wholesale distributors) and even the suspension of the operation (wholesale) license (in the case of wholesalers).

Legal and Factual Issues Raised by the Enforcement of Order No. 269/2017

Order No. 269/2017 does not clarify certain essential elements concerning the fulfilment of public service obligations by the medicine producers (MAHs and their local representatives). Since its publication, numerous pharmaceutical companies have sought legal advice on the right enforcement of the order, in particular after having received a deluge of notices from the local wholesale distributors which related to the exponential increase of orders for Canamed medicines, and urgent requests to meet justified orders received by distributors, respectively.

Firstly, it is essential to clarify the concept of **"public health needs"** used by Article 1.g) of Order No. 269/2018, which defines the average monthly turnover of medicines imposed on MAHs. According to Article 2(2) of the same order, MAHs must ensure a monthly level at least equal to the average monthly turnover of a relevant medicine, which, according to the above definition, would constitute the "necessary minimum to meet the public health needs".

At first sight, the interpretation of the two pieces of legislation would indicate, from a mathematical perspective, that the public health need was strictly related to the average volume of monthly sales of a reimbursable medicine, as reported in the Electronic System reports (SER). On the other hand, considering that the SER reports include both the distributors' >

deliveries to beneficiaries (pharmacies and hospitals) and intra-Community deliveries conducted thereby (a highbrow name for parallel trade), while the purpose of Order No. 269/2017 as well as of the service obligation regulated by Law No. 95/2006 is to protect Romanian patients, the "public health needs" and MAHs' correlative obligations should be considered to relate to the monthly quantities of the medicines effectively delivered to Romanian beneficiaries, which, therefore, do not include intra-Community deliveries. We believe that an official clarification of the above issue by NAMMD is required.

> *" Since the publication of Order No. 269/2017, numerous pharmaceutical companies have sought legal advice on the right application of the order, in particular after having received a deluge of notices from the local wholesale distributors concerning the exponential increase in Canamed medicine orders, and urgent requests to cover justified orders received by distributors.*

Another **major aspect** that has not been taken into consideration by Order No. 269/2017 concerns a situation common in the Romanian market, where a **company affiliated to a foreign MAH acts as a local/legal representative thereof and also holds a wholesale medicine distribution license**, based on which it sells the MAH's medicines to third party distributors and beneficiaries. It is obvious that such a company cannot cumulatively fulfil the public service obligations imposed both on the MAH and the wholesale distributor; otherwise, that company should ensure, firstly, the monthly average turnover covering the entire public health needs in Romania, but also an additional safety stock at least equal to the monthly average turnover, which is obviously excessive and illogical. In this case as well, official clarification by NAMMD would be advisable, i.e., a company acting as a legal representative of a MAH and also holding a wholesale distribution license should exclusively fulfil the public service obligation imposed on the MAH, without having the obligation to ensure the safety stock imposed on the wholesale distributor.

Further to an analysis of the public service obligations incumbent upon MAHs and wholesale distributors, another issue becomes clear, which concerns **the actual level of the average monthly turnover that needs to be ensured by MAH**. Although Order No. 269/2017 defines the monthly average turnover (applicable both to MAH and to the distributor) as a monthly average of the turnover of a relevant medicine for the last three months, the same order obliges distributors to keep a safety stock equal to the monthly average turnover; such safety stock is generated by the MAH as well, but, if we include it in the average monthly turnover required from the latter, this would lead to an artificial and illegitimate increase of the level required by law (in effect, by the amounts related to the turnover for an additional month). Again, intervention by the authorities is necessary, this time amending Order No. 269/2017, by clearly stating that any amount of medicines delivered by a MAH to a distributor for providing/replenishing the safety stock (and declared as such by the MAH) would not be included in the monthly average turnover that must be observed by the MAH.

> *" This legislative act must be correlated to the actual situations on the market and interpreted in good faith both by the subjects of the regulated obligations (wholesale distributors, MAHs, beneficiaries), and the competent public authorities.*

Finally, we reckon that the justified orders received by wholesale distributors from beneficiaries must be sent to MAHs in good faith, in line with the spirit of the law. Thus, the MAH may be requested to meet the justified order placed by the beneficiary only if the distributor is objectively unable to deliver the medicine to the beneficiary (according to Article 2(9) of Order No. 269/2017), as a result of an exceptional circumstance (e.g., shortage of the product in stock or absence of the safety stock provided by law, but only for reasons unimputable to the distributor).

