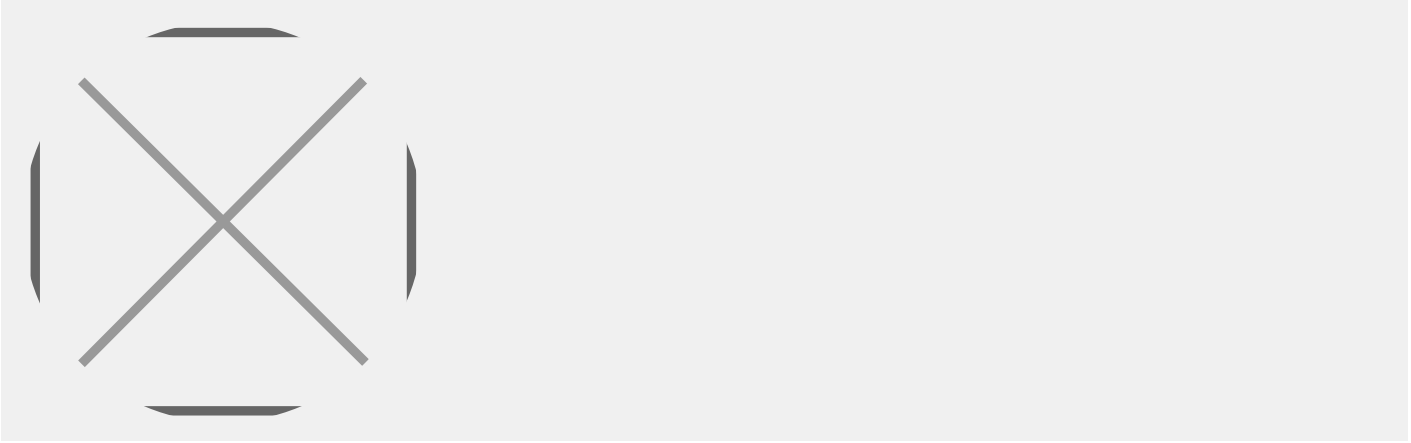
Interview with Bill Batchelor, Counsel, Baker & McKenzie Belgium



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Today, B&M differentiates itself by what it calls its 'fluency' in the way you think, work and behave which enables you to navigate the legal complexities across practices and boarders with ease and allows you to bring the very best of your global expertise to your clients. Has this model continued to give the company a leading edge in Belgium and what is your overall assessment of the firm's positioning on the Belgian market today with regards to the life sciences industry?

Bill Batchelor (BB): Belgium is in fact host to Baker & McKenzie's first international office in Europe since it began branching out of the US in the late 1940's. At the time when the European institutions were being established in 1957, the firm spotted the opportunity and put their first stake in the ground in Brussels, Belgium. As such, Brussels has always been at the center of the firm's European strategy. In that respect, I believe the same principle applies to our life sciences practice; there is no point in isolating Belgium with regards to our life sciences practice. Instead, we aim to work together with our 120 other pharma regulatory lawyers across Europe and think along the same lines together. This is after all what is expected of us from our clients. For instance, any given pharmaceutical organization might inquire about the local regulatory environment, but at the same time they also expect you to know and understand how that would relate to and impact their counterparts across Europe, at least. This is what our commitment to fluency is really about.

Annabelle Bruyndonckx (AB): It is interesting to note that in the 1930's, before Baker & McKenzie was created in 1949, Russell Baker had been working with Abbott Laboratories who continue to be

one of our best clients today. Initially, he had been working with Abbott on a number of small assignments, however, as time passed he was asked to explore international opportunities with them in Latin America and Europe and advise them on an array of topics. This had endowed Mr Baker with 15 years of international experience before he had established the firm along with John McKenzie with the aim of developing a truly international law firm. This clearly demonstrates the importance and significance of our life sciences practice since it has played an integral role in the development of the firm right from the start. It is quite literally in our DNA.

Indeed, B&M is renowned for its strong network of international expertise. Yet each market is as unique as its national culture with its own particularities – as your counterpart Mr Paul Melling pointed out when he said that 'pharma companies in Russia are tempted to cut corners because the chances of getting caught were small while the results were immediate.' Having spent 14 years with the company focusing on the medical industry, what in your opinion are the main challenges that that your life sciences clients are faced with in Belgium today?

