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Post marketing surveillance stepped up in Singapore: Dr Raymond Chua

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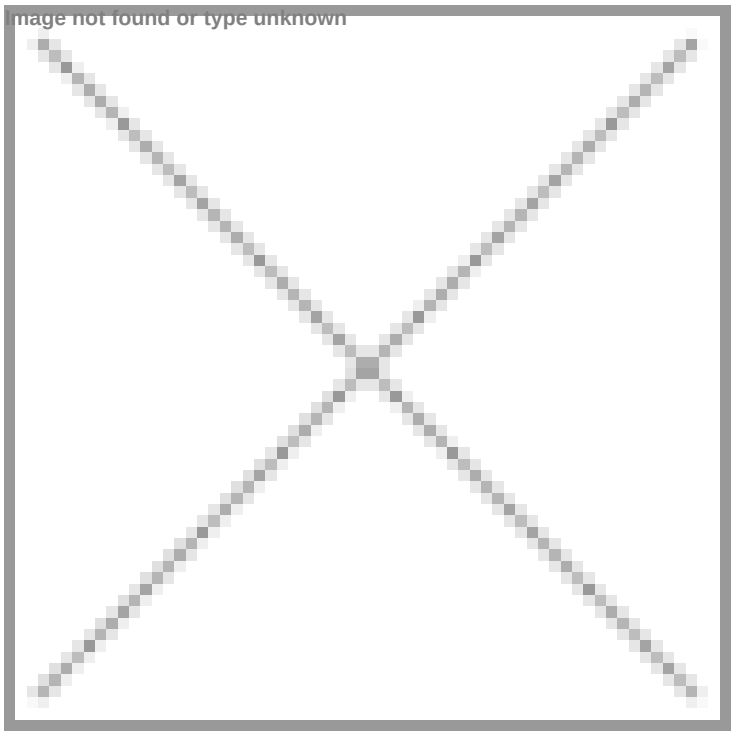
HSA has stepped up post marketing surveillance: Dr Raymond Chua



Singapore's regulatory agency Health Sciences Authority (HSA), since its establishment in 2001, has built a smart regulatory environment to support the development of the biomedical sector and has gained international acceptance. In an interview with *BioSpectrum*, Dr Raymond Chua, group director, Health Products Regulation Group, Health Sciences Authority, Singapore, talks about the role played by the authority in regulating the industry and enabling its growth.

What is the approach of HSA towards maintaining good health practises in Singapore?

Dr Chua: The HSA has taken a holistic approach towards maintaining good health practises. We have judiciously adopted good international regulatory principles and practises to meet Singapore's unique demands without compromising public safety, imposing over-regulations or blindly approving products that are already approved in the international market.

The HSA ensures that pharmaceuticals, biologics, medical devices and health-related products in Singapore are wisely regulated to meet appropriate standards of safety, quality and efficacy through the product life cycle. It has also increased post marketing surveillance activities to keep an eye on approved products. Besides, it has fostered strategic partnerships with international and regional bodies to share information at various fronts, leverage on expertise and work with more advanced agencies.

What activities are categorized under post marketing surveillance?

Post marketing surveillance includes safety vigilance and risk-benefit assessments of marketed health products; risk communication and provision of unbiased information to healthcare professionals and consumers; quality surveillance and compliance monitoring of marketed health products; and investigation and enforcement of legislation and prosecution of offenders.

The HSA also conducts inspections to check compliance with pre- and post market good manufacturing practises, licensing of manufacturers, good distribution practises and licensing of importers and wholesalers.

Is Singapore exposed to generic drugs? How can a generic drug developer access the Singapore market?

