Interview: Philipp Lindinger – Managing Director, Austromed, Austria



"Our main occupation is to push forward the advancement of our members' interests. Shaping regulations and laws is a lengthy process and we work closely with similar European associations to homogenise the regulations across countries"

10.10.2017

Tags: Austria, Austromed, Medtech, Association, Regulatory Reform, EU

Philipp Lindinger, managing director of Austromed, the Austrian association for medical devices and in-vitro diagnostics, discusses the organization's purpose, the impact of European regulation on medical devices on the sector, the importance of a strong notified body system, and the steps required to stimulate future growth within the Austrian medical device ecosystem.

What are the key objectives of Austromed?

Austromed is the Austrian association for medical devices and in-vitro-diagnostics. We currently have 115 members who represent around 45 percent of the annual turnover of the medical device segment.

Our main occupation is to push forward the advancement of our members' interests. Shaping regulations and laws is a lengthy process and we work closely with similar European associations to homogenise the regulations across countries; therefore, we benefit from complementary expertise. At the moment, we are looking forward to the implementation of new EU-regulations on medical devices and in-vitro-diagnostics that have recently come into effect. Additionally, innovation and patient safety are our main topics as these segments' regulations affects the country's attractivity, which has been compromised by recent innovation hurdles.

On a side note, we engage in awareness campaigns for the public. I consider it important that the information on medical devices is widespread, allowing everybody to understand what medical

devices are and how indispensible they are in daily life.

How do the new European Union regulations on medical devices and in-vitro diagnostics affect innovation?

To a certain extent, these new regulations will slow down innovation as the rules that have been set are much stricter than in the past. While these regulations should serve patient safety, in my opinion, it does go overboard in some areas. Every country of the European Union will be affected; although, it was positive to see regulations being harmonized as it has the possibility of ensuring a sense of transparency throughout the European medical device community. Unfortunately, the rules passed are so complex that it has encountered objections.

This complexity is to a point that the approved regulations consists of around 350 pages, regulating from the manufacturing processes to the market access conditions of new medical devices. The ruling established specifies specific processes in terms of proving efficiency as well as the production and registration of products depending on different risk categories of medical devices, especially in the field of in-vitro diagnostics. The main novelty of this law is the detail in terms of conditions to obtain a CE mark.

Austromed expects this ruling to affect small companies to a broader extent more than larger ones, as these companies will lose their advantage in a short turnaround from R&D to obtaining market access; therefore, taking more time for products to be available in the health sector and generate revenues. Furthermore, this regulation affects the governmental bodies in certain countries as many notified bodies which are required for the approval process have closed down due to the structures in place not being able to cope with changes. In Austria, both notified bodies discontinued their activities at the end of last year which is a huge economic disadvantage.

[Featured_in]

What should be done to preserve the current status of notified bodies?

It is of paramount importance a strong network of notified bodies is maintained across Europe to defend the interests of the patients and smaller scale companies. Eventually, strengthening international cooperation of notified bodies could create employment opportunities also. Austria is currently attempting to attract the main EMA in its capital. While I see the economic and reputation impact of such an institution installing itself in Vienna, I am convinced a strong notified body interaction at an international level could have the same repercussions in terms of positive benefits

Austromed, has started widening its network by reaching out to all the health clusters in Austria, as well as research institutes. We must work as a collective group to come up with solutions that benefit the entire healthcare network and foster patient safety.

How would you view the medical device environment in Austria compared to the greater European community?

Austria is known for its distributors of medical devices rather than its manufacturers. Looking at larger companies, production in Austria is an uncommon occurrence as most of these companies choose to position themselves in Germany or Switzerland – while in the meantime – simply distributing their products in Austria. Despite our split being largely in favour of distributing companies in Austria, around 20 percent of our members produce here and we would like to continue recognising the importance of this for the domestic medical device community.

You have mentioned the negative effect of the latest EU regulation on smaller companies. What should be done to promote and protect their interests so they can eventually grow into prominent players in the medical device sector?

In my opinion, a strong network of governmental bodies promoting the funding and investments of these companies is mandatory. Of course, you find examples of some companies that are bought by larger players, however this is less common. The opportunities and incentives for companies to develop their capabilities rather than being bought is more favourable. Unfortunately, the current Austrian regulatory environment is no more favourable than the EU on and our members, and we believe innovation is not rewarded enough and tax rates are burdensome. Indeed, the government has set pricing and margin thresholds even in the case of innovations. It is against the stream of any entrepreneurial academia and raids the innovation spirit.

[related_story]

What additional structures can be put into place to create an innovation friendly environment?

Many companies struggle to get past their mid-size stage because of funding problems. They do not have the necessary resources to increase their capabilities, enter new markets and develop their portfolio. Therefore, funding is an opportunity for improvement and could be just the right push for these companies to kick start their rapid growth.

Which are the real drivers within the Austrian medical device ecosystem?

The medical device market is extremely diverse. There is an abundance of stakeholders, probably more than in any other segment in the healthcare sector because of the diversity of locations where medical devices can be found. While no perfect strategy exists, the most commonly adopted strategy in the market is to become a highly specialised player from which a niche market becomes dependent on your product. On the other hand, certain companies have chosen to focus in a larger range of sectors – although – if you have your focus on many sectors at once, managing the relationship with the customer will always be more complex.

All in all, the key element to success is to have a product that is lifesaving and innovative. Not only will competition be far less intense, but the regulatory authorities will be more favourable in terms of market access; therefore, ensuring a win-win for both government and company in terms of pricing. Often competitive areas of treatment are subject to tenders and less interesting. The governmental bodies look only at the upfront costs of acquisition because the holistic approach to the adoption of a new solution is highly complex and controversial at times.

What more can Austromed do to help create a sustainable medical devices environment for the long-term?

I would like to see a type of campus supporting start-ups, creative minds and think tanks. It is important that we go the extra mile to help these types of companies bring more products into the market. Furthermore, we want to provide more advisory services to help these companies navigate the opaque regulations in Austria. It is not usually the role of those who come up with the brilliant product ideas and innovations to know equally how to find expert solutions to gain market access. Nevertheless, before anything like this can happen, we must actively collaborate with existing start up associations to ensure our contribution fits into the current systems already in place.

See more interviews