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Innovative regulator

08 January 2008 | News

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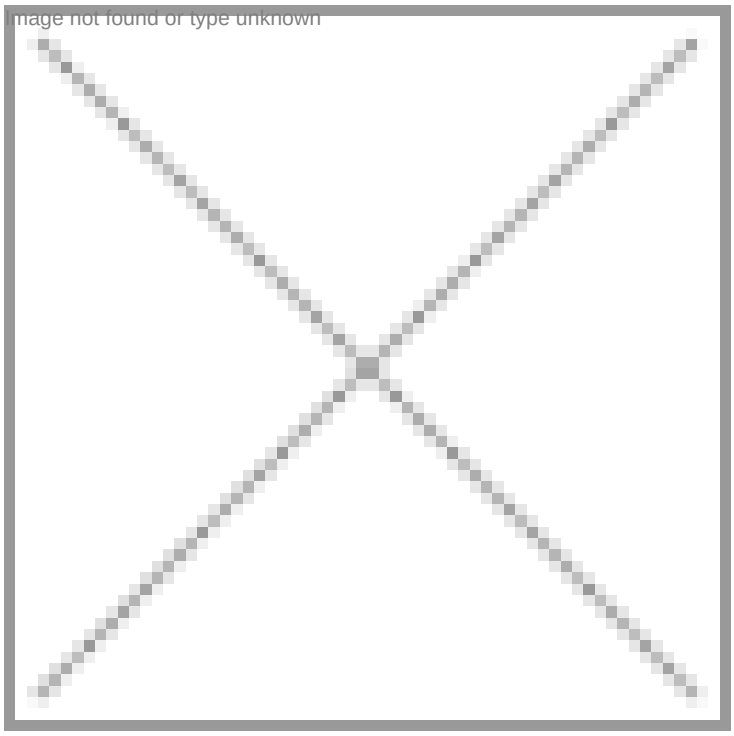
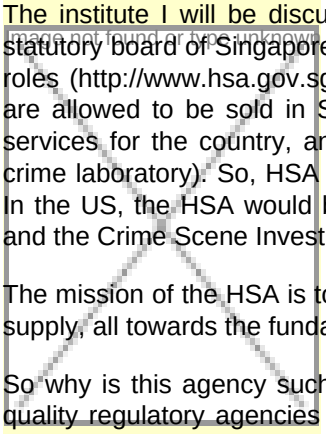


Innovative regulator

The mission of the Health Sciences Authority of Singapore is to wisely regulate health products, serve the administration of justice and secure the nation's blood supply

Talking about government regulatory agencies is as interesting as watching grass grow. On face value, the topic is considered by most rational human beings as bland. So, when I say that one of the most important institutions in Singapore's advance in biomedicine is in the organization that regulates its blood supply and the availability and safety of drugs here, I expect eyes to roll with the exhaled sighs of disbelief. But indeed, this is true.

The institute I will be discussing, and for which I am the Chairman of Board, is the Health Sciences Authority (HSA)-the statutory board of Singapore's Ministry of Health formed in April 2001 that manages a collection of important health regulatory roles (http://www.hsa.gov.sg/publish/hsaportal/en/home.html). The HSA is charged with regulating which drugs and devices are allowed to be sold in Singapore (health product regulation), it runs the national blood bank and transfusion medicine services for the country, and it is the expert center for analyzing biological samples at crime scenes (forensic or national crime laboratory). So, HSA houses under one roof the equivalents of what are normally several agencies in other countries. In the US, the HSA would be equivalent to the Food & Drug Administration agency (FDA), the Red Cross (blood banking), and the Crime Scene Investigations (CSI) or the FBI crime laboratories.



Dr Edison T Liu
Executive director of the Genome Institute of Singapore, reported to a physician scientist who trained with Nobel Laureate J Michael Bishop. He is also the executive director for the Singapore Cancer Syndicate - a funding agency, the Singapore Tissue Network - a tissue banking consortium and is chairman of the Health Sciences Authority of Singapore, the country's FDA equivalent.

The mission of the HSA is to wisely regulate health products, serve the administration of justice and secure the nation's blood supply, all towards the fundamental aim of safeguarding public health.

