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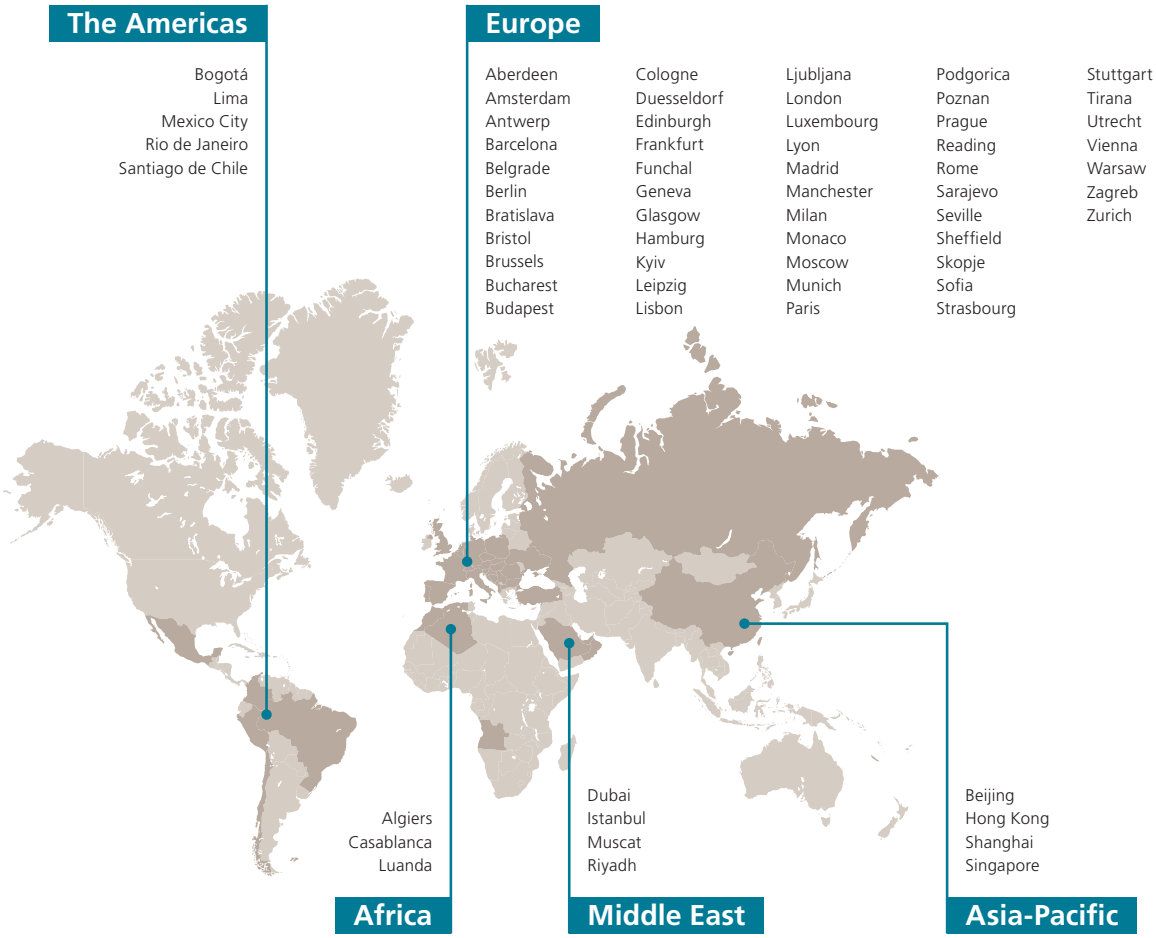
Top developments and predictions for the Life Sciences & Healthcare Sector in China

2018 - 2019

CMS facts and figures



- **73 offices**
- **67 cities**
- **> 1,000 partners**
- **> 4,500 lawyers**
- **> 7,500 total staff**
- **Combined annual turnover:** EUR 1.3bn (2017)
- **41 countries**

European countries

Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, France, Germany, Hungary, Italy, Luxembourg, Macedonia, Monaco, Montenegro, the Netherlands, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Switzerland, Turkey, Ukraine and United Kingdom

Outside Europe

Algeria, Angola, Brazil, Chile, China, Colombia, Kingdom of Saudi Arabia, Mexico, Morocco, Oman, Peru, Singapore and United Arab Emirates

Overview

As we enter the Year of the Pig, we take a look back at the top 10 developments of 2018 and towards what lies ahead with our top 10 predictions of 2019, for you and your business operating in China.

