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Business, Trade and Competition

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Welcome to this month's bulletin covering updates on the regulation of business, trade and competition in China.

International Trade

China Renames Regulatory Agency: What's in Store for the Cosmetics and Medical Device Industries?

In March 2013, the National People's Congress of China formally changed the name of the State Food and Drug Administration (**SFDA**) to the China Food and Drug Administration (**CFDA**), elevating it back to a ministerial-level agency with complete authority over China's food and drug regulatory regime. Reporting directly to the State Council, the CFDA is responsible for formulating policies and development plans related to cosmetics, medical devices, pharmaceuticals, and food safety as well as drafting related laws and regulations. While largely a symbolic gesture to communicate to the public that the Chinese government takes product and food safety seriously, the move to designate CFDA as a ministerial-level agency can also be viewed as part of China's broader strategy to improve consumer confidence, enhance product safety and better regulate these industries. Whether this reshuffling translates into immediate tangible benefits or burdens for business, particularly for the cosmetics and medical device industries, remains to be seen.

Cosmetics Industry

The registration and supervision of cosmetics is regulated by the newly reorganized Department of Health Food and Cosmetics Supervision (**DHFCS**). While this department continues to have broad management and supervisory authority over the cosmetics industry, there have been no official announcements since its reorganization regarding reform of its primary roles, *i.e.*, the DHFCS is still charged with the same specific functions prior to its reorganization. These include application approvals for new raw material ingredients used in the production of domestic cosmetics for special use[1] and first-time approvals of imported ordinary use[2] cosmetics; hygiene licensing for new cosmetic ingredients and special use cosmetics; record-keeping certificate requirements for ordinary use cosmetics; formulation of hygiene standards and technical, testing and labeling requirements for cosmetics; and overall safety of cosmetic products in the China market. Certain key issues remain unaddressed, including a clearly defined process for

1 Products for hair growth/removal, hair dyes, hair perms, spots removal, sunblock, breast shaping, fitness, and deodorizing.

2 Products for care of nails, hair and skin, perfumes, and make-up.

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foreign manufacturers to apply for approval of new ingredients or for cosmetic products containing new ingredients, and the establishment by CFDA of scientific bodies to deal with the regulatory assessment of new ingredients.

One of the most notable changes under the new CFDA structure is that imported ordinary use cosmetics will need to be registered with food and drug administration authorities at the provincial level (the current system requires registration with the state authority in Beijing). As each province has a CFDA local bureau, this move could shorten the overall time required for the registration process for such products. However, it is too soon to tell whether provincial authorities will have the power to *approve* the marketing of foreign cosmetic products or whether the move only *facilitates* the registration process. Likewise, the General Administration of Quality Supervision, Inspection and Quarantine (**AQSIQ**) will no longer be the authority in charge of mandatory inspections and production licenses for cosmetics; such authority now falls under the purview of the CFDA. The CFDA, however, has yet to issue detailed rules on the abovementioned changes and requirements. The role of AQSIQ and local Entry-Exit Inspection and Quarantine Bureaus to inspect cosmetics at the time of import or export remains unchanged. For new cosmetic producers in China, the consolidation of authority under the CFDA could be a benefit in the overall establishment process, *i.e.*, having one less governmental body to deal with in the system, provided it does not lead to discrimination towards imported cosmetic products.

While the elevation of the CFDA to a ministry-level agency is an important development, the Chinese government has already taken a number of steps in recent years to enhance the supervision of the cosmetics industry. With an emphasis on product safety, such actions include improvements in market operations through the issuance of a series of administrative measures[3] and industry standards as well as the establishment of a market access mechanism to deal with importation, production and sales, approval procedures, certificate issuance, and government supervision. In 2012, government authorities achieved three main goals for China's cosmetics industry: (i) an increase in overall safety requirements, *e.g.*, reducing the types of raw material ingredients used in children's cosmetics; eliminating or reducing the use of essence, preservatives and coloring pigments; and discouraging the use of nanometer materials and genetic technologies;[4] (ii) reclassification and enhancing risk assessment management of certain cosmetics;[5] and (iii) release of three draft batches of cosmetic substances in the Inventory of Existing Cosmetic Ingredients in China (IECIC) catalogue, which regulates the use of cosmetic substances. Following public consultation in relation to the three draft batches, the CFDA released two batches for the final IECIC catalogue in February 2013 (411 approved substances) and May 2013 (1,674 approved substances), with plans to publish more batches in future. Notably with respect to reclassification of cosmetic products, the CFDA has not yet announced plans to reform the rules governing this process, which has long been an irritant for foreign manufacturers.

