Interview: Rodrigue G. Schübelin – Pharma and Life Sciences Lead Partner, PwC Italy

For Italian pharmaceutical companies to continue to grow they will have to successfully internationalize their businesses, not only in terms of exports but also investing abroad

28.06.2016

Tags: Pharma, Pharmaceuticals, R&D, PPP, PwC, Rodrigue G. Schübelin, Italy, Healthcare, Pharma, Production, Manufacturing, Interview, Insight, Exclusive, Executive, Free

PwC Italy's

Rodrigue G. Schübelin talks maintaining Italy's impressive growth in pharma production, R&D incentives, public-private collaboration, and PwC's role within the Italian healthcare ecosystem.

Italy's pharmaceutical production increased by 38 percent from 2009 to 2014; what steps does the industry need to take to keep performing at this level?

It is important to recognize that the backbone of the Italian pharma industry is composed of private, family owned companies. This is actually a significant competitive advantage in many regards, as these companies do not have to answer to shareholders every quarter and can act much more flexibly and decisively than their public counterparts. The risk is that without that pressure, some companies may not challenge themselves to grow enough, or have a clear idea of where they should invest; this has been more of an issue in recent years, and firms have increasingly struggled to find the right investment opportunities, either geographically or in terms of R&D strategy.

For Italian pharmaceutical companies to continue to grow they will have to successfully internationalize their businesses, not only in terms of exports but also investing abroad so they do not miss the opportunity to participate in high growth markets. It is essential to select such

markets carefully, as there is a tradeoff between growth potential and regulatory, logistic, and administrative challenges, and some markets have a better risk/reward profile at present than others. PwC has a specialized “growth market center” at the global level that can help clients find the right opportunities, and we can even make the necessary introductions to help mid-sized Italian companies enter new markets in Asia, Africa and Latin America efficiently.

The second element pertains to the market’s trajectory. We see a lot of liquidity in the market, including amongst the family businesses, some of who are quite large and have huge cash reserves on their balance sheet. This concentration of liquidity in the industry, which we see at the global level as well, has driven up prices of potential targets and now there are a lot of companies looking for M&A opportunities not being able to find attractive targets. We are seeing companies looking for help how to handle their liquidity, avoiding how to have too much cash on hand, not being able to invest effectively due to the low interest rate environment and assistance in identifying the right strategic targets for acquisition.

On the other hand, there is a lot of interest in investing in new technologies, and we have seen Italian companies recently venture into areas like vaccines, stem-cell products, gene therapy, and rare-diseases. However, I have some concerns about the current R&D models, and given the increasing pressures on price from payers, it is essential that companies streamline their R&D process and are certain they have the right focus, strategy, and model. It is important to utilize new technological tools that enable virtual R&D structures and methods, and to utilize new big data-driven and innovative scientific techniques. Going virtual is essential, as traditional in-house R&D centers are inefficient and ineffective given the increasingly collaborative nature of innovation.

Could you give us an assessment of where R&D incentives are at right now, and will be going in the near future?

The Italian government clearly became aware that something needed to be done to support R&D investment, after seeing a dip in R&D categories over the last several years. As such Prime Minister Renzi and his team have introduced new tax incentives to encourage R&D spending, although spending is not enough on its own to produce valuable R&D output. There are two significant new measures, the first being a “patent box” that will reduce the effective tax rate applied to revenues generated by products featuring patented innovations, while the second is an R&D tax credit. Both are very positive steps, and the R&D tax credit was in fact quite a surprise as the level of the credit is quite high; companies can get up to a 50 percent credit on R&D costs including the related personnel expenses. When coupled with the new jobs act, the government has done a lot to

improve the cost of R&D labor, which is abnormally high compared to other territories with whom Italian Pharma & MedTech companies ought to compete. The high cost and lack of flexibility of the Italian labor market combined with the big tax pressure and length of Italian justice are, in my view, the three factors that harm most the competitiveness of Italian players on the global market besides discouraging foreign investments.

[Featured_in]

Both the patent box and R&D credit were great news when announced, but they also created as many questions and concerns as they solved. A primary concern was what sort of R&D expenditures would qualify for the credit, as the initial phrasing appeared to be somewhat restrictive in terms of recognition of intragroup R&D activity. PwC, upon having discussed this matter with Farmindustria and its members, approached the tax authorities to discuss and clarify the situation, and it was concluded that in-house and intragroup R&D activities would qualify for such tax credits.

That said, while these steps have been very positive, incentives on the side of taxes are not necessarily enough to compensate for the impact that cost-cutting measures have had on pharma companies' revenue base. Moreover, while the government is generally aware that R&D and innovation should be supported, there is still a deficit of trust between the industry and the authorities, limiting the potential benefits to be gained through greater public-private collaboration.

How has this collaborative spirit been represented more broadly in terms of collaboration between and integration of the life sciences and healthcare sectors?