This past year we saw the Chinese government focus on establishing policies and measures to promote faster avenues for the development and registration of urgently-needed drugs and innovative medical devices, as well as cracking-down on increasing drug prices, misleading advertising and product liability. We expect to see stricter regulations this coming year that fortify existing intellectual property rights protection and data protection regulations as the sector continues to develop its digital health initiatives.

We will be closely monitoring these ongoing developments and predictions during the course of the year, providing you with regular updates and analysis as they happen through our various free know-how platforms: our eAlert service, Law-Now, LinkedIn at 'CMS Asia Pacific and CMS Life Sciences & Healthcare Sector' and WeChat at 'CMSAsia'.

For now, we hope you find our reflections and predictions of interest and help to your business as you plan for the year ahead.

If you would like to discuss any of the developments with us, please do let me know.

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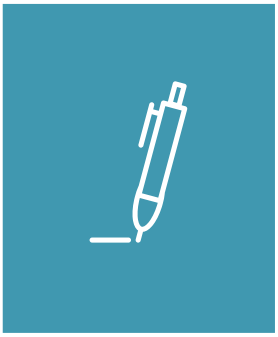
Top 10 developments of 2018

1. **Re-organisation of regulatory authorities:** The newly established National Health Commission ("NHC") has merged with the previous National Health and Family Planning Commission's regulatory functions. A new overarching authority called the State Administration for Market Regulation ("**SAMR**") has been established to supervise all marketing regulated affairs and the regulatory authorities involved. The China Food and Drug Administration has now been re-named as the National Medicine Product Administration ("**NMPA**") and has outsourced its food related regulatory functions whilst increasing its focus on drugs and medical devices.



2. **Accelerated Registration Process:** Several measures have been taken to accelerate the drugs registration process, including changing the clinical trial approval regime into an implied licence regime, providing green channels for certain kinds of orphan drugs and clinical urgently-needed drugs, etc. The registration period has also now been significantly reduced, in particular for drugs which enjoy a priority review process. In April, MSD submitted a registration application for its HPV 9-valent vaccine which entered the priority review process three working days after submission and was subsequently approved with conditions only five working days later.

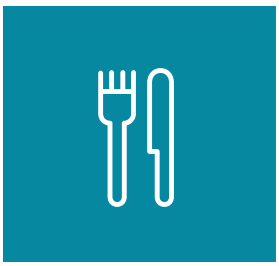
3. **Clinical Trials:** Overseas clinical trial data will be accepted in the drugs and medical devices registration process in order to shorten the registration period of imported drugs. The NMPA has issued the Technical Requirements for Accepting Overseas Clinical Trial Data and the Technical Guiding Principles for Accepting Overseas Clinical Data for Medical Devices which set out the qualification requirements for overseas clinical trial data to be accepted.

4. **Distribution:** An interprovincial centralised medicine procurement process was conducted in 11 cities on 6 December 2018. 25 of the 31 varieties of medicines proposed to be procured successfully reached a procurement agreement. The purchase price of these 25 varieties of medicines reduced in price by an average of 52%, with the largest price reduction being 96%, in comparison to the procurement price of the same variety of drugs in the same cities the previous year.

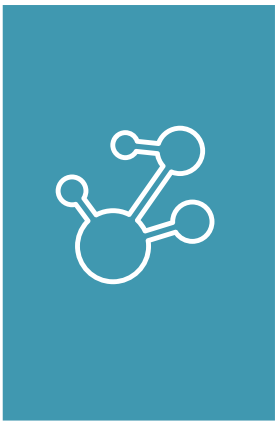
5. **Drug prices:** A film released last year, titled *"Dying to Survive"*, drew the Chinese public's attention to the issue of high drug prices whilst simultaneously bringing pressure on the relevant authorities. Besides the centralised procurement regime mentioned above, a price negotiation regime will also allow for 17 kinds of anti-cancer drugs to be listed on the National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2017 Edition) under the condition that the drug prices are reduced significantly. Anti-trust laws are also actively used to control drug prices. Several companies were punished last year due to monopolistic behaviour in relation to active pharmaceutical ingredients by SAMR, with fines of up to RMB 12 million.