With a growing middle class and increasing demand for imported well-known and luxury brand cosmetics, China is poised to become the third largest cosmetics market in the world according to some experts. Certain circles in China have advocated a reduction in import duties for imported cosmetic products (average rates range between 10-20 percent) as a means to reduce purchases of cosmetics by Chinese nationals when abroad and to boost in-country sales. Even if such a move were taken, foreign cosmetics still would be subject to the Chinese government's strict management. The CFDA requires foreign exporters to have a unique authorized legal agent in China to handle all approval applications and archival filing matters on their behalf, without which cosmetic exports to China would not be allowed. Yet, change is slowly permeating the regulatory bureaucracy. For example, the CFDA has loosened its grip on import application approval requirements. In 2012, the CFDA approved 9,234 out of 11,423 applications for the import of ordinary use cosmetics – an approval rate of just over 80 percent – well and above the approval rate of 58 percent in 2011. Despite this positive trend, special use cosmetics and new technologically advanced ingredients remain the focus of the global cosmetics industry, particularly for the booming Chinese market.

Medical Device Industry

The CFDA is also planning to establish two departments to take charge of quality surveillance and registration administration of medical devices: (i) the Department of Medical Device Supervision and (ii) the Department of Medical Device Registration. However, as the reform of these and other government departments is still underway, imported medical devices must still comply with existing regulations, including the Regulation on the Supervision and Administration of *Medical Devices*[6] and the *Measures for the Administration of Medical Device Registration*.[7]

3 For example, the 2010 *Administrative Measures for Examining the Administrative License of Cosmetics* and the 2012 *Measures for the Inspection, Quarantine, Supervision and Administration of Imported and Exported Cosmetics*.

4 CFDA Notice No. 291 [2012].

5 CFDA Notice No. 263 [2012].

6 Decree No. 276 of the State Council, effective April 1, 2000.

7 Decree No. 16 of the SFDA, effective August 9, 2004.

While the CFDA has not made any official announcements on proposed moves to ease medical device registration, some sources indicate that the CFDA is planning to improve the current medical device classification process (*e.g.*, establishment of an electronic validation for CFDA medical device classification and possible exemptions from China Compulsory Certification (CCC) Mark requirements) as well as introduce a special approval process for imported innovative medical devices in China. Yet, it is unclear when such improvements might be introduced, let alone enforced and implemented. As a result, foreign medical device manufacturers must still adhere to the current three-tiered usage and risk management registration system applied at the central government, provincial and local levels. The CFDA still requires such manufacturers to have a unique authorized legal agent in China to handle the registration process on their behalf and to provide any after-sale services.

Since 2010, imported medical devices have witnessed impressive y-o-y increases in China. Total imports stood at US$7.9 billion, a y-o-y increase of 35.35 percent from 2009 levels. In 2011, the figure jumped to US$10.8 billion. The market is only expected to grow over the next 5-10 years as demand for safe and technologically advanced imported medical devices increases, particularly in China's megacities such as Beijing, Guangzhou and Shanghai. Despite the positive market potential, the registration, inspection and approval process for getting a new medical device into the Chinese market still involves a number of regulatory and bureaucratic hurdles. The CFDA has good intentions, but the status quo is expected to continue at least for now.

China Trade Remedy Cases (January 2013 – May 2013)

Product	Country of Origin	Petitioner Country	Announcement
Potato Starch	EU	China	AD definitive decision made on February 5, 2013
Pulp	Brazil, Canada, US	China	AD investigation initiated on February 6, 2013
Toluidine	EU	China	AD provisional decision made on February 28, 2013
Dispersion Unshifted Single-Mode Optical Fiber	Korea	China	AD definitive decision made on March 1, 2013
Toluene Diisocyanate	EU	China	AD definitive decision made on March 12, 2013
M-dihydroxybenzen/Resorcinol	Japan,US	China	AD definitive decision made on March 22, 2013
Nonyl Phenol	India, Taiwan	China	Definitive decision of AD expiry review made on March 28, 2013
Paper for Electrolytic Capacitors	Japan	China	Definitive decision of AD expiry review made on April 18, 2013
Certain Alloy-Steel Seamless Tubes and Pipes for High Temperature and Pressure Service	EU, Japan, US	China	AD investigation initiated on May 10, 2013
Coated Bleached Folding	US	China	AD investigation terminated on May 16, 2013
Pyridine	India, Japan	China	AD provisional decision made on May 27, 2013
Perchlorethylene (PCE)	EU, US	China	AD investigation initiated on May 31, 2013

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