Interview with Marcus Müllner, Agency Head, Austrian Medicines and Medical Devices Agency (AGES Medizinmarktaufsicht)

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In your opinion, what have been the most important developments of the healthcare market in Austria over the last three years?

To start with, even though we are a national competent authority , regulating medicinal products and medical devices is not only a national responsibility: whatever we do, we need to have the European Union network in mind. In my role as head of this agency, I can only pinpoint EU developments, rather than national events. Taking this angle, the implementation of the new pharmaco-vigilance legislation has certainly been one of the main positive changes.

Being a competent authority, we try to minimise both the administrative burden and the costs for ourselves, but also for applicants, which is an ongoing process for us.

Healthcare members in the EU seem to be fairly connected, but when we talk about healthcare, there are probably as many systems as countries. How much work is done at the European level in terms of harmonizing healthcare systems and policies- working together to find the best sustainable future for the countries?

Talking about harmonising health careproducts such as medicine s, means to consider first of all its workload. There are 27 (plus 3) member states in the European Union, and currently more than 46 national competent authorities in total for medicinal products. This is due to the fact that different member states having different structures in each case. In Austria the medicines agency is

responsible for human and veterinary products, medical devices, as well as blood and tissue. In some member states, however, they have human and veterinary medicinal products separated and sometimes the signal detection of medicines is outsourced from the agency. For centrally authorised medicinal products the European Medicines Agency (EMA) is the scientific secretariat which is manned in terms of scientific knowledge by each national competent authority. Annually on average 20 to 30 full-time equivalents from each national competent authority spend their time either physically in London at EMA working groups or scientific committees or by keeping on working in their countries on European issues. This is a bit less than 10 percent of our total staff. EMA also has a permanent staff providing the administrative background.

In addition, we have the decentralised and mutual recognition procedures (MRP/DCP) which make up the majority of our work. We do about 1000 authorizations every year in the EU; several thousand variations, a third of which are Type II variations. We also have a lot of work with pharmacovigilance, such as adverse reaction and periodic safety update reports. Therefore at the level of ensuring the quality, safety and efficacy of medicinal products, the operative, strategic and legal co-operation with other states is very high.

Healthcare as such is a different matter and a very national or even regional issue in each country.

All over Europe, the healthcare systems have undergone increasing financial pressure, a pressure that affects both the industry and the institutional and governmental bodies. As a national medicines and medical devices agency, how challenging is it to make sure that cost containment does not lead to a compromise on quality?

That is a tricky question and I can only answer from a regulator’s perspective. There is cost containment pressure, particularly on the side of the industry, but we don’t make any revenues but bBy law we are required to cover our costs. Between 2006, when the Austrian agency was founded and its tasks were outsourced from the Ministry of Health, and 2011, the applications and attached income involved were growing between 14-20% each year. Accordingly personnel grew as well, although we also achieved more efficiency gains. 2012 was the first year when we reported only 1% growth, and we are expecting it to remain at that level also in 2013. Sometimes we get withdrawals when companies sift through their portfolios in order to adjust it accordingly.

I strongly believe that the efficiency of co-operation among member states needs to be improved. That has been an on-going issue for years.

How would you compare Austria with its European counterparts in terms of healthcare delivery, and how do you think Austria is seen by your colleagues?

Well I don’t know other systems particularly well, but I would rather be a patient here than anywhere else! In terms of how we regulate our medicinal products, it depends on the indicators you are using to compare yourself with other member states. In relation to its population Austria has an average sized authority and in terms of pharmacovigilance staff we are still of average size, but on the upper limit. Regarding how many case report files are submitted to us- our reactive pharmacovigilance system- we are ranked in WHO as 18th worldwide, and 6th in the European Union. Our system works very well since we were outsourced from the ministry. We also rank 7th in the European Union reference memberships for MRP/DCP procedures. For the European Medicines Agency scientific advice, Austria is ranked as number two, but again this is quantitative. In co-operation with the European Directorate of Quality and Medicines (EDQM) for the Certificate of Suitability, Austria also ranks second.

So Austria is active and we are doing our share. Sometimes we do more than would be expected for our size and I think in terms of quality we enjoy a good reputation.

You mentioned pharmacovigilance, but your agency is also responsible for many other things including inspections and regulation of herbal medicines. What have been your areas of improvement, and the hot topics for 2012?

The problem in 2012 was to deliver the same quantity and quality of work despite the stagnation in income. Although a stable growth had been forecasted, we had to face a decrease in turnover later the year. As a consequence of it we have had to work on the operational and organisational structure more accurately. We had to think a little harder and perform some internal restructuring. By what others say about us, I believe we are very Austrian in the sense of being pragmatic with many things. For example we are publishing a regularly updated list of submission slots in order to submit DCP procedures. Another example of our pragmatism noticed by the EU Member States is that we accept English texts for product submissions, as long as they have not been put on the market yet, to speed up the process.

What are the objectives you have set yourself in the coming three to four years, and what would you have liked to achieve in that time?

Our objectives have not changed. First and foremost we have to fulfil – the European and national regulations with an adequate quality. On the more visionary side we are very pro-European Union, so it is one of our strategic aims to take a good part of the burden of cooperating with the European Union within the network, and we would like to do that in spite of shrinking resources.

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