Tomorrow's Pharmaceutical Market?

Manufacturing Conditions in China are Changing

There's been no trace of the original gold-digging market for a long time. The hyperbole and initial euphoria have been followed by disillusionment and stark reality. For some time now, the Steiff company with its cozy teddy bear has not been alone in recognizing that quality has its price and that perhaps producing at home would lead to more success after all.

Ralph Gengenbach, CEO, Gempex

However, the wheels of time keep grinding, and China is learning. That can be felt all too plainly in the pharmaceutical market. If yesterday cheap production was the order of the day, now the temptation is market opportunity in connection with the name "China."

GMP in China

In 2005, Gempex ventured to gain a foothold in China. It was both by chance and a tempting prospect. Joint venture Gemro Services was founded with the aim of offering good manufacturing practice (GMP) services in China.

Although GMP rules existed at that time, there were significant differences compared with Western requirements. GMP mostly focused on cleanroom technology with a cleanroom classification of 300,000. Whoever had built a cleanroom with all the related airlock systems was practically GMP suitable — but only in China.

The interest in GMP in China in those days seemed to be enormous. People wanted to learn more about Western manufacturing requirements and how to meet them. However, at the end of each discussion stood the simple question of how to get an appropriate GMP certificate as quickly as possible and how much it would cost, but no business was generated at the end of the day.

At that point in time, an estimated 5,000 companies wanted to break into the active substance market and earn a premium in the West. They were bolstered by state subsidies allowing cheap construction land and providing initial financial momentum. But on the Chinese side came the sobering realization of being not only distinctly remote from the Western concept of quality, but also having neither products nor customers.

Legal Regulations

The quality hurdle was recognized by the state, and since 2010, GMP standards have been in place that closely match European standards with only minimal differences. The Chinese government initiated an intensive training program for inspectors to qualify existing personnel. Experts predicted — and the current trend confirms — that from the original 5,000 active producers only approximately 500 reliable companies will remain.

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However, the inspector training is not aimed at home country producers only. They are being trained to supervise producers hoping to serve the Chinese market from outside China. In the meantime, the program has started, so Western producers now have the dubious pleasure of greeting Chinese inspectors in their own plants.

Whereas yesterday it was Western standards that were deemed too high, it is now, paradoxically, Chinese standards that Western companies are finding themselves increasingly unable to meet. The Chinese rules for the production of excipients specifically stipulate conformance with GMP and include validation, which, in the West, is just an industry standard. For all purification and filling steps that do not take place wholly in a closed environment, active substance producers are now required to implement them in a cleanroom Class D (equal to EU GMP Class D). Also producers of primary packaging material are now confronted with the legal requirement to produce under cleanroom Class D where the air exchange rate is at least 15. Meanwhile, that is not restricted to production in China: EU standards are being raised to match those in China.

> *In the future, China will take over a leading role in the global pharmaceutical market.*

A Fast-Growing Market

A country with a population of close to 1.37 billion citizens that, in the last 10 years, has developed rapidly to a near economic and cultural No. 1 in the global market, has suddenly presented new market potential. The population earns significantly more, its prosperity has increased to being able to afford more healthcare and personal hygiene products at least and — lo and behold — the Chinese have become aware of products produced in the West or by Western companies. Those who can afford it do not look to the home market for milk or baby nutrition; imported products are in demand.

So the trend is for more and more Western companies to go again to China, now focusing on serving the Chinese market. For that reason, after nine years of — not particularly fruitful — activity in China, Gempex has also decided to extend its presence and has founded a 100% Gempex subsidiary based in Guangzhou. A team of six well-qualified and extensively experienced Chinese GMP experts together with their German colleagues will offer GMP support.

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The New K-REACh

After Reviewing its Chemical Regulations, South Korea has Drawn Up New Ones

It is on everyone's lips: Since Jan. 1, K-REACh has been the law in South Korea. With this implementation, the global chemical industry faces a list of new requirements. The good news is that by way of optimized processes, as well as an approach to other existing judicial systems, this new legislation is familiar for European chemical manufacturers. For that reason this system is aptly referred to as K-REACh.

Ariane Stoll, UMCO Umwelt Consult

The background for the new provision is the international push to implement more environmental and consumer protection. Little by little, these measures lead to stronger statutory regulation for the import and the handling of chemicals in industrialized countries. The focus is not limited to the chemical industry. Indeed, even importers and distributors of consumer products are subject to reporting to public and government agencies. These reports gather detailed information on products' chemical composition, so an appropriate response can be taken in case of emergencies.

