

Interview: Calin Galaseanu - Country Manager, BMS

Romania



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The country manager of a leading specialty care bio-business reveals how the economic and geo-social fundamentals in Romania are highly attractive from an innovative pharmaceutical producer standpoint. He speaks about how to navigate the complex regulatory landscape and the potential opportunity for preventative care to make the nation's healthcare system more financially stable and sustainable.

BMS is specialty care bio-pharma business that has been present on the Romanian market since 1995 and currently ranks number 12 in terms of market share. Can you please start by introducing the scope of BMS's in-country offering?

Over last 20 years, BMS worldwide has been transitioning to a pretty unique business formula which has centered around highly specialized care that specifically targets disease areas with high unmet medical needs. Romania's national healthcare profile, with demand outstripping supply in critical therapeutic areas, aligns closely with this approach so it is entirely natural that we have been and continue to be highly active in this country.

We have established a strong presence in Romania initially for treating mental illnesses such as schizophrenia and bipolar disorder and more recently for our therapies to counter infectious diseases such as HIV/ AIDS and Hepatitis B. Currently we are underway developing a platform for treating Hepatitis C in cooperation with the authorities. Last but not least, we are developing

innovative medical solutions for the oncology and hematology segments.

At the global level, we have been at the forefront of breakthrough developments related to the role that the immune system can play in fighting cancer and have been successfully pioneering and branding the concept of immune-oncology. Our plan for Romania includes introducing these cutting-edge methodologies and latest generation products on the local market. At Bristol-Myers Squibb, we feel strongly that Romanian patients deserve to enjoy the same level of healthcare as their counterparts across the EU. We very much see our role as helping to drive up the standard and scope of health provision in the therapeutic areas where we are leaders.

Where do you identify the main growth drivers?

We see oncology and infectious disease as the main drivers because of the depth of unmet needs and wide range of high performing products still to be properly introduced to the local market. Romania is really interesting from a pharmaceuticals perspective because you have the demographic profile that situates the country as 7th biggest population after the big five and Poland with some 20-odd million inhabitants. Another distinctive characteristic is the prevalence of certain infectious diseases such as TB where the affliction rate is abnormally high and HIV/AIDS where there is a very specific cohort of patients. Then for other infectious diseases there is a strong degree of correlation with trends elsewhere in the EU: take hepatitis B, for instance, where there is around a 4 percent rate of incidence which is more or less on a par with the Mediterranean reservoir encompassing Italy and the South of France.

When the authorities really put their mind to it they can be pretty effective and that also produces a bit of a bounce and growth spurt. Fine steps have been taken in treating cancer patients, for example, where the waiting lists have reduced to zero for many oncology therapies. A couple of years ago you had a decent range of oncology products reimbursed, but long queues of patients awaiting treatment to the extent that the conditions of many were deteriorating irreversibly before they could start their care programmes. My educated guess is that this was achieved because the authorities refocused financial capabilities towards these areas where we have been witnessing the biggest disparities in healthcare provision and through better optimized spending.

Then again, if you analyze the KPIs and macro indicators, Romania remains well behind the rest of the EU and some non-EU countries too in terms of drug consumption per capita and national expenditure on healthcare. Romania is spending around a mere 4 percent of GDP on healthcare in general (i.e. not only direct expenditure), while France spends more like 7.5 percent and the United States a full 18 percent. Remember, as well, that we're talking about a percentage from a much

lower GDP overall, as well, so when that translates to absolute values it's a tremendously low figure. This means the market has a lot to do to catch up and there's going to be a lot of work up for grabs once spending eventually starts to rise, as it will surely do over time.

As a member of the new generation of GMs, what are your techniques for successfully navigating the regulatory landscape and ensuring profitability on the local market?

The best way to navigate the regulatory landscape is to play an active role in engaging with relevant stakeholders to build a right communications platform. This might sound trivial, but speaking with a single voice in the industry is essential if we are going to be able to facilitate access to optimal innovative treatment for Romanian patients. Bristol-Myers Squibb is a vigorous member of ARPIM, an association for innovative drug companies engaged in Romania, and I am actually the incumbent president. At Bristol-Myers Squibb, we consider it vitally important to be active participants in such configurations because this is our best chance to be heard by the authorities and to impact the decision making process.

Obviously, trying to identify the lowest common denominator for 28 innovative pharmaceutical multinationals is always tricky, but we have managed to unanimously agree upon three pillars and core values which we consider incomplete or absent from the local market and are relentlessly pursuing: transparency, predictability and financial sustainability.

Bristol-Myers Squibb has also developed some fine projects with the assistance of various patient advocacy groups and civil society and this is also helping to mold the regulatory context in a manner that is more amenable to ensuring access for Romanian patients of innovative treatments. If you compare with 2011, there has been excellent progress in the way those sorts of groups have developed and asserted themselves. Many are grouped in confederations and are part of the European association and they are increasingly aware of their rights. They are adamant that Romanian patients should not be treated as second or third class citizens within Europe and are supporting us in our drive to get new molecules included on the reimbursement list and available to patients.