Since it is a well-known fact that the pipeline for innovative drugs is drying up, Singapore is open to generics drugs from all companies and countries as long as they meet the safety criteria. To enter the Singapore market, if the drug is already approved by one international drug regulatory agency, an abridged dossier has to be provided to the HSA for abridged evaluation and regulatory decision. This takes 240 working days. If the product is approved by reference regulatory agency that includes the US Food and Drug Administration, Health Canada, UK Medicines and Healthcare Products Regulatory Agency, Australia Therapeutic Goods Administration and European Medicines Agency, a company has to provide just the verification dossier for the evaluation based on assessment report by reference regulatory agency and regulatory decision. In this case, it takes 120 working days.

Singapore's generic drugs are manufactured in different parts of the world. Based on our registration data from 2010 to 2012, more than 50 percent of generic drugs are manufactured in Europe and the other top three countries are India, the US and Malaysia.

What is the status of approval of generic drugs against new drugs in Singapore?

Over the last two years, the statistics for new drug approval has been on the lower side and generics drugs are on the rise. In 2009, 102 new drugs were approved in Singapore. The number came down to 90 in 2010 and stood at 84 in 2011. On the other hand, the count of generic drugs approved in 2009 was 57, which went up to 73 in 2011. For new drug approval, two percent came through full evaluation, 89 percent through abridged evaluation and nine percent through verification, whereas for generic drugs, 100 percent was approved by abridged evaluation.

The HSA has international collaborations with many agencies. What is the structure of the collaborations?

The HSA's collaborations with different agencies are at different levels. We have memoranda of understanding for exchange of information and training with agencies such as Interpol, and work sharing initiatives such as parallel evaluation and joint GMP inspections. We have mutual recognition arrangements with the Therapeutic Goods Administration on GMP inspection and a partnership with World Health Organization for international medical products anti-counterfeiting task force. We also work with overseas drug regulatory agencies such as Pharmaceutical Inspection Co-operation Scheme.

There are over 10 different regulatory agencies with which the HSA has relations for exchange of information, building capacity and capability, keeping checks on adulteration and counterfeit information sharing. Some of the partners are National Pharmaceutical Control Bureau of Malaysia, Korea FDA, China SFDA, US Pharmacopeia, Swiss Medic and UK MHRA. Singapore is working on harmonizing regulatory requirements with ASEAN and international guidelines.

How many cases of illegal drugs have been reported in Singapore recently?

The HSA has an ongoing post market surveillance program whereby routine compliance and quality checks are conducted on locally marketed health products, comprising pharmaceuticals, Chinese proprietary medicines, traditional medicines, health supplements and cosmetics. Since 2010, the HSA has recalled 26 products from the market through this program. These products were recalled as they contained undeclared or prohibited ingredients or were not complying with approved specifications or legal limits.

What role is the HSA playing in making Singapore a global life science hub?

The HSA is also an enabler in making Singapore a hub for attracting international investors. Stringent regulations act as a safe zone for international companies to invest in a foreign country and the HSA's smart approach has led the Economic

Development Board of Singapore and A*Star to develop it as a biotech hub. The HSA supports the development of dynamic, innovative and sustainable healthcare system and hence a clear regulation is very important.

Also, the HSA has taken some active approach to enable Singapore to be a global life science destination. In order to enable faster market entry of generics drugs, Singapore introduced new evaluation route for generic products in 2011 and reduced the registration process by 50 percent.

We regularly review our approaches and renew our framework in the lines of international standards set by FDA, TGA and the MHRA. We do not want to compromise on medical safety and keep a close watch on the products and their performance. If we have eased the pre-marketing process, then we are stringent on post marketing investigations.

How is the regulatory framework designed to meet the dynamic economic structure? Is keeping pace with the new trends a challenging task?

A new trend is coming up involving multiple players that include regulators, payers, educators, healthcare practitioners, industry and the public. There is a need to keep abreast with technological advances and novel products such as advance therapies like stem cell and biologics. Moreover, complexity is increasing in regulating health products where there is complex combination of drugs and medical devices, drug and complementary medicines and so on. Regulators have to build expertise and regulations for new areas with risk-based application of regulatory tools.