AB: One dominant issue challenging our clients today relates to pricing and reimbursement matters. Of course, there is always the research and development (R&D) aspect of the life sciences industry, however, these activities have been very well established in Belgium and function in a very efficient manner. Moreover, at the level of the Federal Agency, Kristof Bonnarens (Head of R&D Division at Federal agency for medicines and medicinal products) has established a solid team that has worked diligently towards establishing an environment that is conducive to R&D activities.

Hence, life sciences organizations in Belgium are seldom faced with significant challenges in the R&D side of their operations. However, as soon as they are prepared to introduce a given new product to the market, they are immediately confronted with a number of challenges with regards to filing their pricing and reimbursement dossiers. More specifically, these processes tend to be extremely lengthy with an average procedure of more than 300 days for innovative drugs and a slightly shorter timeframe for generic drugs of approximately 220 days. In either case, this is not optimal especially when you take into consideration that the EU Transparency Directive requires a timeframe no longer than 180 days. Indeed, Belgium is among the slowest European countries in the context of pricing and reimbursement procedure.

Like in all other countries, there is an undeniable will to reduce and control Belgium's budget which has placed a lasting downward pressure on their spending levels. What we see is that when governments cannot balance their expenses and the budget, they tend to impose increased taxes on the pharmaceutical and medical devices industries turnover. When our clients cannot obtain adequate reimbursement levels or any at all, they then approach us to evaluate their options. However, in my recent experience I have come to realize that it is not always optimal to challenge a

decision because the INAMI-RIZIV (the local reimbursement body) more and more tends to contend that our clients' products are not a priority in the context of their current budgetary objectives and are therefore ineligible for reimbursement. I find it rather shocking to decline new and innovative products on the basis of a lack of budget, while ignoring the potential socio-economic added value of the products. This is the trend we are seeing today and this is where our advisory role and lobbying activities come into play and direct our clients to the appropriate contacts in the INAMI-RIZIV or the Ministry of Health (MOH) to discuss their individual cases. Indeed, it sometimes the case that unaccepted products can save costs for the healthcare system (e.g. long stay in hospital) while enhancing the treatment of patients.

A similar pattern has emerged for products that are already being reimbursed, where their compensated levels are explicitly being reduced. Of course, there are many such cases. For instance, the bandages sector has been subjected to such measures where the Health Ministry has taken the decision to reduce by €5 million their budget while asserting notably at the same time that part of these measures should not affect the patients. At the same time however, the industry has been excluded from the decision making process. This is a particularly perplexing case since it is unclear who should bear the increased costs: the bandagist or the industry?

BB: Having said that, it is true to say that the relevant authorities are actively looking into the said pricing and reimbursement issues. For instance, Jo De Cock, the CEO of INAMI-RIZIV, is at the forefront of deliberating on how the pricing and reimbursement procedures can be improved, how to accurately value drugs and how we can look at pricing differentiation across European countries. His efforts have helped to introduce some progressive ideas to the process. In fact, I believe that the overall system needs to catch up with some of the ideas being circulated by the officials. Therefore, the issue is not that the authorities are oblivious to the challenges in the market. Rather it is a question of how to best introduce new ideas to the pricing and reimbursement subject during financially constrained times. This is undoubtedly a topic that extends far beyond Belgium and includes many countries in Europe and beyond.

AB: On the other hand, turning our attention to the cost environment, if you were to look in to the tax regime here, Belgium offers some extremely innovative ideas. For instance, life sciences companies are presented with highly attractive incentives such as low taxes on locally registered patent revenues, fiscal incentives for R&D investments and reduced payroll taxes for R&D personnel, among many others. These represent all of the incentives one might hope for where there is a strong presence of research institutions, teaching hospitals, universities and rich talent pool within a focused area where they can create a virtual cluster with commercial investments. This demonstrates that there is no shortage of clever and innovative ideas in this regulatory aspect. Instead I believe that the pricing and reimbursement issue is the weakest link in the chain and the

authorities understand that.

Generic drugs are often seen as the key to controlling ballooning healthcare costs and free up resources to invest in new and innovative drugs. However, the level of penetration of generic drugs in Belgium is quite low. How would you characterize the generics industry in Belgium and what developments have emerged recently?

AB: The authorities have recently introduced a number of new measures designed to promote the increased use of generics throughout the healthcare system. Since a while physicians and practitioners are required to meet certain targets with regards to the prescription levels of generics as compared to innovative drugs.