From this perspective, the automatic sending by a wholesaler to an MAH of any justified order (especially if the MAH is a foreign entity), without the wholesaler unequivocally attesting that it does not have the ordered medicine for reasons beyond its control, may be interpreted as abusive conduct.

We believe that Order No. 269/2017 was>

adopted by the authorities in an effort to mitigate the shortage of essential medicines, for the benefit of Romanian patients, and this should be appreciated. However, this legislative act must be correlated with the actual situation of the market and interpreted with good faith by both subjects of the regulated obligations (distributors, MAHs, beneficiaries) and competent public authorities i.e., NAMMD and MOH. Otherwise, we will soon see numerous disputes between MAHs and distributors, on the one hand, and between pharmaceutical companies and NAMMD, on the other hand.

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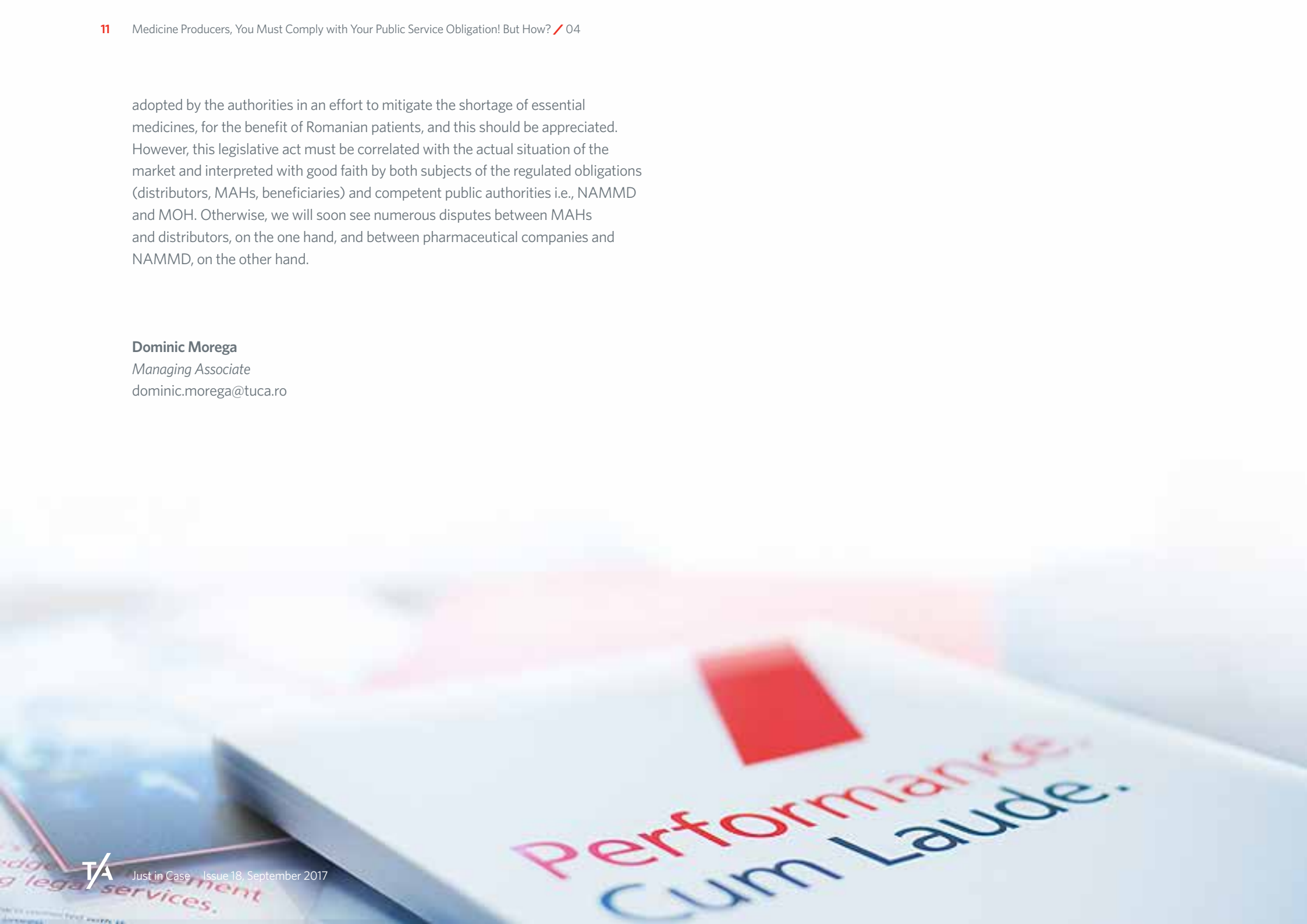

