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Dan Minoiu, partner at Romanian law firm MuÈ?at & AsociaÈ?ii, shares his insights into the main trends shaping the healthcare environment in Romania from a regulatory and legal perspective, the challenges currently facing his clients, and his hopes for the future of the country.

Could you start by introducing yourself and MuÈ?at & AsociaÈ?iiâ??s service offering to the healthcare sector?

MuÈ?at & AsociaÈ?ii is one of the largest law firms in Romania and was established more than 30 years ago. We have offices in Bucharest, Brasov, Cluj and Constanta and we provide comprehensive legal, regulatory, tax and compliance services on a national scale.

I have been working with MuÈ?at & AsociaÈ?ii since 2010 and became a Partner in charge of coordinating the firmâ??s Life Sciences Department, with a client portfolio that includes over 20 international research-driven pharma companies, medical devices companies and private healthcare providers.

We assist our life sciences clients on transactions, mergers & acquisitions, regulatory issues, corporate, compliance, competition and Intellectual Property matters. Our extensive and valuable experience allows us to act quickly and provide solutions in a timely and effective manner. We work with our clients on the marketing authorisation of their products, as well as their promotion, distribution, prescription and reimbursement, so that products are successfully launched, and Romanian patients are able to access the treatments they need.

MuÈ?at & AsociaÈ?ii has one of the biggest and more knowledgeable litigation departments in the country that assists our pharma clients on competition and IP litigations, insolvency procedures and, of course, clawback litigations. We have a very good success rate in clawback litigations, as I have been representing many of the leading pharma multinationals and won 95 percent of the cases. Without going into too much technical details on these litigations, please know that since 2011 pharma companies started challenging the clawback notifications, respectively the consumption data communicated by the National Health Insurance House (CNAS) because they realised that the system was not transparent and it included the margins of third parties.

Also, we regularly advise our life sciences clients on competition issues. The Romanian Competition Council is one of the most active in Europe and is familiar with the pharmaceutical sector. Their last report was published in 2017 and covered the marketing and promotion of medicinal products as well as the distribution system of the pharmaceutical companies in Romania. After four years looking at the top players in the market, and the way they distribute and promote their products, they drew some conclusions. The next step for them is to launch investigations, which means that we will need to represent our clients.

On the patent protection side, we help innovative companies with all the matters related to the protection of their intellectual property rights. It is of paramount importance to anticipate the disputes that will affect those products close to losing their patent protection, in the context of the expected launch of generic and biosimilar drugs. This requires complex assessments on IP and regulatory matters, focused on the marketing authorisation, distribution, pricing and reimbursement of the concerned medicines, as well as on labelling and prescription aspects.

What have been the main trends and changes on the regulatory side in the last five years?

There have been significant updates in the pharmaceutical sector in Romania. I would like to highlight the new methodology for computing the prices of medicinal products created in 2017 â?? there were several other pricing enactments before then, but they were challenged by the industry. Another major legislative change referred to the conclusion of cost-volume agreements with the National Health Insurance House to include new (expensive) medicinal products in the reimbursement list. The clawback legislation was amended to exempt certain medicines from the payment of this tax, such as vaccines, immunoglobins and plasma-derived products, considering that these have a different price computation, as they are extremely expensive to manufacture.

New rules on the public service obligation and on the distribution of medicines have also been implemented. While the authorities acknowledged the parallel trade of medicines from Romania to other EU countries where the prices are higher, they issued new enactments to ensure that the distributors comply with their local public service obligations. Companies intending to make intra-community sales need to report to the National Agency of Medicines and Medical Devices (NAMMD) and to wait for a few days to see if there is any claim from a local pharmacy that needs those products, to ensure that the Romanian market needs are covered.

As you may know, the Sunshine Act was a legislation issued in the US as an annex to the ObamaCare Affordable Care Act that required pharmaceutical and medical device companies to report certain payments and transfers of value made to physicians and hospitals. In the EU, some companies and industry associations decided to implement their own internal regulations following the US. Romania was one of the first countries in Europe to officially issue legislation requiring pharmaceutical and medical devices companies to disclose all sponsorships, reimbursements and agreements concluded with physicians or other healthcare professionals, with healthcare organisations and with patient organisations to NAMMD and the Ministry of Health. This information is published on the authoritiesâ?? website, ensuring the transparency of the system.

Other trends shaping the pharma business environment in the last years were the enforcement of the General Data Protection Regulation (GDPR) and of the related national data protection legislation; the possibility to set up online pharmacies with a government authorisation; changes concerning the pharmacovigilance system, the performance of clinical trials and the manufacturing of medicines; also the changes to the Fiscal Code in 2016 which changed the way companies contract healthcare professionals, and other tax reforms such as the reduction of the VAT rate from 24 to 19 percent.