In February of this year, the authorities introduced a new law that further encourages the prescription of generic drugs. With this new measure physicians are still endowed with the freedom to prescribe what they feel is most appropriate but at the same time pharmacists have the right to substitute to prescribed antibiotics and antimycotics other cheaper medicinal products assuming there are no adverse effects from allergic reactions for instance. Going a step further, INAMI-RIZIV decided as of May 1, 2012, that they will no longer reimburse the prescribed antibiotics and antimycotics if the product prescribed is not the cheapest available option. In that respect, they are issuing, on a monthly basis, a list of the cheapest medicines that are eligible for reimbursement. Of course, patients still maintain the option to use the innovative, and often more expensive, versions of the substitutable antibiotics and antimycotics but will in turn bear its full cost. Hence, there is a trend towards the increased use of generic drugs in the Belgian market. Needless to say however, these measures have been strongly criticized by all stakeholders.

BB: I think the industry understand that there is a symbiotic relationship between the innovative pharmaceutical industry and the generics. Through by utilizing generic outputs, governments can control their healthcare costs while freeing up resources to invest in the latest innovative drugs. However, in reality the authorities in Belgium are signalling to the innovative industry that their new medicines are no longer a priority by not reimbursing them. Hence, I believe it is unfortunate that the logic behind the patent system is never entirely followed through by governments including Belgium. Conversely, it appears to me that if the patent system was being properly honoured, that would provide a more sustainable way of ensuring that their resources are focused on signalling to the pharmaceutical industry that they will be compensated if they supply the market with value added drugs. However, that is not the message they are currently portraying. Instead they are signalling that they are prioritizing dated technologies while the latest drugs are no longer urgent. Certainly, this phenomenon is not unique to Belgium but is prevalent in many markets. It seems to me that there is much room for improvement in that respect. That is if they are to implement increased levels of generic substitution, they must at the same time indicate to the innovators that they will be adequately compensated for their efforts if they can demonstrate a positive therapeutic

and economic cost-benefit analysis of the new drugs they develop.

To what extend does B&M conduct lobbying activities with public institutions like INAMI on behalf of your clients on regulatory topics and market access concerns?

BB: Ultimately, it is entirely up to each country, Belgium included, to decide whether or not it will purchase any given pharmaceutical or healthcare products. EU law can certainly frame the process in which they chose to do so or the transparency or fairness of the procedure. We can also stress the requirements of patients by pointing to the patient groups who can campaign on the benefits of certain drugs for their illnesses as part of the dossiers we submit to the authorities. However, taking the decision to take direct legal action against a pricing or reimbursement decision is challenging. If the decision is overturned, the company needs to start again from scratch making the case on why their drug should be reimbursed.

It is often more effective and successful for us to advise our clients on the arguments to make and connect them to the right people in the right places. Interestingly, the last thing you would want is to have a lawyer in the room because officials tend to be far less expansive and open in their remarks. Hence, the most successful lobbying strategies are often the ones where we advise clients on the lines of arguments they should be stressing and then pointing them in the right direction to get in touch with the right people.

A little over a month ago, pharma.be finally signed a stability pact last month with the Ministry of Health by which the Belgian State commits to create a stable environment for the pharma sector. To what extent will this stability pact have a real effect on the pharma industry and what opportunities does it present?

AB: Generally speaking, companies that chose to invest in R&D or manufacturing activities in Belgium do not do so in order to capitalize primarily on the local market considering its relatively small size with approximately 11 million inhabitants. Instead they do so in order to capitalize on the country’s very attractive R&D environment and engage in regional and global export activities. Hence, the aim of this stability pact is to create a more favourable environment for the life sciences industry so that they may continue to invest in Belgium. In addition to this, the pharmaceutical industry is a leading employer in the Belgian economy, which serves to increase the importance of maintaining a stable environment. However, whether this will have a real impact is yet to be determined considering that the pact was only recently introduced. Nonetheless, the industry is optimistic that it will indeed have a positive impact.

In July of this year the new EU legislation on pharmacovigilance came into effect outlining a set of new guidelines for the conduct of pharmacovigilance in the EU. To what extent does this new regulation help to consolidate the relevant medicines legislations and what effect has this legislation had on the operations of pharmaceutical companies in Belgium?

AB: In Belgium, the Pharmacovigilance directive has not yet been fully implemented. We are still waiting for the publication of the royal decree and therefore it is difficult to assess the extent of its impact on the industry. However, as a member of the education group of the Belgian Regulatory Affairs Society (a non profit organization which members are mainly industry pharmacists), we have organized training seminars on the subject matter for our members. Throughout these seminars the Federal Agency explained the details of this new pharmacovigilance provisions to the pharmaceutical companies. Overall, it seems to me that the industry has reacted quite positively to the new legislation which I also believe were necessary to establish a better system for pharmacovigilance.