Focus

The Pharma Sector. A Recurring Star in the Spotlight of the Procedures Instrumented by the Competition Authority

The Pharma Sector. A Recurring Star in the Spotlight of the Procedures Instrumented by the Competition Authority

In one way or another, the pharma sector continues to be under the scrutiny of the Romanian Competition Council's (**RCC's**).

Relatively recently, the RCC released its final report on the second sector inquiry (**Second Sector Report**) into the Romanian pharma market, while other investigations on the market relating to potential breaches of competition law pursuant to the implementation of limited distribution systems or direct-to pharmacy (**DTP**) systems are still pending (according to publicly available data). Based on the available public information, at least two separate investigations into various DTP systems implemented by suppliers of pharmaceutical products are underway.

> *"The star topics of the Second Sector Report are (i) the marketing expenses and pricing of generic versus original drugs; and (ii) the limited distribution/DTP systems.*

The level of marketing expenses borne by the suppliers of original drugs, especially upon patent expiry, is a major concern for the authority, as it raises barriers to entry and/or expansion for competing generic drugs.

The RCC observed that marketing efforts have a direct impact on market share, and therefore protection measures must be taken.

Unlike other competition authorities, for instance the competition authority of the United Kingdom[1], the RCC appears to indicate that it will not intervene where a regulatory authority should act.

Therefore, on the topic of marketing expenses and cost-efficient drugs, the RCC makes recommendations or proposals *de lege ferenda* to other state authorities, rather than identifying competition policy trends.

Obviously, this does not mean that the authority will not intervene where it identifies a potential breach of competition law.

The main recommendations related to marketing efforts for medicines and promoting cost-efficient>

1. The competition authority in the United Kingdom investigated cases and applied sanctions against pharmaceutical companies relating to excessive prices in the context of generics entry (e.g., the Pfizer/Flynn and Actavis cases).

drugs include:

- Equivalent pricing for innovative and generic drugs based on the International Non-proprietary Name. However, the recommendation is subject to a prior impact assessment study so as to avoid the policy triggering market exits;
- Eliminating from the regulated price list products that are not put on the market in sufficient quantities within a certain reference period (normally 6 months), but are kept on the list with the sole purpose of setting a reference price;
- Levelling the distribution and pharmacy mark-ups by reference to a similar system to a service tax;
- Legal measures to limit maximum discount levels, especially if such discounts are not passed on to patients. Nevertheless, the authority emphasises that the measure should not trigger minimum price thresholds banned under competition rules;
- Close monitoring of prescription patterns (innovative versus generics) by the National House of Health Insurance and potential implementation of the target threshold for the prescription of generics. Also, the sums spent on advertising drugs should be closely monitored and corresponding measures implemented according to the results of the monitoring;
- Information programmes for doctors, pharmacies and patients, as well as a system of financial incentives for doctors not exceeding a certain monthly budget in their prescription activities;
- It is also suggested that lower claw-back taxes for generics may help support the market entry and presence on the market of cost-efficient products.

> *"Another hot topic of the RCC's assessment relates to the different measures undertaken by pharmaceutical companies to ensure rapid and efficient access to products on the market.*

The RCC acknowledges in the Second Sector Report that shortages of medicine may occur on the market due to either insufficient product volumes put on the market or parallel trade. However, the proposed solution to such shortages does not rest on a particular distribution system, but rather to strong legal provisions related to the fulfilment of public service obligations allowing the regulatory authority to (i) verify/monitor the manner in which companies in the production-distribution-retail chain fulfil their public service obligations; as well as (ii) to apply severe fines if such obligations are not observed.

In terms of the various distribution systems aimed at ensuring rapid and efficient access to products on the market, the authority does not discriminate between (i) the traditional distribution system (multiple distributors); (ii) the limited distribution system (e.g., 3 distributors); and (iii) the DTP system, but emphasised that the latter two systems might raise competition law compatibility issues in the case of dominant companies, in particular, if benefits are not passed on to patients[2].

