Interview: Christa Wirthumer-Hoche – Head, Austrian Medicines and Medical Devices Agency (AGES); Chairwoman, EMA Management Board, Austria

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Christa Wirthumer-Hoche, head of the Austrian Medicines and Medical Devices Agency (AGES) and chair of the European Medicines Agency (EMA) management board, discusses the role of AGES within Austria, similarities with other countries' regulatory agencies, Austria's potential as an innovation hub, and the possible relocation of the EMA to Vienna in the wake of Brexit.

AGES and BASG (Austrian Federal Office for Safety in Health) are often compared to the US FDA, what are the similarities and the differences?

First of all – Austria is bit smaller than US. Compared to the US FDA which has eight separate units, AGES has six: the Agency for Medicines and Medical Devices, Food Safety, Food Security, Animal Health, Public Health and Radiation Protection. So AGES is not only responsible for the medicines but also for food, plants and animal health and all topics related to public and animal health. The owner of AGES is the Republic of Austria, represented by two ministers: the Federal Minister of Health and Woman's Affairs, as well as the Federal Minister of Agriculture. The BASG is the link that connects AGES to both Ministries.

Is there a synergy between BASG and AGES?

BASG is the official body where all the applications have to be submitted. AGES provides the necessary resources such as HR, IT infrastructure, and management facilities. Finally, the certificate is issued, again, by the BASG to the applicants.

BASG is a small unit and is composed of three members: the first member is from the ministry, the second member is an expert, and I am the third member with my position as head of the Austrian Medicines and Medical Devices Agency. Together, we sign the authorizations and the certificates.

How do you think the other countries of Europe perceive Austria?

Austria is a rather small country with a mid-sized agency in terms of staff members, but we are a very active partner in all the scientific work in the European network. We play an important role as Rapporteur or Co-Rapporteur in the centralized procedure – new applications and life cycle management as well as within the scientific advice procedure.

We are Austrian, so for us, research & development that benefits the economy of Austria is important.

Financial pressure severely affects the healthcare industry; does it also affect the agencies?

The pharmaceutical industry was affected by the financial crisis, perhaps a little bit later than other industries, but this affected the Austrian agency too, because we got fewer applications.

What initiatives did you undertake to increase the level of applications?

We cannot really influence how many applications the industry submits. But we changed our culture a bit, we did not just wait for applications, but informed our applicants openly about our services and the advantages/unique selling propositions (USP) of the Austrian Agency. So we became attractive to existing and new applicants.

Our European work plan involves revisiting our regulation and administrative procedures and doing our best to take out anything deemed unnecessary for the pharmaceutical industry as well as for us.

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What are the different steps to revisiting the regulation procedures?

The regulatory world is very strictly regulated. However, there is some room for manoeuvre. In Europe, we are work-sharing because the idea is that we have one responsible EU-member-state,

being responsible for the assessment (RMS – reference member state), and the other EU-MS concerned (CMS) will mutually recognise what has been done by the RMS. Otherwise, it would not be possible to fulfil all the regulatory requirements. As an agency, we recommend that companies take into consideration especially our expertise when choosing the RMS, but this flexibility is only possible in the decentralized and mutual recognition procedure, not for the centralized procedure.

Submitting variations or maintaining the marketing authorizations for products means a lot of work for the industry and regulatory agencies, so we are considering the procedures and for example, looking more into the digital workflow, using digital databases. In this world, we must change our regulatory procedures because most of the legislation for the moment is paper-based. 10 to 15 years ago, we started with electronic submissions, now we are fully there. We were just discussing whether to use cloud systems. We are in a digital world and we should learn how to use it. Also, to optimise the regulatory procedures at the European level, EMA and the Heads of Medicines Agencies (HMA) have founded a working group – the ROG (Regulatory Optimization group). It was created to improve the regulatory procedures.

As Austria's regulatory agency, the majority of your work is in market authorizations, but could you tell us about the other services you provide to companies?

We are not only an agency that deals with submissions from the pharmaceutical industry for new applications or during the life cycle, but we also expertise in scientific advice regarding questions related to development of medical products. We invest in the harmonization of the assessment process of Clinical Trials. In 2015, 305 clinical trials were submitted. We are active in assessing Pediatric Investigation Plans and pharmacovigilance, importation of medicines, marketing surveillance and defect products.