6. **Encouraging the development of generic drugs:** In March 2018, the State Council issued a specific policy to encourage the development of generics that satisfy certain conditions, such as being necessary for clinical use, possessing a clear clinical effect, being in short supply, or for treating serious infectious/rare diseases, etc. Such generic drugs may also enjoy a priority status in the registration process. In addition, several measures will be implemented to encourage the use of qualified generic drugs to replace original drugs in clinical use.

7. **Digital health:** In September 2018, the National Health Commission and the State Administration of Traditional Chinese Medicine released three regulations which clarified the regulatory regime for health services (e.g. diagnosis) conducted remotely (e.g. via an Internet hospital). Such regulations are in response to the rapidly developing m-health technologies in China and also aim to solve the imbalance of medical resources between urban and rural areas. Soon after the regulations were published, several medical companies entered into cooperation agreements with giant internet companies to co-develop m-health technologies and their corresponding applications.



8. **Food promotion:** The false promotion of food, especially health food, continued to gain attention. Several health food manufacturers had sold products claiming that the products possessed treatment functions for several kinds of diseases, but had instead ultimately led to serious damage or even death of the consumers and patients. The NMPA and other involved authorities, including the public security authority, implemented specific investigations on such health food manufacturers in order to effectively regulate and punish harmful false advertising.



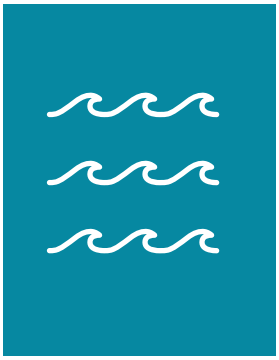
9. **Gene-modified embryos:** On 26 November 2018, a Chinese scientist, He Jiankui, claimed to have created the world's first genetically edited babies, who were twin girls, through the use of gene-editing technology Crispr-Cas9 to modify genes to provide immunity against HIV. Due to breaching a series of ethical and moral principles, his conduct has been met with criticism and outrage across the country and the world. The NHC conducted a thorough investigation against Professor He. The results of the investigation show that He Jiankui fabricated an ethical examination approval in order to continue his research, having retrospectively registered the clinical trial with Chinese authorities well after the work had been completed. The NHC reiterated that any human embryo gene-editing activities with fertility purposes are illegal and prohibited under PRC law. The twins are currently under the care of the local authorities.

10. **Vaccine scandal:** On July 2018, Chinese vaccine maker Changsheng Biotechnology Corporation (Changsheng) was found to have falsified data during the production of 110,000 rabies vaccines. The same company was found to have violated standards in producing around 499,800 doses of the "DTP vaccine", which protects against diphtheria, tetanus and pertussis (whooping cough). Changsheng was fined CNY3.44m and their activities led to the drafting of new laws regarding product liability for vaccinations and sacking of key governmental personnel. In respect of the latter, the communist party's most powerful body, the Politburo Standing Committee of the Communist Party of China, decided to sack 6 top officers after the vaccine scandal, including the former head of NMPA, Mr. Jingquan Bi.

Top 10 predictions of 2019

1. **Patent term extension:** Although the patent linkage regime for drug registration is still at the draft stage, the extension of the patent protection term for certain kinds of new drugs has been covered by new draft amendments to the PRC Patent Law. According to this draft law, an extended term of up to five years may be given to an inventive patent of an innovative drug that has simultaneously applied for marketing in China and abroad, and the total effective term of the patent right of the innovative drug after being put into the market shall not exceed 14 years.

2. **Data protection:** The draft Implementation Measures for Protecting Drug Test Data was issued for public comment. According to the draft measures, during the respective protection terms, the drug authorities will not approve registration applications for the same kinds of drugs filed by other parties, unless the data protection rights holder or MAH agrees to do so or the other parties obtain their data independently. The protection terms would be six years for innovative drugs, drugs for rare diseases and drugs for children, and a 12 year protection term is given to innovative treatment bio-products, with reductions for all protection terms if drug registration is applied for in China later than in other countries.



