Interview with Stefaan Vancayzeele, Vice President of BeAPP, BeAPP

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Can you provide us with an overview of BeAPPâ??s missions & objectives and your role as President of the association?

Stefaan Vancayzeele (SV): The primary mission of the Belgian association of pharmaceutical physicians is to support and represent the interests of its members throughout their careers. In addition to this, we aim to enhance their professional standing and to proactively foster relations with the appropriate bodies. We strive to represent ourselves as a platform that will enable our members to learn about pharmaceutical medicine and be kept up to date with the latest developments in the environment.

Since its founding in 1972, what have been the associationâ??s most significant milestones and achievements for its members?

SV: First and foremost, I believe that the creation of the association is an important milestone in itself. Following the increasing complexity and usage of systems and methodologies in clinical research, there was an absolute need to create the Pharmaceutical Medicine speciality. Moreover, I would say that this has not been a revolution, but rather a continuous evolution towards a deepened understanding of the clinical research methodologies and how to cope with them, in a comprehensive range of topics. This includes educating our members on the development of good clinical practices (GCP), pharmacovigilance, ethical and legal aspects as well as in the post approval environment including life cycle management of products and risk management plans, among others.

What are the key topics on your agenda today that you would like to address as president of BeAPP?

Monique Podoor (MP): Belgium is a small but interesting country because it is not managed in a way that is comparable to France or the Netherlands for instance. Therefore, rather than focusing on key topics, we have been proactive in addressing issues when possible while reacting ad-hoc to specific situations as they arise. Over the last few years, we have established a good network of contacts with all stakeholders in close cooperation with pharma.be â?? the association of the pharmaceutical industry. This collaboration has grown much closer over the last few years and I believe that we have successfully established BeAPP as an association representing a specific area within the pharmaceutical industry. That is, BeAPP is regarded as one of the competent bodies that can contribute to the development of our industry in the context of technical expertise and innovation.

Overall, the scope of our activities has widened significantly since the founding of the association, where there was a more specific focus on clinical research. Currently, we have a more global outlook that extends beyond the medical and clinical development departments to include the post-approval management of drugs, for example.

Belgium is renowned for its leadership in biopharmaceutical and clinical research. However, referring to pharmaceutical physicians; how would you rate their level of expertise and quality and is there room for improvement in their career development?

MP: I do. I believe that the quality level of both the researchers and investigators is very high and they tend to be regarded highly by the international industry, helping attract many companies to Belgium. Moreover, through the 2004 directive that was introduced in Belgium through our support, Belgium was endowed with having very short timelines in the review of authorisation request helping improve the countryâ??s attractiveness to the industry. As a matter of fact, due to these short timelines and the assured quality standards, Belgium is also regarded as a â??pilotâ?? or even a â??rescueâ?? country by pharmaceutical companies with respect to conducting clinical trials.

Overall therefore, there have certainly been many efforts directed towards the development of the local industry, especially from the government and the medicines agency. Nonetheless, despite their efforts, the system as a whole is far from being perfect but we are pleased to be partnered with the relevant authorities that indeed are doing their utmost to develop the countryâ??s potential.

SV: I absolutely agree that Belgium has a very attractive clinical research industry that has become, to some extent, a tradition for the country. Moreover, with several pharmaceutical companies headquartered in Belgium, research and development has been a familiar activity to the Belgian society. This also means that within these companies, as sponsors of foreign based clinical studies, there is a long standing tradition, experience and expertise in all sorts of clinical development and other Pharmaceutical Medicine related aspects. Interestingly, in fact, owing to its dense infrastructure of academic centers for example which all have phase-I units that naturally share their expertise and experience with each other which highlights an important asset of the country. Together with the health authorities, the local industry could be considered as trend setting in the â??first in manâ?? policies, denoting that proof of concept studies are often executed here as well. Of course, conducting such studies here also boosts other confirmatory trials that are subsequently also carried out. A final important thing to note is that the Belgian society is rather positive towards research and development, facing less resistance in patient enrolment, for instance. It comes as no surprise therefore that Belgium is sometimes quoted as the â??Pharma Valleyâ??.

Considering the wide range of roles that medical physicians can occupy with the pharmaceutical industry, what are the most prevalent positions your members assume and how do you see this trend evolving? Are there gaps in the market?

SV: Referring to the fact that Belgium is really a country representing both affiliate and headquartered companies, you would encounter any type of profile of physicians. For instance, you could come across physicians that are active in headquarter centers in the clinical development programs as well as in the large safety departments. On the other hand, there is perhaps even a stronger presence of medical physicians in the pharmaceutical affiliates, for instance assuming pre-commercialization roles. Overall, I would say that there are about 400 â?? 500 physicians working in the pharmaceutical industry, not all of which are members of BeAPP, employing almost every possible profile, from basic research to managerial functions including CEOâ??s.

Has the strong presence and reputation of the pharmaceutical industry in Belgium served to attract talented physicians from abroad or

is there a looming risk of â??brain drainâ?? due to an oversupply?