For historical and political reasons, Italy is behind many other occidental countries in terms of cooperation between the pharmaceutical and life sciences industries and the healthcare system. That said, we certainly see global trends in Italy as elsewhere, including the outsourcing of sales and marketing activities, patient-centricity, the emergence of pay for performance and risk sharing mechanisms, and of course increased cooperation and integration across the sector. Italy is moving in the same general direction as the rest of Europe, however the timing is somewhat different and at present there is a still distance between pharma and healthcare stakeholders as a result and a long way to go to achieve the integration and cooperation that has existed for many years in territories such as the U.S.A or Canada.

What are some of points that need to be solved to close this gap and enable more effective cooperation and collaboration?

The biggest point of contention lies in how AIFA and the regions have implemented legislative cost containment measures. The “payback” measures currently in place both on the Pharmaceutical and MedTech business segments, are paralyzing the industry and preventing collaboration between the healthcare system and private sector; AIFA and the regional health authorities have been subject to numerous legal claims pertaining to the legitimacy of the pharma payback measures and the way they have been implemented with a lack of clarity and major backlog in communicating payback ceilings and settling paybacks for public overspending of past years. We are now nearing the close of Q2 2016, and pharmaceutical companies have not been provided with their individual budgets for 2015! This has created many concerns related to companies’ financial reporting in general, particularly for public foreign companies that must file quarterly financials with the SEC or other market regulators.

In August 2015, a new law was introduced to implement a version of the pharmaceutical payback mechanism for medical devices as well; when it was passed, it stated that an implementation decree would later be passed clarifying how it would be implemented, and that an agreement between the central government and the regions was imminent. However, by the time December 2015 arrived and year-end financials were due for SEC registrants and other foreign filers, no such decree or agreement had been made.

These delays and associated uncertainty involved did not just require companies to introduce significant provisions to their financial statements, but instead cut to the core of their revenue recognition: a financial year ended and companies faced major difficulties in determining their reportable revenue for that year. This uncertainty is highly problematic for foreign investors, more-so than cost containment measures and price pressures. It is one of the biggest issues discouraging investment in the Italian pharmaceutical and life sciences industry, alongside with the other deterrent factors mentioned earlier.

[related_story]

Until the aforementioned payback issues and other regulatory matters get resolved and a new governance model is put in place, there will remain too much uncertainty and lack of trust to allow effective cooperation and collaboration between the Italian Pharmaceutical industry and healthcare system, i.e. between the players and the payer.

What role has PwC played in the industry discussion regarding these issues, and in developing solutions?

PwC’s global purpose is to build trust in society and help solve important problems. Thus, we strongly believe that for complex and broad topics that have aspects involving legal, regulatory, tax, accounting and other aspects, particularly where Italy’s global reputation and trust from foreign investors is involved, PwC has a responsibility and capacity to add significant value through integrating these components. Our ambition is to be perceived as a multi-divisional multi-functional partner who can help develop the right solutions to complex issues, both for our clients and business communities in general. We want to be available and accessible to anyone who wants to have a discussion and hear our perspective on these issues that affect the whole industry. More importantly, we want to ensure that we learn through discussions with all players involved to arrive at said solutions.

As such, we collaborated extensively with the Italian Pharmaceutical and Medical Device Industry Associations on the payback issues among other topics. We organized and led several roundtables, seeking to understand the real impact and nature of the various payback mechanisms, and how they should be interpreted from a theoretical standpoint, monitored from an internal control standpoint and accounted for from a financial reporting standpoint. We met with numerous players of the Industry, be they PwC clients or not, looking at how the pharma payback mechanism arose in the first place, as it was a continuation of what had originally been compulsory discounts and companies had been given the choice to switch to a reimbursement/payback model instead. These discussions led to very relevant conclusions from a financial reporting standpoint. For multinational companies listed on international stock exchanges any ambiguity or risk of error in financial reporting is unacceptable, so coming to a well-founded industry consensus on how to treat the payback mechanism was important. There were arguments for treating it as a tax or operating expense, but in the end it was clear that any funds to be paid back should be treated as counter revenues.

Similarly, we at PwC aim to facilitate the dialogue mentioned earlier between pharmaceutical companies and the Italian healthcare authorities and providers. This happens for instance in the area of Market Access as we elaborate independent economic impact evaluation models in order for both the drug maker and payer to determine thoroughly the right pricing and comparative convenience of reimbursed drugs taking into account not only the mere price component but a more holistic view with other relevant factors such as the overall cost of the entire patient path associated to the choice of a given drug. This also happens as we help our clients draft and analyze innovative collaborative agreements such as *Cost Sharing*, *Risk Sharing* or *Pay for Performance* contracts, which by focusing on drug effectiveness clearly respond to the changing needs and requests for “Value for Money”, especially in the case of innovative drugs. In that sense, we as PwC

believe to have a major social responsibility as well as a role to play in changing the general perception of the Pharmaceutical sector. After almost 20 years working for the industry it continues to strike me how an industry whose purpose is to drive health and save lives often bears a negative common perception with a reputation index lower than those of the tobacco sector and defense industry; I strongly believe that working all together on the challenges above this may be changed and harmony may be found amongst the various stakeholders forming the Pharma/Healthcare industry to the benefit of patients.

See more interviews