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[Infrastructure, education, and healthcare] are the key to better serving the Romanian citizens and making the country more attractive

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*Sévan Kaloustian shares his first impressions of the Romanian healthcare ecosystem and pharmaceutical market as newly appointed managing director of Janssen Pharmaceutical Companies of Johnson & Johnson Romania. Kaloustian outlines his intention to maintain the strategic position of Janssen as a key player in Romania, working to facilitate the access of Romanian patients to innovative medicines.**

After 11 years at Janssen and having worked in France, the US, Poland and Romania, what have been your first impressions of Romania in comparison to your previous experience?

My first impressions have been very positive. The economic dynamics of the country show continuous and impressive progress over the past 15 years and there is an ongoing open conversation between the private and public sectors, which offers fantastic prospects for the company.

Looking at Janssen, I have no doubt that we have an excellent team in Romania. This has been the most positive aspect of the past four months: the strength of the team, the spirit of Our Credo, the engagement of the employees, and the affiliate's growth over the last few years. Now, my number one responsibility is to ensure that the working environment is in the best situation to serve our purpose: covering the patients' treatment needs and bringing innovative medicines to market.

In November 2019 you were entrusted with the task of leading Janssen's affiliate in Romania. What are your short and long-term priorities?

In the short-term, I would like to make sure that we continue the positive trend we are in now. Janssen Romania is treating more patients than ever before, which is our number one priority.

Globally, Janssen has invested a significant amount on R&D to develop new innovative medicines. Those assets are now being transferred to Romania through the approval and reimbursement processes. In the mid- to long-term, I would like to bring those innovative therapies to Romanian patients.

What is your assessment of the healthcare environment in Romania?

I think that the best way to assess it is through looking at life expectancy – after all, this is why we are here, to bring more and better-quality life. In the last 15 years, life expectancy in Romania has moved from 71.5 to 75 years old, while the Eurozone average increased from 77 to 80.5 years old – Romania is still behind, but it is progressing faster, which is a key aspect.

From what I have witnessed in the last four months, this progress has been motivated by a very strong willingness to collaborate and make it happen from both the public and private sectors. In this context, I am proud of Janssen's strong footprint and active involvement in this debate.

How is Janssen supporting the authorities and other healthcare stakeholders in Romania to improve the ecosystem?

We are doing everything we can. We are part of the Romanian Association of International Pharmaceutical Manufacturers (ARPIM), through which we are in constant dialogue with other trade associations to maintain a unified conversation with the public sector.

In February 2020, I attended the first edition of AmCham Romania's CEO Forum, where Prime Minister Ludovic Orban was the key speaker in the event. What struck me the most in that conversation was the unanimous agreement between the public sector and the more than 100 managing directors from all industries in Romania that attended the event on the three priorities for Romania: infrastructure, education, and healthcare.

These three priorities are the key to better serving the Romanian citizens and making the country more attractive; there is a clear understanding that the three of them are essential. Personally, I think that healthcare has a special flavour because regardless of the country, its culture, its size, or its climate, when a disease or health condition hits your family or any of your loved ones, you go through a difficult moment. This is why we are here and why it is important that we transmit this message with a united voice.

In order to make a difference, the key issues that need to be addressed are the clawback situation, the regular quarterly update of the reimbursement list and the framework around the validation process of clinical trials. At Janssen, we believe that finding a solution to these three elements together with the authorities will translate into positive outcomes for the Romanian population.

The combination of clawback, the minimum reference pricing methodology and the delays on the reimbursement list update and the clinical trials validations has created an unfriendly environment inhibiting and constraining innovation in Romania. Which solutions are being proposed?

In February, ARPIM, the Local American Working Group (LAWG) and the Romanian Association of Generic Producers (APMGR) advanced a shared proposal for the authorities to consider capping the clawback tax – 25 percent for the innovative companies and 20 percent for the generic producers.

We hope to be able to build on these premises so that eventually it passes as a new law.

This change will ensure Romania continues moving in the right direction to deliver the best healthcare to patients.

