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The associationâ??s longtime executive director outlines the opportunities and challenges for generics companies in the Romanian market. Analyzing in depth the local market regulatory landscape, he proposes modifications to the claw-back mechanism.

A non-governmental organization that aims to foster improved the access to affordable medicine for Romanian patients, The Association for Generic Medicine Producers (APMGR) was set up in 2009, at the behest of the leading generic medicine producing companies present in the country. You yourself became executive director in 2011. How has the organization evolved with time?

When I joined back in 2011 we had around 14members whereas the tally today stands at a full 19 companies. The other major shift had been a dramatic improvement in our public profile. Having affiliated with the European Generic Medicines Association (EGA) we now possess international recognition and have become highly active in both national and international public health policy debates. Last week EGA actually singled us out for acclaim for having the best online presence amongst our peers.

Right now we are in the middle of conducting a first-of-a-kind awareness campaign about the benefits of generics in partnership with the ministry of health and the national drug agency. Merely a few years ago this sort of collaboration in Romania would have been unthinkable despite the fact that such initiatives are the norm across Europe. It is a sort of pilot campaign that started in December and will run until the end of February, but opens the door to more sustained private-public cooperation. The fact we have been able to pull this off represents real step forward.

When we last asked you about your personal priorities, you spoke about the need to formulate a meaningful and consistent message (both vis-Ã -vis the government and consumer) about what benefits the generics manufacturers are bringing to the market. How successful have you been in realizing this goal?

The ultimate message that we strive to transmit is that generics are affordable compared to branded products not because of a diminution of quality, but because we donâ??t have to make the same

investments on R&D and because of the comparatively much higher competition in our category. This means generics are the vehicle through which patient accessibility to quality medicine can be enhanced and sustainable financing of public healthcare realized.

As far as the government is concerned, we have succeeded in delivering a strong message and are now reaping the rewards for it. Nowadays I canâ??t imagine anything happening in the legislatory process to do with generics without our lawmakers consulting us. We now have a seat at the discussion table as a matter of course. This was certainly not the case in the early days when the APMGR was still finding its feet.

Joint campaigns with the government are today possible because our lawmakers are finally beginning to acknowledge that the credibility of generics and the credibility of the national pharmaceutical industry are intertwined. All drugs on the market must receive prior approval by the authorities, so if the common misconception that generics have inferior medical efficacy were to hold true then that would by implication be casting the competence and integrity of the nationâ??s regulatory regime into doubt. Equally there is much greater recognition in national policymaking circles that embracing generics represents the only pathway to achieving improved patient access to treatment within a balanced budget.

Even at the international level a tangible shift can be identified. Under the European semester of deficit reduction, Romania is actually one of the few countries under special measures to possess articles on healthcare as part of its country specific recommendations. After much lobbying on our part, there is a clause that calls for the pursuit of more efficient national healthcare spending. This essentially is an indirect way of promoting generic usage though the European Commission would never say as much explicitly.

And what about public acceptance of generics?

The Romanian consumer has always maintained an open mind towards purchasing generics and this is reflected in terms of sales volumes that have, at times, reached as high as 70 percent. If the figure right now is lower it is less to do with consumer preferences and more to do with the behavior of the pharmacists who are forced down a path of favoring the sale of expensive branded products in a bid to keep their cash registers afloat. In other words, long payment terms risk making many pharmacies insolvent and one of the more obvious strategies for them to shore up their cash-flow scenario is to privilege the sale of the more expensive categories of products.

If generic medicines were more available then there is little doubt that the end consumer would buy. The sad reality, however, is that many of the cheaper drugs are being forced out of the market by a very hostile fiscal regime dominated by the claw-back mechanism. In many instances that fiscal burden has become so high it is not economically efficient to produce and keep many kinds cheap drugs on the national market anymore.

Meanwhile the public perception is of escalating prices. Itâ??s not that prices really are increasing, but rather that the cheaper options they used to enjoy are exiting the market and their range of product choice is contracting. Patients suffering from chronic disease find their co-payments are rising month on month, but this not about price hikes, but rather a reflection of the fact they are forced to treat their ailments with more expensive categories of drugs in the absence of the cheaper alternatives that would formerly have been there.