How is the government set up to support the trend of digital health and medical data?

The Romanian government is proud to be among the first countries in Europe to implement the use of electronic patient cards and electronic patient files. Since 2013, CNAS, the Ministry of Health and other players such as the National Institute of Statistics have gathered huge amounts of data and local records.

In 2019 the government created an eHealth agency focused on IT, data correlation and digitalisation matters. Every year, the authorities organise an industry event together with the largest pharmaceutical companies, IT companies, insurance companies and private healthcare providers to identify the steps to be followed in terms of electronic patient registries, disease registries and telemedicine. The authorities know that digital medical services will grow tremendously in the coming years and they are willing to find solutions in this regard.

From a legal perspective, what do you see as the main trends currently shaping the Romanian pharmaceutical industry?

Romania became a member of the European Union in 2007. Since then, the majority of EU directives have been transposed into the national legislation regarding healthcare and the pharmaceutical industry. However, there are still significant differences in terms of the pricing, reimbursement, distribution and promotion of medicines and medical devices in comparison to other EU markets. There are some specific rules in Romania that should be considered by those companies conducting business here.

The Health Law is the main enactment, and there are numerous secondary pieces of legislation in each field. The Government approves the national reimbursement list and the national health programs. The Ministry of Health approves the medicinesâ?? prices and regulates the performance of the medical services. NAMMD regulates and supervises the marketing authorisation, distribution and promotion of medicines and medical devices, the performance of clinical trials, as well as the health technology assessment for new products. CNAS further regulates the supply of medical services, medicines and medical devices to the insured patients in the national health insurance

system. All these authorities are very active and constantly issue new enactments affecting the business of our clients.

According to our experience, it is very important to have a continuous dialogue with the government and with the healthcare authorities, to be active in the working groups they organize on various healthcare topics and to offer support on the elaboration of new legislation, acting in a proactive manner. This is why we have been advising for many years the leading industry associations in the pharma, medical devices and business fields, working together with our clients and with the authorities to improve the Romanian healthcare system and the national regulations.

NAMMD is now going through a significant reorganisation process. They need more people in order to speed up the approval process of clinical trials, which has been decreasing in the last few years. Currently, there are a few companies coordinating their clinical trials from Romania, through teams which provide support to other countries, instead of conducting clinical trials here. This business model was implemented also by other large corporations such as Amazon, Microsoft, Ericson and Oracle which conduct operations here because they realise there is a lot of potential and talented people in Romania.

What are the challenges associated with the pricing and reimbursement policies in Romania?

According to the legislation issued in 2017, prices in Romania are set at the lowest level of the 12 reference countries: Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Belgium, Italy, Lithuania, Spain, Greece, and Germany. There are two different price catalogues for medicines. First, we have the CANAMED catalogue, which sets the prices applied in the National Health Insurance System â?? which are the lowest prices. Second, we have the Public Catalogue, where prices are set as an average of the lowest three.

All products go through an annual price review. If the price of a drug decreases in Romania at a level that will impact its price in other countries, the marketing authorisation holder will have to challenge the local price and even request the withdrawal of the product from the pricing list. The consequences of doing this are to withdraw the product within a year or stay in the market afterwards and be sanctioned with an additional five percent price decrease.

Our clients always stress how hard it is for them to have the lowest prices in Europe while paying a clawback tax of over 20 percent â?? it is not economically viable for them to keep certain products on the local market. The good news is that the authorities intend to amend the clawback legislation in the near future.

In spite of all the obstacles, what makes Romania an attractive destination for pharma companies?

From a practical perspective, Romania has a large and ageing population that needs medicines. Moreover, the use of preventive medical services is very low in Romania, so most patients start directly with medication â?? often expensive medication â?? as a last resort. Romania has an attractive tax regime that encourages pharmaceutical companies to set up an affiliate here â?? except for the clawback tax, of course; and a well-educated workforce and healthcare professionals which are open to learning and using innovative therapies with their patients.

Some pharma companies are doing extremely well in Romania, while others can only be present in one of their niches. This depends very much on the companyâ??s portfolio. In most cases, having a very large portfolio can be an issue and they end up withdrawing some of their products.

What do you wish for 2020?

On the one hand, as part of MuÈ?at & AsociaÈ?ii, I hope we remain engaged with the pharmaceutical and healthcare industry at the local and EU level as a trustworthy partner for all our clients. I wish to continue helping them identify the best solutions from a regulatory, tax and legal standpoint.

On the other hand, I understand that the success of our clients in Romania depends very much on the regulatory and legal framework. Therefore, I wish to continue seeing a strong collaboration between the industry, the main associations â?? ARPIM, APMGR and RASCIâ?? and the regulatory authorities to improve the legislation and introduce new guidelines that will benefit more patients and create a friendlier environment.

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