Interview: Luciano Finardi – Country Manager, Celgene Brazil

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Luciano Finardi, general manager of Celgene Brazil, describes the unrivalled commitment of the company to Brazilian patients and documents the remarkable dedication of Celgene to registering its flagship product in Brazil, as well as the company's willingness to cope with the country's unpredictability while establishing its operation in Brazil.

Celgene came to Brazil at a relatively later stage than many other international companies. Could you provide us with an overview of the history of the operations of the company in the country?

Firstly, we need to remember that Celgene was founded in 1986, which is fairly recent in comparison to most of the pharmaceutical companies in the global top 20. Celgene has however experienced solid growth primarily as a result of REVLIMID® (lenalidomide), which prompted the company to bring its life-changing treatments to an increasing number of countries and patients around the world. Celgene initiated its activity in Latin America around 2007 through local partners and distributors. This strategy has borne fruit as Celgene products became available across 18 Latin American countries.

Nevertheless, Brazil and Mexico are relevant markets that truly require the presence of local affiliates, the hiring of nationals and the set up of local clinical trials in order to fully enable the integration of the company into the country's health ecosystem. More importantly, these two

countries taken together make up an overall population of around 350 million people, whose therapeutic needs are important for a patient-centric company like Celgene. Furthermore, Celgene felt that directly bringing its expertise into these two countries could truly contribute to shifting the treatment paradigm in the hematology oncology arena; our historical area of excellence.

In 2014, Celgene's flagship product REVLIMID® received COFEPRIS marketing authorization in Mexico for two indications, multiple myeloma (MM) and myelodysplastic syndromes. Where does Brazil stand in the registration process of this product?

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We expect to receive ANVISA's marketing approvals before the end of this year. For regulatory matters and the registration of innovative products, Mexico has therefore proven itself as much faster than Brazil, although it seems that the second stage of the access process – the inclusion of innovative products into the Mexican public health system – still stands as a lengthy endeavor. Unfortunately, in Brazil, both stages of this process are still very difficult, but the country holds a dynamic, 52-million people strong private healthcare market.

Nevertheless, the significance of Brazil's private system also perfectly illustrates the paradoxical situation in which our healthcare ecosystem finds itself – at the moment its long-term sustainability is clearly compromised. In Brazil, most government and regulatory officials are particularly keen on highlighting that Brazil's SUS *[the country's universal, public system, e.d.]* stands as the largest, government funded universal health system in the world. However, limited budget availability and the exceptional size of the population covered also implies that only basic products are integrated into the SUS. To give you an example, a cancer patient who exclusively relies on the public healthcare system would most likely only be treated with first-generation therapies.

Nevertheless, we cannot blame CONITEC *[Brazil's Health Technology Assessment Commission, e.d.]* for this situation. Every new innovative treatment reaching the Brazilian market puts the commission in an untenable situation, where allocating resources to include innovative treatments is extremely difficult as our country remains marked by the persisting significance of more basic health issues, such as infectious or cardiovascular diseases.

Overall, I deeply believe that Brazil's health system should evolve so we could pride on the healthcare quality that our citizens are able to access, whether it comes through the public or private healthcare market or through a combination of both. In this regard, we are still far from achieving the level of care and access standards that are expected since Brazil decided to include

healthcare for its citizens as a constitutional right.

Why do you see this specificity as a problem?

It is a problem as there is no way to make it viable. Our 1988 Constitution mandates the equality, universality and integrality of healthcare access to our entire population, but on the other hand the state does not hold the financial resources to guarantee this constitutional right, especially in a country where the relationship between the private and public healthcare systems is not well enough delineated.

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As healthcare needs and treatment technologies have been tremendously evolving over recent decades, most countries in the world have refined the relationship between their private and public systems, with the implementation of copayments for example. In Brazil, the abovementioned constitutional right enables patients covered by private health plans to “double dip” and access expensive treatments and healthcare services through the public system every time the latter are reimbursed.

As a result, our public health system is not able to concentrate its efforts on the 75 percent of the Brazilian population that exclusively depends on the SUS. Furthermore, every time CONITEC assesses the inclusion of a new healthcare technology into the SUS, they have to bear in mind that 205 million Brazilians hold the constitutional right to freely access it – although more than 50 million of them hold private health plans.