We are also very active in the area of inspections – GMP, GCP, GLP, GVP. In the EU we also have worksharing and mutually recognition of inspection reports, so we rely on the expertise of another colleague in the EU, but we do a lot overseas. We now have a mutual recognition agreement (MRA) with the USA, but only for finished products.

Vienna is the world capital for plasma fractionation; we import a lot of human plasma from the USA, so our inspectors go there and this activity will remain also under the MRA. We are also performing inspections in other areas of the world, like India and China. The importance of these inspections is growing.

How do the different Agencies within the EU complement each other?

Depending on the type of medicine, companies are free to choose the authorisation procedure that they want and the Agency they want to cooperate with. For new active substances, the applicants have to submit via the centralised procedure, so via the EMA to the members states. If it is a generic, most of the products using the MRP / DCP procedure. Therefore, the applicant can choose the reference member state(RMS) and the concerned member states (CMS) and submit directly there. After submitting the dossier, it will be validated and assessed. If it is of a high quality and if the requirements are met a short list of questions will be forwarded to the applicant, answers will be received and at the end, hopefully there is a positive opinion. The marketing authorisation will be granted by the national authority in each MS – for Austria it is the BASG.

If the company chooses the centralized procedure, the dossier will be submitted to all EU-MSs via EMA, assessed by Rapporteur and Co-Rapporteur and after a positive opinion the European Commission will grant the authorization.

As soon as there is the marketing authorization, the marketing authorisation holder must ask nationally in each member state for pricing and reimbursing. When they get a price, know if the product is reimbursed, and can launch the product on the market.

In Austria we have an independent agency for the evaluation of the dossier of a medicinal product and another independent agency for granting reimbursement. This is good, and it should remain because one agency is accepting the dossier according to scientists' rules and standards, not because it is cheap or expensive. Pricing and reimbursement has to take into consideration all the budgetary situation. The only area we are cooperating is giving joint scientific advice to companies to deliver all the necessary data for scientific and economic assessment. This is ongoing especially at EU-level EMA is providing joint scientific advice to companies and HTA.

Can you expand on the positioning of Austria in terms of innovation and development?

For companies investing in R&D in Austria, is it important to have a competent agency in the background. We educate and train our people in life science because we need to deliver the best support and good expertise in those areas for companies that are investing in Austria which are important for our economy in Austria.

What are your objectives for the next few years?

The main challenge currently is preparing for Brexit; the problem right now is that nobody knows what will happen at the end of the negotiation phase. I plan to increase the number of staff at the agency and take on more responsibilities within the EU network in all different activities (like

procedures, clinical trials, inspections). We want to be a big player in the European Network.

Another challenge is the implementation of the new clinical trial regulation. We are cooperating with all the different stakeholder on this issue.

Last week you were in London to discuss the key achievements of the EMA in 2016. As you were appointed chairwoman last year, could you expand on the scope of your role and on your main achievements so far?

It is my first year as Chair of EMA's Management Board. The management board has a supervisory role with general responsibility for budgetary and planning matters, the appointment of the Executive Director and the monitoring of the Agency's performance.

The Agency is responsible for coordinating the scientific evaluation done by the EU-MSs, supervision and safety monitoring of medicines in the EU.

The key initiative for 2016 was the launch of PRIME (PRIority MEdicines), which aims to speed up the delivery of drugs for patients who needs it right away. We focused on what the power of big data could bring in term of safety and improve our ability to detect medicines issues. Last, in the interests of transparency, we started publishing clinical data that support marketing authorisations for new medicines in Europe. We are the first regulatory authority in the world to do so.

2016 was also a year with huge significance for EMA's future. On 23 June 2016, the UK voted for the Brexit. The next step for the EMA is the relocation of all its staff and scientists. The location is still unknown, but in the meantime we have to prepare EMA for its relocation, so that EMA can fulfil is duty – the protection of public health in Europe.

With Brexit meaning that the EMA headquarters leave London, how prepared would Austria be to host the organization?

We are preparing a bid to host the EMA in Austria and will do our best. Vienna is fulfilling all the necessary criteria for the new location for EMA. We have created a brochure highlighting the advantages of Austria, as well as a website, illustrating that Vienna will be the ideal place for EMA. We are looking forward to the decision which is expected in November 2017.

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