AN AUDIENCE WITH…

Thomas Lönngren

After 10 years at the helm of the European Medicines Agency (EMA), Executive Director Thomas Lönngren is set to leave on 31 December. During his tenure, he has facilitated the expansion of the agency, stewarded reform and overseen the approval of hundreds of new drugs. He has also had to contend with the implications of high attrition rates in drug development, safety concerns and the integration of new science into regulatory decision-making. Here, he discusses his achievements, regulatory science and the challenges his successors will face.

Looking back, what do you make of your 10 years heading up the EMA?
A lot of things happened while I was with the EMA. When I started we were a very small agency with 150 staff; now we are more than 850. We've also had a constant flow of reforms. We had the orphan disease legislation in 2000, a complete revision of the pharmaceutical legislation in 2004, the paediatric regulation in 2006 and the advanced therapeutics legislation in 2007. And I think we've done very well at implementing these reforms. We followed all our timelines and delivered tremendous performance, and I am very proud of that.

Any regrets?
We could have moved quicker on transparency, but it has not been easy to do so. There are conflicting legislations, and we also need to protect personal data as well as commercially confidential information. If we had been more proactive on this, I would have been happier.

The EMA, along with the US Food and Drug Administration, have increasingly pushed the importance of 'regulatory science'. What are your key concerns?
In a way, as regulators, we are a little bit of a factory. There are applications coming in and there are timelines to meet, and this occupies most of our scientists. There is little time to take stock and think what tools do we need to develop to address emerging science? For instance, what tools do we need to assess issues of clinical trial design and to look at new manufacturing technology?

Another issue is the methodology of our decision-making. The way we have made our decisions at regulatory agencies, in general, has not changed much over maybe 20 years. There is an assessment by individuals, followed by a committee who discusses things, a vote and then a decision on the benefit–risk balance. But it seems that the volume of information we are requesting from sponsors is increasing, and I am not so sure that the way we are balancing this information has changed appropriately. We need to develop a new science to study our decision-making, and to see whether our decisions improve patients' clinical reality.

What have you done to address these issues?
We have a lot of activities going on within the EMA, and we are also working together with other academic institutions. The most high-profile project we have is an assessment of our benefit–risk decisions, which is being driven by interactions with Health Technology Assessment (HTA) bodies.

These bodies are requesting more and more information from us, and want to understand the basis of our decisions to grant marketing authorizations. So, we have recruited experts to see whether we can develop new tools for our decisions-making processes. We need to be able to explain the rationale behind our decisions to HTAs. What were the important aspects that put high weight on the benefit versus the risk of a medicine, for instance? We need to make sure that our decision-making process is more structured, more quantitative and easier to understand.

Has the EMA done enough to catalyse industry's use of emerging technologies?
I think that industry has struggled to make use of new discoveries, which are mainly coming from genomics and pharmacogenomics, but this is a commercial issue not a regulatory one. Marketing people realize that the treatable population at the time of first approval for genetically targeted drugs will be limited. And, by the time additional indications are approved that could increase sales, the important patents will be out of date. A solution to this extends far beyond the mandate of the EMA.

Are the different legislations in the pharmaceutical field that influence, and steer, the way research is done properly coordinated with one another? We may need to take a more holistic view of the life cycle of medicines, and look at how different kinds of legislations and circumstances steer the development of medicines. Does the patent system reward the right discoveries or does it steer drug development in the wrong direction, for instance?

What other challenges do you see ahead?
I think globalization is an important issue. The EMA was constructed to control things — research and manufacturing, for instance — in Europe, but these activities are not necessarily taking place in our territory anymore. We need to start thinking on a global scale, and working together with our partners in China, India and other parts of the world where manufacturing and research are located.

Advances in science will also change the type of medicines that we deal with. We have responded quite well so far with the introduction of the advanced therapy legislation for example. But if you look 10–15 years into the future, classical pharmaceuticals might be much less common and we may see treatment methods based more on prevention, regeneration of tissue and individualization. These could provide regulatory challenges. Maybe we will also need to move away from the classical vertical view of pharmaceuticals and take a broader perspective. How are other medical tools — surgical interventions, diagnostics and devices — becoming integrated with pharmaceuticals, and what does this mean for our legislative and regulatory frameworks?

Where are you off to next?
I have been very busy, and so my thoughts about where I am going next have not yet matured. But let me assure you, I will continue to work on the regulatory issues that I feel so strongly about.

Interview by Asher Mullard