Our country has been entangled in this gridlock since 1988, and shifting this paradigm will undoubtedly required a coordinated effort from all stakeholders – the government and regulatory authorities, patient organizations, and pharmaceutical and healthcare companies. We have to build a more sustainable healthcare system in this country, where the rights, responsibilities and relationships binding the private and public healthcare markets are more clearly defined and where ANVISA has the appropriate resources to expedite its review of new compounds.

Regarding this common objective to build a more viable health system in Brazil, what do you see as the responsibility of pharmaceutical companies?

First, we have the responsibility to engage in an open, long-term dialogue with the government – at all levels and as early as possible. Fulfilling this endeavor means providing government and regulatory authorities with a clearer visibility of our product development roadmap. In this regard, I would highlight that Celgene is already conducting clinical trials in Brazil, in hematology, oncology

and Inflammation & Immunology (I&I).

While patient-centricity is high on the agendas of most pharmaceutical companies, we should not overlook the importance of being payer-centric either. It is extremely difficult for Brazilian payers to assess products based on pharmacoeconomic studies performed in European or North American health systems – whose cost structure is completely different from that of the Brazilian healthcare system. Nevertheless, we see that most companies in Brazil are still reluctant to perform local pharmacoeconomic studies.

Given the registration of REVLIMID® in Brazil has been an ongoing process since 2008 – even before the affiliate was set up and you took over in 2012 – how do you handle the expectations of the company's headquarters, which might struggle to understand why this product registration is taking so long?

I see myself as a translator. My direct boss sits in the United States, and my job is to ensure regulatory challenges do not force Celgene to reconsider its commitment to Brazil while – in the meantime – I have to convey in a very transparent way the ups and downs we have been through over these past five years. In this regard, I believe that the ability to translate Brazil's unpredictability into actionable strategies is crucial for all pharmaceutical executives operating in Brazil, and this is definitely not an easy job.

Many observers describe Brazil has a uniquely complex-to-navigate market and a particularly stringent ecosystem from a regulatory standpoint. I disagree with this analysis: at the end of the day, ANVISA's processes and requirements are closely aligned with those of the FDA in the US or NICE in the UK.

What sets Brazil apart from these markets is its unpredictability, and this also applies to registration timelines and the pricing approach by regulatory authorities. Speed to market in Brazil is still very slow, whereas we should be surfing the same wave as Europe and the United States. When international companies take into account this unpredictability as they calibrate their product launches, they sometimes favor a wait-and-see approach, observing competitors make the first move.

Celgene is a relatively new company in Brazil. How do you want the company to be perceived by healthcare stakeholders here?

During a recent ANVISA public hearing, one of the agency's directors seized this opportunity to praise Celgene for its resilience and commitment to Brazilian patients, as illustrated by "the

REVLIMID® case". After REVLIMID® initial application was submitted by a representative company in 2008 and rejected by ANVISA, Celgene did not forget the crucial importance of bringing this product into the country: we set up an affiliate and built a quality control laboratory, hired the relevant regulatory and medical experts and designed a world-class risk-management plan. These efforts are now about to yield marketing authorizations in the upcoming months.

This compliment from the agency's director perfectly embodies the image we want to build for Celgene Brazil: a long-term, unquestionable commitment to Brazilian patients.

Celgene is now about to reach a very important milestone with the upcoming approval of REVLIMID® in two critical indications. Where do you envision the affiliate in three years?

I believe that the best way to handle Brazil's unpredictability is a step-by-step approach: not getting too excited and overinvesting when things are coming along fine, as you might regret it when the situation becomes tougher. Today, Celgene Brazil has a very lean structure composed of medical, regulatory, product quality, corporate affairs and finance expert staff. In three years, I expect that Celgene Brazil will grow but will also remain focused on who we serve: over 70 percent of our positions will continue to be customer facing.

In the grand scheme of things, Celgene in Brazil will only have accomplished its mission as a member of Brazilian civil society when it becomes a leader in helping people suffering from multiple myeloma and – in a second phase – when it establishes a prominent position in the I&I field.

Being a patient-centric organization is an endeavor that requires courage before anything else. Challenges lying ahead might seem insurmountable and incite us to shy away, but we must never forget our fundamental mission: we are here because people are still dying of multiple myeloma and our tireless efforts can help them.

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