So why is this agency such a lynchpin for good public health and of biomedical innovation? A related question is why are quality regulatory agencies essential for the public good and national wealth? The answer is easily found in the economic sector where the regulation of the monetary and financial system is essential for advanced and competitive economies. The critical role of the Monetary Authority of Singapore, the Bank of China, the Federal Bank and the Securities Exchange Commission of the US to national prosperity and economic growth is uncontested. A more dire example is the recently reported disasters involving the Chinese drug regulatory agency the SFDA whose corrupt practices jeopardized the health of Chinese citizens and caused global product recalls costing billions of dollars. Some would say, equally problematic is over-regulation as has been seen in the Japanese Ministry of Health's ban on birth control pills until 1999. Over-regulation blocks access to key drugs, sometimes life saving medicines. Any process involving human transactions needs a fair set of rules and good referees. The alternative is distrust and chaos: progress stops.

Challenges of regulation

To be a government regulator is one of the most difficult jobs because there is no clear metric to determine success. Unlike business where positive cash flow is a simple single measure of success, or academia where the publication record is paramount, no one can specify simple performance targets for a regulator. How many products approved or rejected, or measuring the number of recalls are clearly inappropriate measures of goodness. Instead, a good regulator should be judged by three characteristics: efficiency, transparency or clarity, and righteousness. The first characteristic can easily be measured: what is the turn-around time for products to receive a decision (not time to be approved). Transparency can be measured by: how clear a regulator's guidances are and the brevity of the rules book (the shorter the better). Righteousness is the hardest to measure, but is found in the respect of one's own governmental peers in the regulatory institution. For example, the US Supreme Court receives very high ratings from other governmental agencies.

In this fast moving environment spurred by heightened expectations by Singapore's citizens and government, the HSA has recognized that it cannot function in a business-as-usual or traditional mode. The challenge for the HSA is how to regulate the same number of products that another sovereign nation like the US regulates but with 1/100th the human resources of the US FDA. So, what are some of the solutions?

First, one must regulate with intelligence. This means that whenever possible, for drugs already examined carefully in key index regulatory agencies (like the US FDA, the Australian TGA, and the European Union's EMEA) HSA will expedite its review and not reinvent the wheel. The HSA concentrates on those drugs that have no regulatory history, and those with unique properties such as medicines with significantly different effects across ethnic groups.

Though these may be difficult aims to achieve given that HSA is and will always be a small agency when compared to large agencies like the US FDA. But these can be achieved if there is (a) clarity about HSA's regulatory philosophy and operations, (b) international networking and benchmarking to add value in fundamental regulatory activities, (c) organizational innovation with a focus on efficiency, and (d) intelligent and appropriate resourcing in manpower and financing.

Regulatory innovation

While HSA must adhere to international regulatory standards, it cannot simply follow the operational and organizational plans used in larger countries. Instead, HSA seeks to take advantage of the compactness of Singapore and the presence of mature networking systems to enhance its surveillance and enforcement capabilities.

The Singapore government has given the HSA a major legislative tool recently in the new Health Products Act

(http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_legdisp.pl?actno=2007-ACT-15-N&doctitle=HEALTH%20PRODUCTS%20ACT%202007%0A&date=latest&method=part&sl=1). The Act's modular approach

and mechanism to activate relevant clauses means that instead of a one-size-fits-all approach, the regulatory requirements can be tailored according to the degree of risk. At the same time, the Act provides the necessary flexibility making it simpler to fine-tune the regulatory regime for different products over time. This is important in order to accommodate new discoveries that will come into the market in future.

In another on-going example, the National Healthcare Group (NHG) which covers almost one-half of the country's public health care delivery has a system that automatically prompts physicians to input information on unusual side effects of drugs (or commonly called adverse drug effects), but then passes this information to HSA's Pharmacovigilance Unit. This effectively means that HSA is able to receive 100 percent of adverse event records from NHG institutions in a secure manner. In this manner, HSA can pick up key adverse events more efficiently and effectively than its developed country counterparts.

At the end of the day, there is no perfect model for a health regulator to adopt. But the HSA aims to be innovative and flexible, always acting with integrity and continually seeking efficiency. In so doing, it has a high likelihood of making a positive impact not only on the health and safety of Singaporeans but also, as a model of an effective regulator, on world public health.