Pierre-Claude Fumoleau – General Manager, AbbVie France



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Abbvie France's Pierre-Claude Fumoleau outlines his strategic priorities for the affiliate, AbbVie's unique corporate culture and ethos, and how he envisions upcoming regulatory reforms playing out in France.

You were appointed general manager for France 1.5 years ago having won plaudits for successfully turning around the Norwegian affiliate and returning it back to growth. What specific mission have you been assigned for this posting?

My mission here in France has been well articulated and there are similarities to what I managed to accomplish back in Norway: notably overseeing the transition from a small affiliate to a big one, putting in place a well-oiled and efficient product launch machinery and contributing to overall pipeline development. On top of that, we are very attentive to making sure that we are patient-centric in everything that we do and in being proactive and bold in shaping the market environment that we find around us.

What is also rather exciting about being in AbbVie is that we are still a very young company – indeed the youngest bio-pharma actor of this magnitude and reach – having been spun out of the mother company, Abbott, a mere six years ago and that means that we are still very much in the process of constructing a differentiated culture and distinctive corporate identity.

How would you describe this corporate culture and ethos today?

We are particularly vocal and energetic. Our voice already carries much further than you might expect in proportion to our market share. What marks us out from many of our peers is how we really live our passion and embrace the limelight. Being bold and young, there is a real sense of momentum and drive. We possess a super engaged workforce and deploy our youthful sense of energy to establish a real connection with the patients.

The term “patient-centricity” has become a buzzword to the point where it risks being emptied of all real meaning. What does being patient-centric actually mean to you and AbbVie in France?

We consider it to be about much more than just patient advocacy and awareness raising campaigns. Here in AbbVie, everything is anchored to same overarching principles, but we are empowered to localize the execution. This means we can really listen to the on-the-ground needs and experiences of the French patient population and adjust our value offering accordingly to suit.

Patient centricity, for us, starts with engaging with the users of our therapies to better understand the patient experience so that we can focus on the unmet needs and the most difficult to treat pathologies. Listening to patients’ needs also allow us to optimize adherence, to develop information services dedicated to patients and their healthcare professionals, and to ease the delivery of our treatment. If you consider our historic anti-TNF Alpha treatment, we have been conducting clinical development programmes for 18 years to develop 15 indications. So did we to create new formulations and dosages with a view to improving upon the delivery mechanisms and ensuring that they are as patient-friendly as possible. Equally, in oncology and onco-haematology, we are always on the lookout for new modes of action and bespoke pathways that align as far as possible with the lifestyle expectations and aspirations of the patient.

Can you give some concrete examples of specific adaptations that AbbVie has made in the French market with a view to rendering patient lives easier?

Absolutely. Last August, we launched our pan-genotypic, treatment for chronic hepatitis C virus (HCV) infection, on the French market, but still faced an issue of reaching out to the 100,000 or so

patients, not on treatment with some 75% of those not even yet aware that they had the disease. Not only that, but many of the already diagnosed segment of patients, having endured torrid experiences in the past following unsuccessful treatment regimes in French hospitals, were proving reluctant to return to those hospitals to receive the new therapy.

We needed to get the medicines as close to the door of the patients as possible. We thus took the unprecedented step of making our treatment available in town pharmacies, even undertaking direct retail delivery to those pharmacies ourselves.

For those that are unaware that they have the disease, this step is also beneficial. Pharmacist conversations with at-risk groups, such as those who have a history of injecting drugs, can provide an important bridge that leads to the diagnosis and France's ability to track and treat this disease until its elimination by 2025, so as the French Ministry of Health set the goal

Is it not rather unusual for a company that overwhelmingly produces hospital drugs to be engaging so closely and directly with the pharmacies?