One subject area within this legislation that I have been receiving a large number of inquiries relates to social media tools. More specifically, module VI of the good vigilance practices outlines under its section B.1.1.4, the obligation for the marketing authorization holders to “regularly screen the internet or digital media under their management or responsibility for potential reports of suspect adverse reactions.” In particular, they are responsible for screening internet domains such as their own website and their own social media pages for potential adverse effects. This represents another facet of the pharmacovigilance regulation which grants patients the right and opportunity to report any adverse reaction they may have. In addition to this, the definition of adverse effects has now been broadened to include excessive or off-label use, for instance.

Overall, I believe this move towards patient empowerment is a fantastic step forward since patients are the first to learn of any adverse effects and this allows pharmaceutical companies to make use of that information and address the relevant issue. In addition to this, by exposing themselves to the feedback of their patients, pharmaceutical companies can learn a great deal about their products and patient’s attitudes towards them and use that information to enhance for instance the packaging, taste or appearance of their product. Nonetheless, there are still some challenges for the seamless integration of this provision. For example, there are not stated guidelines on how exactly companies should be collecting the information they gather from the internet and social media. Finally it is likely that an important part of the information collected from patients’ reporting will not meet the 4 conditions for effectively reporting adverse reactions.

Mr Donald Niesten of Deloitte highlighted that owing to their dedicated team of life sciences experts, they are able to address each market segment of the life sciences industry across the entire life cycle. In that respect, what would you say makes B&M unique? What makes the firm the partner of choice to potential clients?

AB: I believe that our ability to rapidly advise our clients in a broader context, going beyond Belgium alone, to include their other territories of relevance within a 24 to 48 hours’ time is a significant differentiating factor for Baker & McKenzie. Our global coverage and expertise is certainly a strong competitive advantage for our firm. For instance, even in India, a country that is

reputed for the difficulty associated with establishing ones operations there, we have a very respectable correspondent law firm there that allows us to promptly advise our clients on any issues they may encounter. In addition to this, we conduct a range of what we call ‘multi-jurisdictional surveys’ in which we analyse the inquiries our clients have spanning 10 to 15 countries for instance. Indeed, this is something we can execute in a rapid and efficient manner because we possess a dense network of experts and contacts across the world. In that respect, the first thing we do when we approached by a client is to map our foot print of their footprint in order to be able to match their requirements with our capabilities.

BB: The underlying vision of Baker & McKenzie is not to have a central office in one location that concentrates its expertise in that space, but rather to have a widely dispersed and all-encompassing presence of its expertise across the world. Fundamentally, this is what shapes the Baker & McKenzie as a full service firm. Of course this is paramount because it is clear that the answer in each country to any given subject matter will differ from the next country. This is what makes us local experts, with a global mind-set.

In conclusion, where would you like to take the life sciences operations of B&M in to following 2 to 3 years and what goals would you like to realize?

AB: This year has been the year of changes in the pharmacovigilance system, over the next year, the medical devices industry in Belgium will be undergoing significant changes as a result of the PIP scandal that arose in 2011. Amending the legal framework for medical devices is one part of the priorities of the Medical Devices Plan of the Minister of Health. It is to be expected that the traceability system the Minister of Health wants to implement will become effective next year and that Belgium will not wait for the adoption of the new regulation on medical devices. Thanks to my many contacts in the medical devices sector, I have a good understanding of the background of the formation of this new law which should allow me to gain a better understanding of this law when it will be adopted. On the other hand, with a background as an assistant at the university (UCL) with a passion for analysing and writing, I had the chance to participate with 16 other authors in the writing of a Treaty on pharmaceutical law (Traité de droit pharmaceutique published by Kluwer in June 2011). As this project is now completed and in view of the upcoming development in the medical devices sector I have been encouraged with Olivier Mignolet (lawyer at Simmons & Simmons Ltd.), by the industry to produce a similar study on the medical devices industry since there is a shortage of such writings. This will be our next challenge since there are a number of issues in the industry that have not been fully addressed including promotional activities for example. For too long, medical devices have been forgotten or treated as medicinal products (which is inappropriate) with no specific guidelines. Needless to say, these industries are widely dissimilar and that is another element driving the expected changes in legislation. This has been made a priority by the Minister of Health, Minister Onkelinx, whose hope and will are, I believe to have a the new legislation adopted and implemented before the next round of elections in June

2014.

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