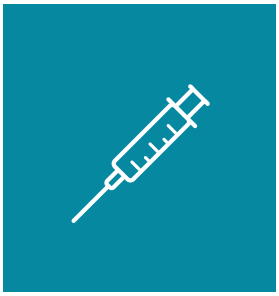
3. **Controlling overseas' products' quality:** By the end of 2018, NMPA released a regulation which sets out a working procedure for the NMPA to verify whether foreign drug and device companies' R&D and manufacturing activities adhere to applicable PRC statutory requirements and standards. In addition, MAHs are now required to establish an effective internal governance system to ensure that adverse drug reaction ("**ADR**") data is directly reported to the competent authorities under strict time limits, depending on the type of ADR recorded (serious, death and others) both within and outside of the PRC. Domestic agents for imported drugs and medical devices are required to take joint liabilities with MAHs to ensure the product quality.

4. **Distribution:** The Dual Invoicing System has been applied in public hospitals on drugs and certain kinds of medical devices in most provinces. The centralised procurement of medicines is also currently being piloted in 11 cities. Depending on the outcomes of both regimes, the relevant authorities may also consider expanding both regimes to a wider scope, i.e. applying the Dual Invoicing System to private hospitals and more kinds of medical devices, or applying the centralised procurement regime nation-wide.

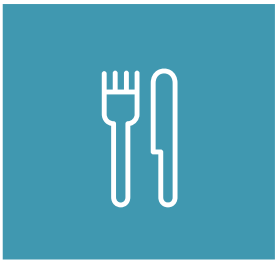
5. **Anti-bribery:** Anti-bribery has consistently been a hot topic in for the life sciences industry year after year, and the government have been given stronger tools for the crackdown of illegal bribery in 2018. The National Supervision Commission, a new anti-corruption agency established to investigate any government employee and act outside the court system, is technically more powerful than the judiciary in certain cases. In addition, the revised PRC Anti-unfair Competition Law prohibits individuals and entities from giving money or property to a business counterpart or public official. Penalties include fines for RMB 100,000 to 3,000,000, confiscation and revocation of business licences and criminal detention with up to life imprisonment.

6. **Drug prices:** In 2018, the Chinese authorities have taken a number of measures to reduce the price of drugs, including new regulatory regimes on drug distribution, free tariffs for imported drugs, frequent anti-trust investigations and the encouragement of generic drugs use to replace original drugs, etc. All of the abovementioned measures are expected to be continued to be applied or even expanded in the coming year to further decrease drug prices and ensure patient accessibility.

7. **Digital health:** According to a press conference held by the State Council, there will be some favourable policies regarding "Internet + Healthcare" issued to encourage the application of internet technologies, such as Artificial Intelligence, in the conventional healthcare industry, including encouraging developing telemedicine via internet hospitals that have been established by physical hospitals. The policies also encourage the allow supply of drugs online, and allow pharmacists to review online prescriptions and drugs to be distributed by a qualified third party that is entrusted by drug distributors and medical institutions.



8. **Vaccines:** In November of last year, the draft PRC Vaccine Management Law was issued in response to the vaccine scandal to further tighten the regulatory requirements on vaccines. The draft law intends to impose greater obligations on the MAH of a vaccine product to ensure the safety, efficacy and quality of vaccines during the R&D, manufacturing and distribution processes. Heavier liabilities may be imposed for non-compliance, ranging from fines and the cancellation of business licences to minimum 10-year business bans in the pharmaceuticals industry and potential criminal punishments.



9. **Food Safety:** Besides the false or misleading promotion of food, food quality is still a key area that the regulatory authorities are keeping an eye on. Following the registration requirements for infant formula milk powder, authorities now plan to apply a recordal regime for infant formula foods as well. Manufacturers should record raw and auxiliary materials, additives, formula, and labels of infant formula food with the authorities before they begin manufacturing foods.

10. **IP rights protection:** In response to the trade war with the US and the claims that China is lacking a sufficient system for the protection of IP, the Chinese government has further updated its IP judicial structure, including setting up 16 IP tribunals in local intermediate courts, IP-specific courts in Beijing, Shanghai and Guangzhou, and a newly established IP tribunal in the Supreme People's Court. As a typical technology-clustered industry, sufficient IP protection for key technologies is essential for life sciences companies to survive in the Chinese market. It is expected that the new IP judicial structure shall provide a safer IP protection environment and benefit the whole industry.

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