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Editorial

Out of the Blue, CFDA Proposes Giant Steps Forward to Boost Drug Innovation and IP Protection

James J. Shen

Pharma MNCs have been overwhelmed with good news one after another from China in recent months. From numerous innovative new product approvals, which have been held up for years and years, a draft policy to ease clinical trial and NDA procedures for foreign new drugs (especially those with international multi-center trials in China), to a string of four more proposed policies to liberalize the review and approval process of innovative medicines, loosen grip on clinical research institutions, and strengthen data and IP protection.

All of the areas now proposed by the CFDA for liberalization have been lobbied by MNCs and their governments for many years, if not decades, without success. In particular for the subjects of patent linkage and restoration, I bet even the most persistent lobbyists have given up the hope of persuading the Chinese government, which has stubbornly ignored outside calls for them.

The official reason given for the sudden and giant progress is the Chinese government's commitment to drug innovation, while some foreign press attributed to its realization of the need to improve people's access to innovative medicines and a few opportunistic industry executives jumped at the chance to praise CFDA Minister BI Jingquan as a great reformer. Well, I guess they forgot to thank Chinese President XI Jinping too.

I have no evidence to argue against the above observations, but such out of the blue moves by the CFDA, which will have far reaching impacts on the landscape pharmaceutical marketplace in China, does seem unusual without external forces. I suspect, therefore, it may have everything to do with U.S. President Donald Trump. In our issues earlier this year, we spoke about the tremendous pressure President Trump asserted on China over fair trade even before his official presidency.

Against odds, he toned down attack on China trade following phone conversations with President Xi and the pair even became extraordinary friends after they met in Florida. While Trump offered Xi face and support, he was rewarded with immediately boosted Chinese sanctions against North Korea and a fast ten point trade deal predominantly favoring the U.S. Although the trade deal did not mention pharmaceuticals specification, it does call for China's fair approval of U.S. biotech product and there are reasons to believe it is only the first step of the agreed 100-day initial trade negotiation between the two countries. I bet issues relating to drug products are already on the table and the latest CFDA proposals may reflect preparations of the CFDA on these matters.

Supporting my observation, CFDA Minister BI Jingquan reportedly met with the delegation led by Dr. Theresa Mullin, Director of the Office of Strategic Programs of the Center for Drug Evaluation and Research (CDER) of the U.S. FDA and chair of the Management Committee of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) on May 19, 2017. It is revealed that both sides exchanged opinions on matters including promoting drug innovation through regulatory reform and China joining the ICH.

Broad Chinese economic falls back again despite official optimism

The broad Chinese economy has slowed from its recent bounce, with retail sales, urban investment and industrial output all posting slower growth in April than the previous month, amid authority's clampdown on debt risks in an effort to stave off a potentially damaging hit to the economy.

Official data released on May 15 highlighted the broad economic impact of these regulatory curbs, with below-forecast factory output in April and fixed-asset investment in the first four months of the year reinforcing evidence of a weakening manufacturing sector and slowing momentum in the world's second-biggest economy.

Factory output was up 6.5% in April from a year earlier, down from 7.6% in March, and fixed-asset investment rose 8.9% in the first four months of the year, off the 9.2% pace in Jan-March. Analysts polled by Reuters had predicted

factory output would grow by 7.1% in April, and tipped fixed asset investment to rise 9.1% in Jan-April.

Fixed asset investment in the manufacturing sector also slowed over Jan-April, with growth of 4.9% down from 5.8% in the first quarter. Infrastructure spending, however, continued to grow over 23% year-on-year in the same period, supported by Beijing's Belt and Road initiative to expand investment links with Asia, Africa and Europe.

Analysts say Beijing is keen to ensure steady economic growth ahead of the 19th Communist Party Congress later in the year. Chinese leaders have pledged to shift the emphasis to addressing financial risks and asset bubbles which analysts say may pose a threat to the Asian economic giant if not handed well.

China's central bank has been guiding short-term interest rates higher to help contain debt perils, though it is treading cautiously to avoid hurting economic growth.

A red-hot property market, fueled by speculative investments, has been identified by analysts and policymakers as one of the biggest risks to growth. Latest official data showed investment in property development picked up in April, although sales growth was significantly slower, suggesting investment in the sector remained robust even as intensified government controls to rein in the market began to take effect.

Retail sales rose 10.7% in April from a year earlier, weaker than March's 10.9% gain as home appliances and automobile sales growth slowed from March. At the same time, growth in the services sector slowed to 8.1% year-on-year, down from 8.3% growth in March and the slowest since December.

"Slowing domestic consumption growth and softer external demand appear to have driven the slowdown in China at the start of the second quarter," Capital Economics' Evans-Pritchard said in a note following the official data release.

The country's first quarter economic growth came in at a faster-than-expected 6.9%, the quickest since 2015 on higher government infrastructure spending and a gravity-defying property boom.

Conversely, the State Information Center under the NDRC said in an article that China's economy will likely expand around 6.8% in the second quarter of 2017. It forecast consumer inflation in the world's second largest economy of around 1.4% and expected an increase of about 6.5% in producer price inflation in the second quarter from the same period a year earlier.

