Interview with John C W Lim, CEO, Health Sciences Authority

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Tags:

Health Sciences Authority

HSA celebrated its 10th anniversary in 2011. How different is the organisation today from when it started?

HSA covers the regulation of health products in Singapore. However, we are quite unique because we also run the national blood service and we have an Applied Sciences Group that looks into laboratory testing, covering forensic services as well.

In the last ten years, important achievements for the regulatory group of HSA include the strengthening of the whole regulatory framework, and the modernisation of the legislation. In 2007, the Health Products Act was enacted. The significance of this Act is that it has a fairly broad scope and gives us flexibility in terms of the subsidiary legislation. This is important because with the rapid development of the whole area of pharmaceuticals and related biotech and biological products, we need a risk-based regulatory approach rather than a one-size-fits-all regulatory system.

The Health Products Act gives us the tool to calibrate the regulation to the degree of risk of the product. While we are planning to port the categories of products from the old legislation to the new, the key ones that came under this legislation initially were medical devices and cosmetics. Now we are moving the whole area of Western Pharmaceuticals under this Act.

We have also introduced more streamlined routes of access into marketing authorizations. Originally, Singapore used an abridged evaluation route, where we would wait for a pharmaceutical product to be approved in another jurisdiction and then we would look mainly at the clinical and quality data. In the last ten years we have strengthened the full evaluation route for products that have not been approved in any other jurisdiction.

In addition, we introduced a third route, a verification route. This is applicable for new drug applications and authorizations, where we have identified reference countries â?? the US, Australia, Europe, the UK, and Canada. As long as we can verify that the product that is coming into our market has been registered in at least two of these jurisdictions, has similar indications, and is from the same manufacturing source, we can expedite the access of this product to the market.

We then extended this approach to generics, and also for medical devices as well. This gives options to the industry in terms of what routes they are using to come into the countryâ??s market. We then refine our pre-market authorization to the level of risk. In areas where the risk is lower, we can expedite access and track products more in the post-market domain.

Another development we have made in the last ten years is in terms of the post-market regulatory framework. Our whole pharmacovigilance (PV) system has been strengthened and now we feed into the IT network across the public sector hospitals to pick up adverse events signals. In fact Singapore is now ranked number one in terms of the number of adverse events per million inhabitants by the WHO-Uppsala Monitoring Centre. This does not mean we have a lot of adverse events, but it shows that the PV system allows us to pick up ADR reports fast and analyze them. Because our population is small, we still share these reports with other regulators to understand the implications better.

We have a fairly robust system in terms of picking up signals early and addressing them proactively. This is particularly in the area of complementary health products that have been adulterated and have caused some significant health issues in the population.

In the area of collaboration, we have extensively cultivated international partnerships. We have signed memoranda of understanding (MoUs) with key counterpart regulatory agencies around the world. As a result, we have very close links with the US FDA, Canada, Australia, China and other counterparts. We have not signed a specific pan-European agreement as yet, but we have MoUs with specific agencies within Europe, for example the UKâ??s Medicines and Healthcare products Regulatory Agency, and the Paul-Ehrlich Institute in Germany.

We have also expanded significantly our links with the ASEAN countries.

Have all of these achievements been recognized?

The WHO, for one, recognizes our system as being appropriate for a small regulator that uses smart regulation. We are focusing on key areas with limited resources.

Although we have grown in size over the last ten years, and perhaps compared to some other countries we may be viewed as fairly large, we are nowhere as large as agencies in the developed world. We cannot just adopt wholesale regulatory systems that other countries use, but find appropriate and smart ways to regulate health products in Singapore.

At the same time, we do not compromise the quality of regulation. We are able to streamline the system so that we do not have unnecessary regulatory obstacles, but we are still in a good position to ensure the safety and quality of health products.

Why is it important to include blood banking in the portfolio?

It is mainly historical why the functions are together.

Before we were created as a statutory board 11 years ago, these functions were all under a division in the Ministry of Health. So when the HSA was formed, these functions were all pulled together. What we have done in the last ten years is to streamline the structure because we actually started off with eight centres of varying sizes. We are quite unique in the world, because you do not find another organization like HSA anywhere in terms of the diverse functions we have together.