> *"In any case, out of all the assessment topics put forward by the RCC in the Second Sector Report, the undisputable front stage star is the DTP system.*

The RCC is currently investigating various DTP systems implemented on the Romanian market. Based on public information, one of the investigations is currently exploring the commitments option, meaning that the investigation will be closed with no consequences subject to a set of behavioural rules being adopted by the party under investigation for a determined period[3].

Even though the investigations are still ongoing, the Second Sector Report includes some important conclusions on the DTP system going forward:

- The DTP system is not illegal *per se*, but may be anticompetitive if implemented by a dominant company;
- The DTP system is normally based on services provided by a logistics agent. It is recommended that the selection procedure of the logistics >

2. Under Romanian Competition Law No. 21/1996 there is a rebuttable presumption of dominance above a 40% market share threshold.

3. The RCC submitted for public consultation the commitments proposed by GlaxoSmithKline in connection with its DTP system in Romania. Public information may be found at: http://www.consiliulconcurentei.ro/ro/docs/177/10391/consultare-publica-cu-privire-la-angajamentele-formulate-de-catre-s-c-glaxosmithkline-gsk-s-r-l-in-cadrul-investigatiei-declansate-prin-ordinul-presedintelui-consiliului-concurentei-nr-715-17-12-2013.html

agent is based on competitive and transparency principles;

- The switch from traditional distribution to the DTP system should allow distributors sufficient time to adapt and develop new strategies. However, the applicable reasonable time-frame for this is still to be determined. In any case, it should be adjusted depending on the product concerned; and
- The DTP system should be based on objective needs and should lead to efficiencies such as: (i) ensuring product availability; (ii) passing benefits on to the patients and pharmacies (both in terms of financial benefits and the service provided, including timely delivery and ease of order); and (iii) reducing the risk of counterfeit products coming onto the market.

Also, the DTP system should not represent a means to implement anticompetitive practices such as the restriction of parallel trade.

The final conclusions on the DTP systems will be clearer once the RCC issues its final position on the ongoing investigations into DTP systems already implemented by some pharmaceutical companies in Romania (e.g., GSK[4]).

In any case, it is obvious that the implementation of a DTP system would require careful consideration, in particular if this system were considered for dominant products. This should not represent an absolute barrier to the implementation of a DTP system, but it would require extensive efforts even from the moment the DTP system were merely on the drawing board. Also, the system may require careful assessment not only from competition-law perspective, but also from regulatory perspective.

Even though the pharma sector presents particularities that are not applicable to other industries (e.g., FMCG), for instance, given the compensation of certain drugs by the National House of Health Insurance and the role of the prescribing physician in patient care and acquisition trends, the concepts developed by the RCC relating to the DTP system might be considered by dominant companies in other industries as best practices, were a similar system used in their sector of activity.

> *"In addition to the extensive comments on the DTP system (the actor in the leading role in the Second Sector Report), the best supporting role is attributed to the limited distribution system, including up to 3 distributors investigated by the RCC in relation to the system introduced by Pfizer.*

Posing fewer risks of negatively impacting the competitive environment than the DTP system, the limited distribution system seems to be regarded with less concern by the authority, without being granted an absolute green light.

The assessment undertaken by the authority showed both positive and negative sides.

The positive effects of a limited distribution system are:

- Enhanced service level and collaboration between supplier and distributors. Distributors being selected following an objective process would represent an important step towards such results;
- Enhanced product availability; and
- Support in the fight against counterfeit products.

Nevertheless, the limited distribution system also has its drawbacks:

- Disadvantages (e.g., in delivery and commercial terms) for independent pharmacies as distributors tend to primarily supply their vertically integrated pharmacy chains;
- Potential disadvantages for small or regional wholesale distributors; and
- Potential risks of anticompetitive behaviour.

Even though the approach appears to be more relaxed in the case of the limited distribution system, upon the implementation of this model, especially in the case of dominant products, it could be sensible to adjust some of the rules developed by the RCC for the DTP system in order to mitigate potential competition law risks.

To conclude, the Second Sector Report, although>

4. Commitments proposed by GSK on its DTP system are publicly available at http://www.consiliulconcurentei.ro/ro/docs/177/10391/consultare-publica-cu-privire-la-angajamentele-formulate-de-catre-s-c-glaxosmithkline-gsk-s-r-l-in-cadrul-investigatiei-declansate-prin-ordinul-presedintelui-consiliului-concurentei-nr-715-17-12-2013.html

it does not take the form of best practice guidelines from the authority, represents a useful assessment tool for companies implementing a DTP or limited distribution system. Its general conclusions may also be relevant to other industries.

