Singapore Investing in the Future of Life Sciences

Singapore was once an Asian Tiger together with Hong Kong, South Korea and Taiwan. They are all high income, high investment countries, with education high on their agenda. Each country specialises in different areas. Singapore and Hong Kong have been known as financial centres, and South Korea and Taiwan are hubs for manufacturing. They are all used as centres for clinical trials. At the present time, Hong Kong is running 928, Singapore - 1235, Taiwan - 3428 and South Korea - 5234[i].

The Singaporean government decided more than a decade ago to target the life sciences industry. They focus not only on local manufacturing but also on research and clinical trials, and aim to be the first-choice logistics centre in Asia Pacific, and the first choice for regional distribution of pharmaceutical products.

Heavy investment in infrastructure, including regulation, has been made to ensure that Singapore is the regional hub for trials and research. For example, the country boasts seven research institutes and five research consortia in a country with a population of just 5.3 million (around the same size as the Washington DC metropolitan area). The government also encourages international companies to set up their regional offices in the country. Many international companies have invested in Singapore to build their storage and distribution centres, using the most up-to-date supply models to allow just-in-time deliveries of clinical trials supplies to investigator sites. Singapore works with companies that fit their requirements to bring in high-end investment and the possibility of knowledge transfer. Their aim is for quality, not quantity.

Shipping into Singapore

If materials are ultimately delivered within Singapore then they must be completely cleared and subjected to 7% GST tax. They are exempt from duty. Shipments may be tax free if the importer is registered with the tax department for tax exemption status. A licence may be required, and this includes when shipping samples for testing. Drugs for local use require the relevant licence, applied for by the CRO, which takes around a week to be issued. The importer of record must apply for an import licence, which is a controlled document. In addition to this, all importers must be registered with Singapore Customs in order for the Customs Permit to be applied for via trade net by the transport company. Once registered, companies are issued with the importers' UEN (Unique Entity Number) which is used across the clearance paperwork, and a customs clearance permit (CCP) must be issued which can be applied for before the flight from the origin point arrives. This requires a master airwaybill, a house airwaybill, and a copy of the invoice to be submitted with the relevant forms. The invoice must be identified as an invoice or commercial invoice. "Proforma invoices" are not acceptable to Singapore customs.

Importation requirements have been simplified for supplies when they are being sent to a storage location in Singapore to then be forwarded into other parts of Asia Pacific. They are subject to a redistribution licence which must be applied for by the local depot. It is normally immediately approved. Items undergo a limited clearance, but must be re-exported from Singapore for the short flights into countries such as Vietnam, South Korea and Cambodia. This allows companies to ship bulk trial drugs into the depot and have them in physical proximity, ready to make deliveries once patients are enrolled at a particular clinical site, without having to be concerned about a full clearance and full re-exportation.

Regulatory & Facility Considerations

The Health Sciences Authority works within PIC/S (Pharmaceutical Inspection Co-operation Scheme) - an international body for the appropriate standards of GMP and GDP. Additionally, they operate a voluntary certification scheme for interested companies to seek official certification. A GDP Certificate is issued when the company's quality system has been audited and found to comply with HSA's GDP Standard. All companies importing material into Singapore should conform to the PIC/S GMP and GDP standards. Practical information and guidance is available on the HSA's website[ii]. The HSA is closed at the weekends so no approvals can be given at those times. Clearance can take place at the weekends if everything else is in place, and all the details are arranged during business hours on the Friday.

Singapore Changi Airport has a perishables handling centre, situated within the free trade zone, with the areas available ranging from -28°C through 2-8°C, to +18°C. This is located at Airfreight Terminal 2. The facility allows for shipments to be accessed to replenish refrigerant (add ice, change gel packs, change batteries etc.) while still under Customs control, and when under the control of the airline authority. This allows for the maximum flexibility in controlling temperature whilst undergoing clearance.

Singapore chose to invest heavily in the infrastructure needed to smooth the transit of pharmaceuticals - including clinical trial supplies. Their decision to do so is now reaping rewards with all the significant players in the market setting up facilities, and bringing knowledge, trade, and international investment into the region.

References

i. http://clinicaltrial.gov/

ii. http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/GMP/gmp_gdp_standard.html

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