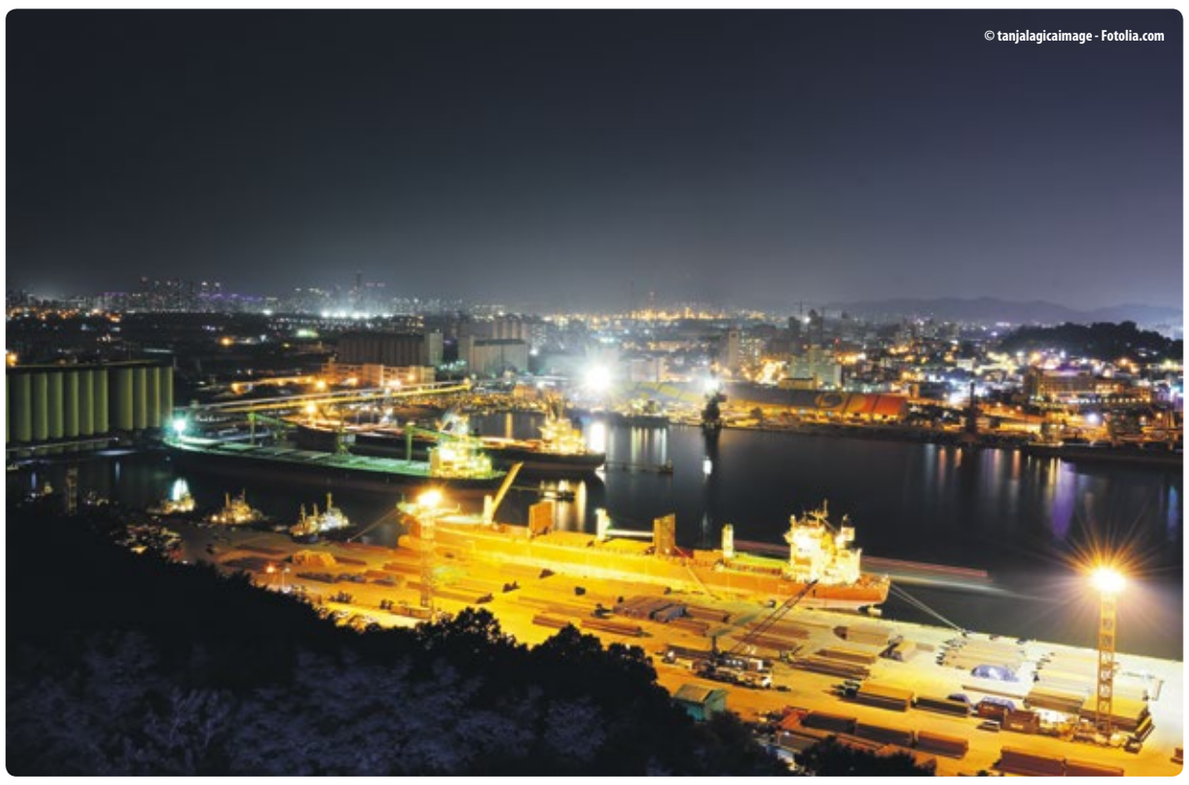
K-REACh

The foundation of K-REACh is based on four principles: reporting, registration, communication along the supply chain, as well as product notification. In order to comply with legal requirements, the appropriate steps must first be ascertained and implemented prior to every import. Just as in the EU, foreign companies may appoint an only representative (OR) for South Korea. The use of an OR is highly recommended in cases in which a foreign company that wishes to import chemicals to South Korea does not have headquarters or branch offices in South Korea. Not only will this ensure that importers comply with all K-REACh requirements, but it will also ease the hurdles that could be faced because of the language barrier. In general, only companies that have a seat in South Korea can implement all four processes.

Reporting And Registration

An important note for the future: Before the first shipment, it must be clear what materials in what amounts are to be imported into South Korea. Here the differentiation is between "new chemicals" — those that must always be reported — and "existing chemicals," which are only subject to the reporting process starting at one ton per year.

Any registration is mandatory for any new or existing chemicals listed on the priority evaluation chemicals (PEC) list. The first PEC list, which was published in October, lists 518 substances that are currently in focus. Information resulting from the registration process must be included in all communications with customers. Specifically this means that the indented use of the registered substances must be included during the sale of mixtures.



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Incheon, panoramic view over the city

Notification Requirement

The sale of consumer products brings about the requirement to test the ingredients for their hazards as well as their potential exposures. For example, products such as cleaning agents or detergents mandate a notification if they contain more than 0.1% hazardous chemicals and they are imported in excess of one ton per year. A substance is considered hazardous if the Ministry of Environment (MoE) has placed it on the list of toxic substances in the Chemical Control Act (CCA) or if the substance is listed on the PEC list.

GHS-Hazard Classes

South Korea has been working on implementation of the UN Globally Harmonized System (GHS) since 2003. South Korea has adopted most of the GHS building blocks, similar to the adoption of the European Union by way of the Classification, Labeling and Packaging (CLP) regulation. Particularly European companies should note the differentiation in the hazard categories flammable gas, aerosols, aspiration hazard and hazard to the ozone layer.

South Korea currently has two agencies responsible for the classification of chemicals and the implementation of GHS. These are the previously mentioned MoE and the Ministry of Labor (MoL), whose Chemical Control Act was the first legal foundation for the classification of chemicals. Similar to the European system of classification according to index number, the CCA has an obligatory classification of 789 chemicals. The C&L inventory of the MoL should be used only in the second step, after the classification has been determined. These classification systems are currently being harmonized, in order to have a uniform scheme for the classification of hazardous chemicals.

Labeling and Safety Data Sheets

The Safety Data Sheet (SDS) in South Korea has been adopted in accordance with GHS and depicts the necessary labeling requirements of chemicals. It is highly recommended to depict the proper label on shipments. Large-scale inspections conducted by Korean regulatory agencies have shown that deficiencies are commonplace. The absence of a Safety Data Sheet at the workplace can carry a fine of up to $500, and incorrect labeling of a container can be fined up to $200 per violation.

Advice For Stakeholders

Any new regulation must first prove its functionality through practical experiences. A big advantage for companies is that similarities with the EU regulation exist and that similar test methods, namely those according to the Organization for Economic Cooperation and Development (OECD), are used for the registration of products in South Korea. As always, it is recommended to seek a business partner that is fluent in Korean, irrespective of if the partner has regional presence or is merely a consultancy. Despite the fact that South Korea is very westernized, it can be invaluable to have a solid command of the Korean language in order to fully understand the conduct and structures of authorities. If applied successfully, these can be the first steps one takes into the Korean market and the avoidance of fines of up to $100,000.

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