In any case, it will be interesting to follow the final RCC conclusions from its ongoing investigations into the DTP system, as they will be of the utmost importance in fine-tuning the legal approach.

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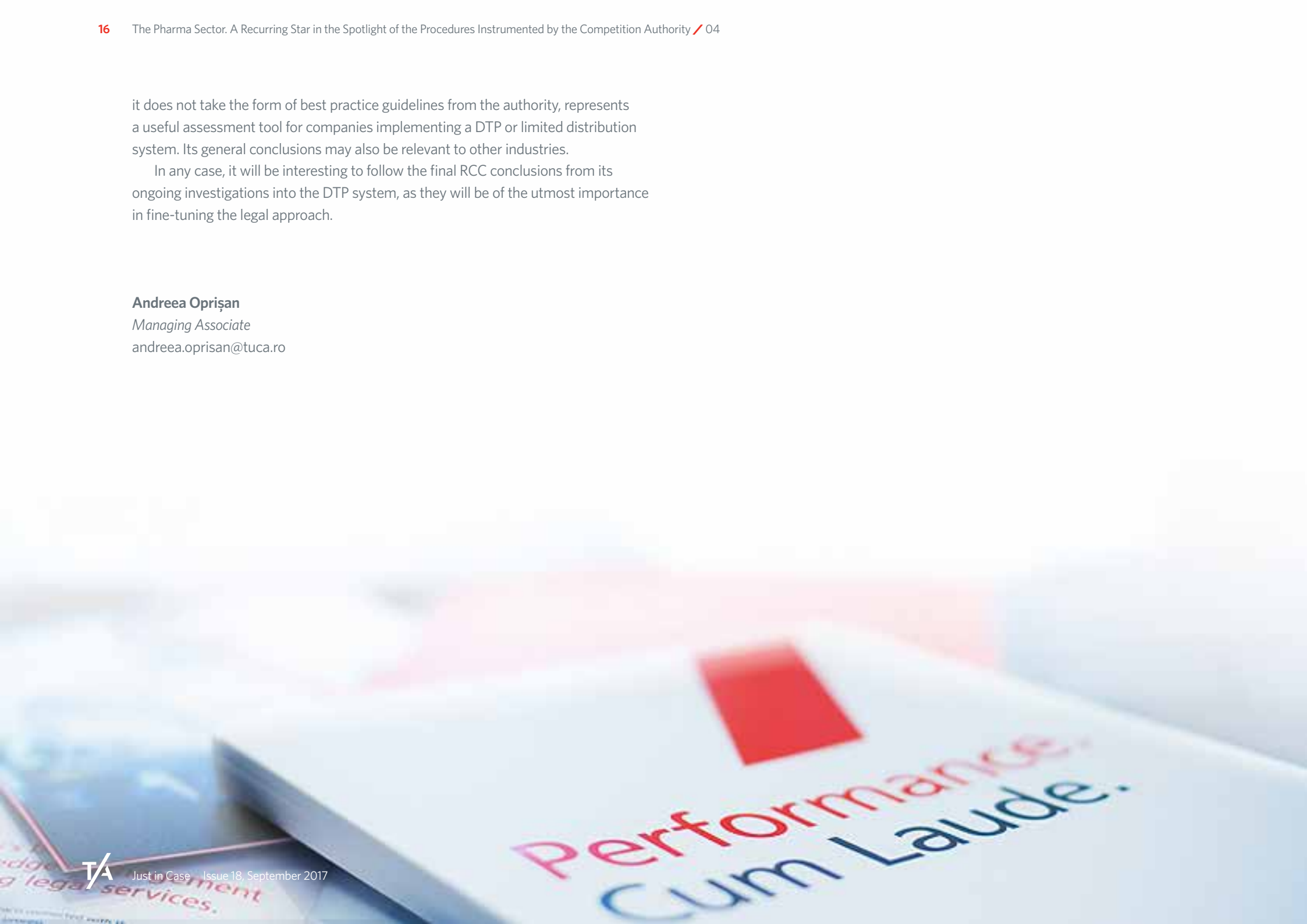

News and Views

Antitrust Risk Assessments by Compliance Systems

Antitrust Risk Assessments by Compliance Systems

The assessment of various risks is performed in different areas of activity depending on the rules applied to the specific situation.