BMS represents a new breed of bio-pharma company, uniquely combining the reach and resources of a traditional "big pharma" player with the entrepreneurial dynamism and agility of a biotech outfit. You also enjoy one of the most productive pipelines in the industry. What opportunities, then, are there in the Romanian market for a firm like yours?

Our bread and butter activity is innovation so our intention is naturally to channel that productive pipeline towards the local market. Romania has had to cut corners since 1989 and sometimes they achieved this successfully, sometimes not. The result is a lopsided and only part-developed market that lacks in maturity even if many of the main private sector actors have been present for the past 20 years. This may limit our space for action in the short term, but does nothing to reduce the reality that we have a major contribution to make in assisting Romanian healthcare get on to its feet.

The mega opportunities that are out there are clear for all to see. Average life expectancy across the EU is 83 to 84 years whereas in Romania it's a full ten years less and this is linked directly to the comparatively poor quality of the healthcare and reduced access to innovative therapy. We have, alongside other pharmaceutical innovators, positioned ourselves to address this shortfall.

The primary obstacle that we are confronting as an industrial partner is the high level of political volatility. If your partner of dialogue is changing so rapidly, there is little scope for having a truly mid to long-term strategy or for forging an enduring partnership. For six years we've effectively endured a hard period with zero access for introducing innovative medicines and this is impeding us from fulfilling our natural role.

The outlook nevertheless is very bright. What happened last year, with a tentative opening up of the reimbursement list, was not by chance and was actually the culmination of a highly coordinated effort on the part of ARPIM with harmonization at the EU level and vocal lobbying by the patient groups as well. There was a bottom up approach where the civil society groupings started demanding their rights. They're becoming more empowered and a degree of maturity is materializing. We are therefore optimistic about the future.

How does clinical research fit into the mix?

One of the most important activities going on in Romanian healthcare and life sciences is the vibrant clinical trials market. At the level of ARPIM, our member companies contributed a combined investment of some 400million euros last year. In a country with late access you can easily spot immediate benefits from engaging in clinical research. Firstly you can have a good chunk of the population accessing very innovative drugs. Secondly is you are raising the bar for local doctors who will gain exposure to cutting edge treatments and methodologies that otherwise they would remain locked out of. Thirdly it also produces a cost-saving effect on the public purse as clinical trials operate outside the reimbursement system. That way we're really taking about a win-win-win scenario.

Bristol-Myers Squibb, for its part, maintains a very strong footprint. We possess a research and clinical operations department that has doubled in size over the past 2-3 years and we're involved in the full range of research covering immune-oncology infectious disease and rheumatoid arthritis. I'm proud to say our colleagues in Romania are involved in same level of work as their counterparts in Spain and Holland both of which have great renown as clinical trials destination countries. There is also the benefit of high skilled individuals as investigators in Romania.

You keep on returning to the fact that baseline health expenditure is very low. What can you do in terms of promoting cost-effectiveness through disease prevention?

Looking across Europe, you cannot find one solution that fits all. The vast majority of countries are having to resolve upon transformative changes to render their healthcare systems sustainable. German healthcare today is a totally different landscape from five years ago in terms of market access even if their financing looks rosy compared to the rest of Europe. Even in Germany, we're seeing access becoming more and more focused and means-tested rather than the broad-brush universality of previous eras. In Romania, we have to leapfrog a lot of the developments that have been undergone in Western Europe and more mature markets.

At the same time, there are a number of areas that are not necessarily cost-effective, but still require urgent attention and where Bristol-Myers Squibb is proud to be playing a part. Over the last 10 to 15 years cancer palliation was left virtually untouched with little provision for patients suffering from terminal degree illness. Bristol-Myers Squibb Foundation, alongside other partners, has started to change this situation and has been contributing to a state-of-the-art hospice in Bucharest which includes a dedicated section for pediatric cancer patients with advanced states of illness. Meanwhile the BMS foundation has been well engaged in Romania as part of the 'bridging cancer' program which is a humanitarian initiative to reduce oncological disparities across Europe. I am proud to reveal that Romania has successfully bid for 5 out of a total of 7 grants towards these activities and has done so for three consecutive years which is testament to the success of each project and the real difference being made on the ground.

How strategically important is the Romanian market to BMS' global operations?

If I look at our current geographical footprint, Romania is without doubt one of the heavyweight players in BMS' CEE basket of countries. We enjoy a decent growth rate due to our agility in delivering good results with legacy products despite not having new items on the reimbursement list. Behind all the facts and deeds is a professional, dynamic and enthusiastic team which goes a long way to ensure success. Speed, agility and versatility are crucial to reach our goals in this

market. You need an energetic and forward-looking team fit for the purpose of creatively adding value when the rest of the market is tired and exhausted.

How will you define your success?

In line with our current benchmarks, I would like to see us extend to Romania the same sorts of medical solutions we are deploying in Western Europe. I would want to see Romania normalized with more emphasis on the social aspects and smart healthcare with a focus not just on treatment, but also prevention. Bristol-Myers Squibb should be at the forefront of this process. The health of a nation is the sine qua non for economic and social progress and I am keen for Bristol-Myers Squibb to be one of the drivers behind a much more impactful national healthcare system. From a personal perspective, I hope to be seen and remembered as the person who took our local employees out of their comfort zone and challenged them to realize their full potential.

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