Instead of regarding that as a liability, we have firstly attempted to clarify what we doâ??which is why HSA currently has three main groups. We regulate health products (drugs and devices), we have the national blood service, and we have the Applied Sciences Group, which covers both forensic science as well as analytical science. We also do food and water testing.

Over the years we have looked for scientific synergies across the groups even though intuitively you probably would not create an agency like this if you were starting from scratch. But the fact that we have them all under one roof can also help us in our work. We can draw on the expertise within the

other groups that can help the regulatory group in terms of technical or scientific advice, and vice versa, rather than us having to go and look for expertise outside.

In fact, our first core value is â??service to the nationâ?• because we basically see HSA as covering several national centres. In other countries, they may be separately located â?? but again because of Singaporeâ??s small size and the need to be efficient, having this under one roof is advantageous.

What are the main objectives of the HSA Academy and how has it enhanced HSAâ??s activities?

It is still in the developmental stage, because it only began two years ago. Its main aim is not to provide training, as the name might suggest, but it is actually viewed as a platform to help HSA promote itself in terms of thought leadership. In fact, our vision statement is to be the leading innovative authority in protecting and advancing national health and safety.

This idea of thought leadership is very important for HSA. The purpose of the Academy is to push the thinking and the boundaries of how we can do things, so we can be innovative and actually multiply the scope of what we are doing across the whole range of HSAâ??s functions.

In partnering with institutions around the world, what is Singapore bringing to the table?

Collaboration is critical. I do not think there is a single regulator, no matter how large, that has the solutions to all the issues that are being faced. So for example, while the developed regulators have been focusing more on the issues in the Western world, now with the rise and development of Asia, we also have to look at issues that may be more Asia-specific, but will have a link to the rest of the world. I think we can help bring issues to the table to discuss international collaboration, and we are also looking at new development paradigms.

There is an MIT-based project called NEWDIGS (New Drug Development Paradigms), which is looking at whether, for certain types of products, we can allow an â??adaptive licensingâ?• approach. So if you are looking at products which, in the traditional drug development phase may take a longer time for regulatory approval, through NEWDIGS, it may be possible to allow some of these carefully selected products into the market earlier and track them in a real life, closely monitored situation.

In adaptive licensing, you could potentially introduce a product with conditions for limited populations, track it, and then either enlarge or refine the scope of the use of that particular product.

This is in a conceptualisation stage. We are involved through MIT with the FDA and EMA, and several of the big pharma companies and some Contract Research Organizations have also become part of this project. We are trying to find candidates that potentially can go through the system. While HSA is willing to try, we are very judicious, and it must involve a product with a favourable safety profile and have conditions that are relevant to our demographic profile, like for treating chronic diseases.

Singapore is recognized as being good in terms of systems and then implementing them in a way that is effective. I think this is where we have been able to make headway and bring value to the table when we are sharing with our international partners.

We are very well networked in Singapore as we are small, so we are able to track things, for example in adverse event monitoring through the databases which are in the hospitals. This is something that other countries may find some difficulty in implementing, but because the whole IT infrastructure in Singapore is strong, we can do it in terms of signal detection and potentially data

mining in the future.

The cost of registration is an issue. How can the HSA collaborate with the local industry on such matters?

This is linked to the whole philosophy of business in Singapore. With cost comes assurance of standards and quality. We do have a lot of dialogue, not just with the big Multinational Corporation players, but also the local Small and Medium Enterprises. I think the important thing is that we get their feedback. What we have also tried to do is streamline the kinds of regulations and processes we have so there is no unnecessary cost.

We have been working very actively with them to minimize regulatory costs because we are very conscious that it is to no oneâ??s advantage if we have a lot of regulatory obstacles and at the end of the day, people cannot do business. However, because we are benchmarking internationally, we have to set the standards to international standards â?? and that in itself brings a certain cost, in terms of expertise and international connectivity.

Is the India-Singapore MoU going to also apply to the non-generic drugs of multinationals?

When India and Singapore signed a free trade agreement, there was an agreement that we would introduce an expedited route for generics. That was viewed as part of the broader plan to introduce an expedited route for generics from any source. India was the first, and it still, under the terms of the free trade agreement, has a slightly shorter turnaround time committed to it.

The approach uses referencing in other agencies and it applies to generics from any source. Therefore, it is a level playing field in terms of application to other countries.

A challenge of the industry is counterfeit drugs. Can you comment about HSAâ??s role in preventing this?