In this idea, a certain risk situation could be evaluated based on the law requirements or on the business ethics rules or by compliance criteria. However, in many cases a specific risk or area of risks could be evaluated from all three aforementioned domains perspective. Thus, the case of an agreement aiming the resale price maintenance at a certain level is mainly a subject placed in the antitrust law zone, but in the same time this risk could be evaluated also from ethics and legal compliance perspective, especially within the corporations that had implemented appropriate compliance internal policies.

The Interfering Domains

Probably some minimal clarifications about the differences between the abovementioned domains would be useful, even if in general extent.

In this respect, the law has many similarities with the ethics, both domains having the same objectives in treating with the morally good and wrong behaviours. The main differences being constituted by the fact that the law doesn't deal with every ethical aspect met in the day-by-day activities. That's why even law and ethics (or business ethics) interfere on various aspects; they still have zones with no overlapping topics. *Ethics* and compliance offer the same image as law vs ethics comparison, these two domains have a certain distinctness between, even if having same purpose are designated to enforce the values, or in in case of corporations, to support the mission, the codes, regulations and other internal rules. The compliance domain is closer to the law; the compliance being related the legislation enforced in a particular domain of activity, since the ethics, as mentioned above, is mainly concerning the good behaviours also outside of the law coverage area. *The Compliance* assures the implementation of the values, good practices and the applicable legislation into internal rules of the organizations, the continuous updating of the policies, the evaluation of relevant risks and the prevention function in order to keep the organization in line with the observation of all the applicable legislation. The law represents one of the most important sources for compliance, especially in the field of legal compliance, but there are clear>

discrepancies when talking about the nature and effects of these two domains.

Risk Assessment Methods

In practice, these three domains are combined in the evaluation and the implementation of appropriate measures applicable in a variety of risk areas. This case is applicable also for the antitrust - competition risks assessment. An efficient system created with the scope of identification, evaluation and finally the prevention of antitrust risks within the organization is the one which may combine in a very structured manner some specific elements of Competition law, Legal compliance and Business ethics. The components of this type of compliance system would be preferable to incorporate elements as codes and regulations, checking tools, trainings and workshops, operational processes, additional risk identification committee, specific repository tools etc.

Antitrust Risk Cases – Compliance Assessment Methods

As a consequence, the primordial element for an efficient evaluation of an antitrust risk case is represented by the adoption of a compliance regulation which would be necessary to provide a comprehensive overview of the competition law within the respective organization. This regulation, code need to be first of all relevant to the organization's commercial activities strategy. In this document, which will contain eminently legal elements, may be drawn the directions to be followed by the organization regarding the antitrust risk assessments, in order to determine the manner in which will be applied the compliance monitoring, checking, the form of the workshops with the employees, the induction trainings, the specific processes, the repository instruments etc.

The main objective is to offer the support to the employees of the organization in order to ensure their activities are fully in line with the antitrust laws but also to check their understanding about the non-compliance effects. By introducing the regulation on antitrust, competition laws the organization needs to enforce the idea of fair competition by forbidding anti-competitive agreements or understandings both horizontal and vertical ones, by forbidding an abusive conduct by a dominant company and by reviewing any M&A project in order to avoid the creation of dominant positions or for other situations which can affect the market by distortion the competition.

All these aspects are likely to be addressed further by specific measures capable to detect the antitrust risks and to permit the implementation of an efficient policy for prevention. The tools that can be implemented are internal processes: Standard Operation Procedures, Working Instructions etc. to support the organization in mitigating the risks of antitrust infringements and creating the possibility of an efficient prevention. For example, in order to mitigate the risk of abuse of market dominant position a relevant internal process would be a procedure with clear tasks for all relevant departments where the own market share data to be assessed periodically according the local legislation.

As a logic measure, with the purpose to meter the efficiency of an internal or specific process, checking tools need to be enabled for monitoring the antitrust risk cases.

The rest of the measures: workshops, trainings and risk data repository are playing the same important role in this complex mechanism of detection and mitigation. In conclusion, for maintaining really useful antitrust risk compliance program is important to have specific methods and to appoint a permanent risk Committee, competent to adjust the mechanism to all changes of the antitrust legislation.

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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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