You keep on referring to APMGRâ??s work on the European stage. How important do you consider your membership of the European Generic Medicines Association (EGA)? What tangible benefits does it bring?

Firstly, it allows us to keep stock of the way things are happening in the other European countries. Sharing experiences with the other national associations ensures we remain at the cutting-edge of best practice. Secondly, itâ??s important to know what the bureaucrats in Brussels are planning for the industry so as to be prepared well in advance. Forewarned is forearmed as they say.

To give you specific examples of our activities, there are planned directives for counterfeit medicines which risk having an immense impact on the world of generics not just in Romania, but elsewhere too. The APMGR is at the forefront of countering falsified products having signed MOUs at the national level with the Romanian police and judicial apparatus, but we are opposing this particular directive because the act of compliance would place massive additional financial burden on drug manufacturers.

The proposed directive would entail placing a security coding on every box and safety device allowing for the data checks and tractability right down the supply chain from manufacturer to wholesaler and distributor to the pharmacies. Though laudable as a concept, making the manufacturer foot the bill for these additional measures would particularly victimize generic producers on fine profit margins. We, for example, calculated that for some of the cheapest products on the Romanian market, the holograms and security devices on the boxes would cost more than the medicines they contain which is of course totally economically unsustainable. Because we are, along with our counterparts in other counties, actively participating in the legislative process through consultations, we can seek for a compromise.

You mentioned that payment terms are, in some instances, driving generics out of the Romanian market. In light of the passage of new EU-directives, to what extent is this situation improving?

Payment terms used to be in the region of 300 days, but the EUâ??s directive 7 is condensing that down to more like 90 days. Being at the end of the repayment chain the manufacturer is always in a precarious position. First the state has to reimburse the pharmacies who in turn pay the wholesalers and distributors who finally pay our clients (i.e. the manufacturers). The real difficulties occur when the wholesalers enter bankruptcy because that means the manufacturer will probably never receive the money that he is due. To add insult to injury, the producer will have already have paid the claw-back mechanism for those products he has never received payment for. This is an unattainable state of affairs, but at least with the new directive entering into force, the pharmacies and wholesalerâ??s cash flows should stabilize more and ultimately the manufacturers should feel the trickle-down benefits.

We understand that the claw-back mechanism became more burdensome than ever in the last quarter. How is this?

Claw-back was meant to be a temporary emergency measure to meet the troikaâ??s demand for a closure of the national budget deficit, has become institutionalized over time as a source of revenue generation for the government. Though the concept of a claw-back has been used elsewhere in Europe, it has never before been deployed in this way as a tax. Technically it is not a tax because it is not mentioned in the fiscal code, but rather classified as a â??contributionâ??. For the

government, the claw-back avoids a widening of the deficit because whatever they spend of healthcare is covered in advance with the mechanism making up any shortfall.

Today the claw-back is paid on the shelf price excluding VAT. Originally VAT was also included but we successfully managed to have that overturned in the constitutional courts because it was obviously absurd to have generic manufacturers being taxed for revenues of the state. The situation remains thoroughly irregular nonetheless, because the manufacturers are still being â??taxedâ?? for the profits of the wholesaler and pharmacy sectors. This is by far the worst fiscal environment in Europe for medicine production.

As you rightly point out, last quarter the claw-back was more burdensome than ever. In quarter 3 the amount of claw-back to pay was calculated at 21 percent of the overall price of the products, but by Quarter 4 this had risen to more like 25 percent when there had been no noticeable growth in the market according to IMS and Cegedim data. For this reason the APMGR called on the prime minister to force the CNAS to release its figures and make transparent the way that the claw-back is calculated, but unfortunately this was to no avail. Manufacturers are now in a very vulnerable position because, despite your sales volumes going down, you could actually end up paying a greater proportion of claw-back contribution. This makes it exceedingly difficult to maintain any kind of company strategy.