Pharmacies are critical in the AbbVie mindset and indeed one of our fundamental points of differentiation. We constitute an outlier amongst our peers in having established a strong and dedicated "*'Information et au Bon Usage (IBU)*" team which we deploy to the pharmacies so as to inform the pharmacists so that they understand our medicines, their functionalities and the benefits that they bring. Despite the fact that our therapies are all prescribed at the hospital level, we recognize how the pharmacists are closer to the patients and are keen to leverage that dynamic as much as possible so as to ensure optimal adherence.

Precisely because we have fostered such close relations with them they can be mobilized as an important source of information about patient concerns and experiences. They, therefore, form a useful pillar in our commitment towards patient-centricity.

Surely this benefits the state too, by alleviating pressure on public hospitals?

Another objective we hit through pharmacy provision is, indeed, generating cost savings for the state. Transitioning our product users from hospitals to outpatient treatment translates into significant savings and aligns with the epidemiological trend in which many more patients are surviving acute diseases, but still require ongoing care so that the disease essentially becomes

chronic. Under these circumstances, prolonged treatment within the context of a hospital no longer makes sense, financially and socially. Our aim is very much to contribute to the outpatient care and home-care shift as long as it is a source of medical value for the patient and more efficiency for the healthcare system.

Most recently, we launched our haematology therapy in the retail setting. This is a first-in-class medicine that selectively binds and inhibits the B-cell lymphoma-2 (BCL-2) protein so it can be effective in countering some blood cancers.

2018 marks AbbVie's most successful year since the launch of the company back in 2013 (delivering on average 15% of growth across 2018). What has been the French affiliate's contribution to this success story?

Every year, since inception, has been our most successful year and the French affiliate very much plays its part in this amazing growth narrative. We might not have a dedicated R&D facility in France, but we are nonetheless partnering with some 230 clinical centres and have multiplied by 7 the volume of clinical trials that we are conducting. We have a dedicated in-country team of 130 personnel dedicated to clinical development. This means that we are positioned at the vanguard of new product development. Right now, we stand as the first country to include patients in oncology trials after the domestic United States market. By next year near 50% of our in-country trials will be in the exciting area of immunology.

As a company, we possess a very well stocked and highly prospective drug development pipeline and it is entirely natural that we should be making use of France's excellence in life sciences sand rich clinician base especially in target areas like oncology where the country boasts world-beating institutions like the Institut Curie and Gustave Roussy, Europe's premier cancer centre.

How would you describe France's overall strategic importance for the Group?

We employ an in-country workforce of around 600 personnel and if you take into account indirect employment this figure probably rises to around 10,000, so our local footprint is considerable. Moreover, we are one of the very few non-French pharma multinationals to have situated our European headquarters here. Actually, we have two regional headquarters stationed out of France: one that presides over Eastern Europe, the Middle East and Africa, and the other looking after the West European space plus Canada.

How attractive and relevant will the proposed reforms unveiled at the 8th CSIS be for an innovation-driven biopharma company like AbbVie?

Macron’s ascension to the presidency has brought in a business-friendly political class that finally understands the true value of the pharma industry both to the healthcare system and economy. The immediate consequence of this is that the doors to the authorities have reopened and we are now able to engage in candid and fruitful discussion. The CSIS was a milestone moment that has allowed for beneficial reform to start gaining traction. This has not translated much into accelerated access to innovation for the patient yet. We are nonetheless optimistic that we will eventually see some kind of breakthrough.

We, along with our other industry peers, do not underestimate the budgetary pressures and constraints that the state apparatus is grappling with and acknowledge that it is not an easy job to balance competing objectives.

At the same time, it is essential that we find new ways to deliver growth back to the pharma industry because without growth you simply cannot innovate. It is our obligation to candidly transmit this message and that is exactly what we are doing through channels like the LEEM and mechanisms such as the CSIS. At end of the day, it stills takes almost 500 days to get a product reimbursed on this market and revenue growth remains minimal, flat-lining at much the same envelope that it was 10 years ago. Right now, as demonstrated by the PLFSS, the authorities are still playing the short-term game chasing budget cuts. There will be no real improvement until structural reform is enacted.

What sort of structural reform are you envisioning?