Moreover, better health will bring improved life expectancy and more productivity, allowing patients to recover faster after a disease. In a country like Romania where the GDP growth is over four percent and the unemployment rate in cities like Bucharest stays below five percent, it is important to maintain these figures for as long as possible. For instance, in the Netherlands approximately 83 percent of the oncology patients (head and neck cancer diagnostics) can go back to their productive professional life and most within six months; in the case of France, women diagnosed with breast cancer can go back within 10 months. In a country with the dynamics of Romania, it is fundamental to follow these trends in order to unlock the potential of the country.

Five years ago, Romania was seen as likely to become the next hub for clinical trials but, as you pointed out before, this has not been possible due to the constant delays on the approval process. What is Janssen's approach in this regard and what is the scope of its clinical trial activities today?

Clinical trials are imperative to bring innovative drugs to the patients; whether we should do them or not is not under question. They are the core of R&D and innovation and they could bring many additional benefits to the country. Firstly, clinical trials bring innovative solutions and therapies to the patients in need. Secondly, they offer new treatment options for hospitals and practitioners, allowing them to learn about upcoming drugs and to give better treatment to the patients. Thirdly, from a country perspective, clinical trials bring investment – approximately 100 million euros per year in a country like Romania.

Nine years ago, there were approximately 260 clinical trials conducted every year in Romania. Two years ago, the number went down to 180. These numbers speak for themselves and prove that we are missing a chance to the benefit of patients, the healthcare professionals, and the economy of Romania.

At Janssen Romania we have a Global Clinical Operations (GCO) unit. We are engaging with the authorities to reduce the time needed to validate the clinical trials dossiers. The average waiting time in Europe is 60 days, while in Romania it can take up to eight months. I'm sure we can do better.

Could you highlight the therapeutic areas in which Janssen is present in Romania?

We are present in Oncology, Haematology, Immunology, Pulmonary Hypertension and Neuroscience.

Two years ago, Janssen acquired Actelion's active portfolio, which we also aim at developing and potentially launching new medicines in other areas of treatment. Our current focus is on mental health, as well as on Neurology, for which we have partnered with Biogen. Innovation is part of Janssen's DNA. Every year Janssen spends eight billion dollars in R&D globally, focusing on bringing innovative treatments for highly unmet medical needs. This investment has resulted in the development of over 17 assets launched in last eight years, which we are extremely proud of.

During the last five years we have launched a total of nine new indications and products in Romania. This has been possible because of the private and public sectors' willingness to make

these assets available and reimbursed for the patients and the constant dialogue between them.

In the future, we plan on bringing several products in Immunology, Haematology, Neurosciences and Neurology.. We are also developing new CAR-T therapies that we hope to launch soon.

What is the strategic importance of Janssen Romania at the regional level?

It is extremely important. Here, Janssen is a key player in shaping the healthcare environment. We are focused on our mission and I think it is fair to say that Janssen Romania has been disproportionately successful in the region in comparison to similarly-sized markets. I am extremely grateful to my predecessors for building such an efficient organisation and a strong team. I see it as my responsibility to continue along this positive path.

What are your objectives for 2020?

At the industry level, we are 100 percent committed and focused on improving the ecosystem both independently and through ARPIM. Any progress on the clawback aspect, the quarterly update of the reimbursement list or on the clinical trial process validation framework would represent an achievement in this mission.

Internally, I expect Janssen Romania to follow the path we are on. We are an operational company where the average age is 38-39 years old; we have a flexible space in which no one has an office or a desk - we have a very particular leadership style and I can only see benefits. I would like to focus on bringing our people closer together and on meeting their needs and aspirations. Our people are millennials and they want to be challenged, to have more learning opportunities and to feel closer to the mission of the company. My main objective is to create the perfect environment to achieve this; to protect, keep and expand the organisation that we already have.

Finally, I will make sure to maintain Janssen's trust and reputation in Romania. We already have a seat at the table, not only because we want to be there, but because we are expected to. We have earned our position following Janssen's Credo standards and I intend to keep and further enhance this legacy.

* Interview conducted on March 5th, 2020

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