MP: With respect to employment standards at local affiliates, Belgium is unique since people would have to be at least tri-lingual in order to be able to understand and function in the environment. Therefore, the dynamics of the local talent pool in Belgium is rather neutral. In the academic setting however, I believe that there is to some degree a larger prevalence of talent mobility; however, I would not go as far as classifying it as brain drain.

SV: A significant proportion of our association consists of physicians working not only at the local affiliates but also outside these circles. For example, the local recognition of Pharmaceutical Medicine relies on physicians working in other countries abroad as well who try to remain linked to Belgium. Therefore, we see that a certain proportion is working abroad but an important brain drain is fortunately not the case.

BeAPP has organized a lunch meeting to discuss the EUâ??s new proposal for clinical trials. Can you provide us with a sneak preview of what in your view will be the impact of this new directive on the pharmaceutical industry and your members?

MP: This is my personal view: it was the first time that I saw a text which is so clear, comprehensive and unambiguous. Of course, looking into the finer details, there might be room for discussions; however, in the broader sense we can only agree and praise the efforts that have gone into making such a straightforward framework.

By comparison, the preceding directive â?? which aimed to put Europe at the forefront of clinical trials â?? failed to stimulate the harmonization in clinical trials across. Instead, each country within Europe was able to implement the directive in their own manner, as long as it met the requirements of the ordinance. As a matter of fact, as a result of the pan European incongruence, the administrative burden and costs of international trials soared.

By 2009, costs had risen by 40%, prompting all industry members to voice their concerns over the resulting consequences. Although it has been a long journey since, we are all very pleased with the progress we have made so far.

On the other hand however, a side effect of this harmonization could be the erosion of Belgiumâ??s competitive advantage of rapid approvals. Therefore, I would recommend that Belgium proactively incorporates the new framework as soon as possible in order to maintain its competitive advantage ahead of other European countries. In that context, I believe that this should not be a very challenging task since the Belgian industry is already experienced with short timelines and, to some extent, possess the necessary infrastructure.

What is the importance of partnerships and collaborations for BeAPP with other industry associations and administrative bodies in order
to ensure the best environment for its members and the industry?

MP: In Belgium, the collaborative activity among the medicines agency and the industry is rather strong. Certainly, there is a healthy degree
of discussions, consultations and goodwill from both sides of the table.

SV: In Belgium, in general, all stakeholders are on a level playing field. If we look at the pharmaceutical conference that we co-organized with pharma.be in April of this year, there were many points of agreement with regards to the way in which we can advance. This is especially applicable in the context of the academic as well as research and development fields.

MP: For instance, in 2010, we established an initiative together with pharma.be, BeAPP, BAPU (Belgian Association of Phase-I Units) and ACRP (Belgian chapter of the Association of Clinical Research Professionals) to maintain the countryâ??s competitive and highly attractive clinical trials industry. To that end, we mandated a report by PwC (PriceWaterhouseCoopers) that detailed the economic footprint of clinical trials in Belgium including a strategic plan to promote them.

SV: In deed, and I believe that the initial merit lies in the fact that these types of initiatives actually exists. Certainly, this helps to build awareness among relevant persons and organizations as well as tools to measure current performance levels and note the evolution.

In conclusion, looking back on your collective years of experience as presidents of the association, what are the main lessons learnt and where would you like to take BeAPP in the next 2 to 3 years?

SV: As an association, I think that it is imperative that we are well organized. Along with the increasing complexity of the pharmaceutical industry, we see that the time availability of our members and ourselves has been decreasing, limiting the time we have to analyse the core strategic items important to us. Therefore, together with Dr Podoor as former president of the association, we have both endeavoured towards professionalizing the organization so that the board and its members have more time to focus on their strategic imperatives.

MP: Another central issue that we wish to address is related to the fact that Pharmaceutical Medicine is not a recognized speciality. This is because the traditional role of a physician is to treat patients. Thus the issue in the case of pharmaceutical physicians is that since they do not engage in any reimbursable activities, meaning that there is no institutional body that is able to deliver recognition for the profession which is entirely unlike other specialities. After all, this has been our goal since 1972.

SV: To that end, I also think it is important we continue to develop BCPM â?? the Belgian College of Pharmaceutical Physicians, a sister association, if you will, of which academics and BeAPP are the co-founders â?? and its role as an independent accreditation body that maintains a list of pharmaceutical physicians that have been established in Belgium. Once the profession is properly recognized, only then can we ensure formally the quality of the medical people in the pharmaceutical industry. Moreover, on a European level, there is an increasing trend towards this recognition through the Innovative Medicines Initiative (IMI) which has several branches focused on making such formal trainings and qualifications available and even mandatory.

Similarly, we are also directing our attention towards attracting younger members to BeAPP that are insufficiently aware of the importance of Pharmaceutical Medicine.

MP: Actually, this highlights another reason as to why we are so dedicated to the recognition of the profession. That is, as practitioners transit into the pharmaceuticals industry from a general practitioner or specialist background, their careers are left virtually unprotected since they may have halted their permanent education â?? a prerequisite for exercising the medical profession in Belgium. Therefore, if for whatever reasons a pharmaceutical physician wants to transition back to becoming a practitioner, he will not be able to do so. This is certainly a topic that we are very conscious of and we understand that it is an important one for the younger generations.

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