France’s Health Technology Assessment (HTA) infrastructure requires a thorough overhaul. The current methodologies in force are not well suited to an age of precision medicine. Many latest-generation, breakthrough innovations relate to tiny, niche indications where you cannot generate the level of data at the time of reimbursement that is being requested. What’s needed is a mid-term, provisional or conditional assessment to cover the period until full maturity of data can be attained. Right now, owing to the lack of complete data, these state-of-the-art therapies are being undervalued in the assessment. You only have to consider the huge discrepancies between FDA and French HTA decisions to realize how outmoded the latter is. It’s the same molecule and same

evidence in the dossier, but a totally different adjudication, which confirms there is a failure of process.

Also, if I look back to being general manager in Norway, in that market every citizen now possesses a digital file that tracks him or her from day one throughout life and which includes all manner of data relating to tax and housing right through to medical records. This means that every patient is fully understood by the pharmacists and physicians wherever they meet them in the country and can see the full prescribing history. Because these records are individually exhaustive they can equally be extrapolated at the macro level to track epidemiological trends and measure the performance of different treatment pathways, which, in turn, can inform decision-making and lead to optimized healthcare provision.

Which improvements has the Macron presidency delivered to date?

Firstly, the Macron presidency has generated a lot of goodwill and his global charm and PR offensive proclaiming that France is open for business again certainly seems to be paying dividends in raising the interest of the international investor community. Secondly, there have been some concrete improvements to the ATU process, which is critical to the French market because it helps patients access certain therapies more swiftly and this was a mechanism that looked to be in danger about a year ago. Also agreed at the CSIS, was the commitment to extending the ATU system to include 2nd and 3rd inductions. Though it has been included in the 2019 PLFSS so has to happen sometime this year, we have not yet seen an authorizing decree. This is unfortunate because 10% of the year has already passed without patients yet benefiting from this move.

There have also been some positive steps in simplifying the bureaucracy around clinical trials with a view towards abbreviating the approvals timeframe, which would be very welcome. The inclusion of unique contracts is also a good move as it saves a lot of time. Ultimately, however, everything hangs together holistically in the sense that obstacles to market access will risk spilling over into the clinical trials domain as well. For instance, we find that there are certain clinical trials that we simply cannot run because the patients don’t exist: if we come for patient relapse in the most recent therapy, but the most recent therapy is not yet approved in the country, then you don’t find the relapsing patients so you cannot open the trial. A lack of innovation today therefore quickly snowballs into a lack of innovation tomorrow as well.

To what extent does the ATU mechanism increase the appeal of the French market?

It is important to understand that only a limited number of molecules actually meet the stringent eligibility criteria for the ATU: it has to be an indication of the high unmet need and, to date, 2nd and 3rd inductions are disqualified. For a long time, we have been arguing that this is nonsensical because non-breakthrough, incremental innovations can also deliver sizable benefits. Meanwhile, the process for navigating a molecule through the ATU has become increasingly complex and opaque and it's not always clear how the price is decided. Still, ATU is a useful device and work around solution to getting certain therapies to patients faster.

How optimistic are you for the future?

Out of the CSIS, I think we can certainly expect better visibility and predictability for the industry even if there are outstanding issues with the social security financing law that still need to be ironed out. At the moment, we don't get full tax understanding until 4-6 months into the next year. What the industry is now pushing for are 3-year work contracts so as to reduce this element of uncertainty and to allow for better continuity of business plans. This would have a big impact for us because AbbVie's French affiliate is not just competing against all the other rival companies in France in our therapeutic areas, but also with other AbbVie offices around the world for a finite investment envelope.

Today, there are great hopes, expectations and goodwill riding on the Macron Presidency's ability to get the life sciences industry back on track so the time has come to start converting the promises into tangible actions. That said, we are feeling the momentum and continue to believe.

Within the affiliate, we are going through a very exciting phase: going into new therapeutic areas, hiring new talent and stick to our vision: delivering innovative solutions to transform people's lives.

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