There were actually tens of millions of euros worth of investments placed on hold only last year as a direct result of this unpredictability. Even big investments in new R&D centers and production facilities with state aid schemes already approved by the European commission were jettisoned because producers were in the dark about how much they would be asked to pay in claw-back each quarter because the coefficient is calculated for the entire market rather than individual firms.

In the past youâ??ve actually called upon the troika to take a position on the claw-back, but theyâ??ve refused. Why is that?

They agree with us that the claw-back is not sufficiently transparent in the way that it is calculate, but ultimately the troika is not on our side. Their priority concern is to ensure that the national budget deficit be covered and the claw-back contributes to this. By not taking a stance on the claw-back, it then makes it easy for the Romanian government to pass the buck and say that the claw-back is the only way of meeting the troikaâ??s conditions and demands.

How then would you like to see the claw-back amended?

We have proposed to have a different calculation for generics producers because at the moment the innovators are increasing national drugs bill and the poorer guys (the generics producers) are paying for it. The solution we have put forward is to combat this by having different calculations according to the type of producer and the troika has backed us on this, just so long as there is no public deficit at the end of the day.

Everyone more or less agree a new mechanism is needed. By law, the generics price can only be up to 65 percent of that of the equivalent branded product so why not keep this proportion when applying claw-back? Though many parties and stakeholders have agreed with this premise, there have been a number of stalling tactics deployed during the legislative hearings which have so far prevented such a reform taking effect.

What strategies are your members taking then to adapt to this situation?

Many are putting on hold investment plans and a fair number have found themselves forced to fire personnel. Nevertheless the bulk of our members are adamant that they are here to stay and are adapting the best they can to the environment. There are not so many strategies to survive. One is to focus on exports. Another is to reduce their offering for prescription medicines and going more for OTCs and supplements. In the short turn this can generate new revenue streams because OTCs and supplements donâ??t have regulated prices and the claw-back doesnâ??t apply. The risk, however, is this could mean the hollowing out of an 80 to 90 years industry. Nor do supplements and OTCs generate as much added value as real prescription medicines so itâ??s the patient who loses out at the end of the day.

How does the business outlook for generics manufacturers change given the recent (and surprise) transformation of political regime?

We have a new president, but same cabinet and same majority. President Iohannis could potentially improve the business context by promoting market discipline, transparency and a stable and predictable regulatory framework. There are, of course, huge expectations but it is too early to forecast the political implications. The new presidential team is not yet ready to start meeting with particular industries, but that moment will come with time. I am conservatively optimistic. He already looks different in style and approach and there are good opportunities to effect positive reform, but lets wait and see because, over the last few years, many decent opportunities were squandered.

What is your final message to our international readers?

We live in times of financial stricture and fully embracing generics would mean better access to treatment for patients while still confining budgetary deficits.

Meanwhile the generics companies and innovators need to join forces in encouraging a better business environment for pharmaceutical manufacturers in general. The market is large enough for both of us to coexist in a complementary and synergistic manner. I see much scope for generics rendering healthcare financing more sustainable which, in the long run, would benefit the originators as well.

You only have to look at history elsewhere. In 1982 the US congress passed a comprehensive legislative package increasing the use of generics and many commentators said that this would kill the R&D industry. The end outcome was actually that investments from 1983 to 1990 increased four fold from 5 billion to 20 billion dollars because the pressure of the generics obliged the innovative companies to up their game.

The problem with the healthcare market in Romania is, at base, the chronic under investment. In this climate of diminished resources we end up fighting each other. Just like in Animal Planet Channel when the resources decrease the big cats end up one against the other. The generics companies that APMGR represents are not usually this aggressive, but having so few resources at our disposal force us to be like this merely to survive. The intelligent way forward would be to band together to force a new business context that is more sustainable for the industry as a whole.

Personally, I am full of admiration for APMGRâ??s members. My colleagues are very talented businessmen. It takes incredible strategic gymnastics to stay afloat in the environment within which they are forced to operate. Generics producers accounted for 1.5percent of GDP last year and that was after having to fire some 300-400 people. We still account for some 8,000 personnel working in our area and could achieve ever so much more given the right business context. In short there, is a lot more to achieve. A lot more to play for.

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