We signed our MoU with INTERPOL in June, 2011. The main focus initially was on training because INTERPOL views HSA as a good partner in terms of training for enforcement work, mainly targeted at adulterated, counterfeit and sub-standard products. So they have been engaging HSA to train officers from agencies in other countries to give them more skills and expertise in order to detect and deal with such products.

A second area where INTERPOL is working with us is in terms of testing. Our Pharmaceutical Laboratory in the Applied Sciences Group that supports the regulatory group, has also been able to work with INTERPOL in terms of faster detection of whether products are sub-standard, counterfeit or adulterated. Interestingly, we found that our forensic laboratory is also able to value add in the identifying of counterfeit drugs through visual examination of their packaging and the characterization of their chemical fingerprints.

This is where INTERPOL sees HSA as a good partner to help boost their capabilities, primarily in the region. However, any innovation and best practices through this partnership can also be shared internationally too. When INTERPOLâ??s Global Complex for Innovation opens in Singapore in 2014, we anticipate that there will be ongoing strong links between INTERPOL and HSA.

Aside from international collaboration, how has HSA positioned itself in ASEAN-related collaboration?

The ASEAN Pharmaceutical Working Group is actually the longest standing of the ASEAN working groups. It has been very successful in ensuring that all the agencies in Southeast Asia are talking to

one another. In terms of information exchange, we have moved forward and have been very effective in sharing post-market adverse event data. There is a template that is adopted which allows us to push information from one country to another very pro-actively, so we pick up signals and work on these.

Common Technical Requirements (CTR) have also been implemented, which has introduced a certain level of harmonization already. Different countriesâ?? legal jurisdictions prescribe how much harmonization can be implemented immediately.

One interesting thing that came through in terms of the CTRs, is when Indonesia highlighted that some of the international stability requirements for drugs did not fully take into account the humidity conditions and supply chain distribution of products in our type of environment. We were able to come together and support Indonesia in making its case, so that a sub-category was introduced to allow additional stability requirements to be recognized. It is of no use having stability requirements that are fine in a temperate country, but when you bring a product into our humid tropical environment, you may find that the whole product actually degrades.

So, that was one clear example of how this group of agencies across Southeast Asia that had been working so closely together, could have a significant impact in enhancing the supply chain across our region as well as internationally.

We are continuing to progress. Those countries that are able to move ahead first can proceed to implement common requirements and others will do so when their capacity allows. But the communication and referencing helps, because each agency can learn from sharing of best practices.

HSA has five core values. As the CEO, how do you apply them every day?

As part of our development program, every batch of new staff that comes in undergoes orientation, during which I personally conduct an orientation talk to share the history of HSA, our vision, mission, and the significance of our core values.

We have ongoing team-building programs where we bring together staff from across the organization. During these programs, the core values actually form the basis for the interaction and activities of team building. What we try and encourage them to do is to take the core values and figure out what it means for them in their context and to share it. This way it becomes part and parcel of what they are doing on a day-to-day basis.

â??Passion for excellenceâ?•, â??developing our communityâ?• and â??living innovationâ?• are a bit more obvious for a scientific organization. I particularly highlight, firstly, â??service to the nation,â?• because we have several national centres under us. This generally strikes a chord because the nature of the work we are involved in is focused on public health protection, and I find the people that join HSA are quite altruistic. They want to apply science to do good.

The second value I focus on is â??inspire trust.â?• That is very important because of the nature of what we are doing â?? whether it is regulation, ensuring a safe blood supply, or ensuring our tests in the forensic group are up to standard. We have to ensure that people believe in our scientific decisions and results. It is very important that every member of staff sees themselves as an ambassador.

What is your final message for our readers?

Given the nature of the pharmaceutical and the whole bio-medical industry â?? where the world has become so globalized now and there are so many different products that are not just coming out of traditional markets, but also from Asia â?? collaboration across regulatory agencies is absolutely critical in going forward. However, in terms of effective partnerships, I think if there are too many players it can become very difficult to advance and make things work. The â??small is beautifulâ?• type of approach is often the way to make partnerships succeed.

In Singapore, collaboration has always been a given, because we are so small. We must ensure our scientific standards are high, and then we need to work with other regulators and scientific partners. The future must involve a lot more international collaboration, coordination and working together to move forward.

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