"Overall, China's economy will remain stable but with a slightly slowing trend," the official think tank said.

China has cut its economic growth target to around 6.5% this year to give policymakers more room to push through painful reforms and contain financial risks after years of debt-fueled stimulus.

Before the month of May wraps up, however, one more piece of bad news emerged. Citing a worsening debt outlook, Moody's lowered China's rating to A1 from Aa3, the same level as Japan and the Czech Republic. "The economy is dependent on policy stimulus and with that comes higher leverage," Marie Diron, associate managing director, Moody's Sovereign Risk Group, said after the announcement. "Corporate debt is really the big part."

The move, which the Finance Ministry blasted as "absolutely groundless," may add to pressure on mainland companies to fall back on the local debt market, reinforcing risks that have been roiling the nation's financial markets.

But with the ambitious new Silk Road global development initiative and the Xiong'an "satellite" capital plan, analysts don't expect China to stray too far from the investment-led growth model. Indeed, Chinese President XI Jinping's Xi pledged an additional US$124 billion for the Belt and Road initiative.

"Growth will continue to be underpinned by a strong infrastructure pipeline which also echoes the Belt and Road initiative and urbanization projects like Xiong'an," ANZ economists Raymond Yeung and Betty Wang wrote in a note. "China seems to have returned to an investment-driven growth strategy."

Pharma companies reposition as CFDA shifts gear with innovative medicines

First of all, QuintilesIMS reported recently that the total marketing and sales expenditure of the Chinese pharmaceutical industry rose 8.1% year on year in 2016 to US$17.8 billion. Such expenditures were used primarily (87.7%) to fund physician visits by medical representatives or medical liaison officers of pharmaceutical companies, followed by conference expenditures (11.1%).

MNCs generally laid low in May in anticipation of many proposed new policies potentially benefiting the R&D-based pharmaceutical companies, except J&J. Its subsidiary Janssen revealed a plan to expand its investment in China to drive growth as it races to seize more market shares in lung-related diseases. Janssen is reported to set up a global R&D center in China. During the next five years, Janssen will launch more than ten new drugs and expand its line in 50 existing medicines. In addition, the company will promote sustainable growth through core product mix and innovative measures.

Meanwhile, MSD China celebrated the final reward to its 11 years of regulatory efforts – belated CFDA approval of the company's HPV vaccine Gardasil for use by women aged between 20 and 45.

Boehringer Ingelheim also cheered the beginning of its commercial production site for biopharmaceuticals in Zhang Jiang Hi-tech Park of Shanghai (China) on May 16. The site, with the first-phase investment of more than EUR 70 million, is the first and only biopharmaceutical facility established by a leading MNC active biopharmaceutical manufacturer in China utilizing mammalian cell culture technology.

AstraZeneca China and Peking University's Beijing Institute of Big Data Research (BIBDR) signed an agreement on May 26 to form a joint laboratory for healthcare big data research. The two parties plan, with support of the new joint laboratory, to begin with their cooperative project which aims to promote disease perception, diagnosis and management of COPD. AstraZeneca China will also open its internal primary data to the BIBDR conditionally, which is reported to be the first attempt of such information sharing between the pharmaceutical industry and academic research institutions in the country.

Sorrento Therapeutics announced May 4 that its subsidiary, Levena Biopharma Co., Ltd., has completed construction and put into operation a 25,000 square foot GMP manufacturing facility in Suzhou, China. The facility will be fully dedicated to supporting Sorrento's antibody drug conjugate (ADC) pipeline and growing service business.

South Korea's Celltrion Inc. announced the CFDA has approved a clinical trial for Remsima, its biosimilar drug to treat autoimmune diseases such as rheumatoid arthritis, making it the first foreign antibody biosimilar approved for an efficacy and safety test in China. The drug is already marketed in Europe and the U.S.

There were numerous licensing and strategic alliance deals, most of them between foreign and domestic players.

Eli Lilly China and 3SBio subsidiaries entered into a strategic alliance agreement on May 16 for distribution and promotion of

insulin products. Under the agreement 3SBio has been granted exclusive rights in China of distribution and promotion of Humulin, an insulin product of Lilly, as of July 1, 2017. Lilly China will be responsible for the production and supply of the Humulin products produced in accordance with its global quality standards.

Pharnext SA, a French biopharmaceutical company pioneering a new approach to the development of innovative drugs based on the combination and repositioning of known drugs, entered a strategic agreement with Tasly Pharmaceutical. This partnership includes three axes: a financial investment by Tasly in Pharnext; the development of a new pipeline of synergistic combinations through a shared platform; and the license of Pharnext's lead product for the Chinese market.

Uni-Bio Science Group Limited (HKSE: 690) announced on May 4 that, with the exclusive global rights to manufacture and commercialize Mitiglinide acquired from Jiangsu Hansoh Pharmaceutical in 2015, it is launching this new oral anti-diabetic drug (OAD) under the registered brand name (Bokangtai) in Fujian province, subsequent to the drug being included in the 2017 NRDL.

On the front of domestics, 245 of listed Chinese pharmaceutical companies released their performance results in the first quarter of 2017. In general, the net income of these companies had been on the rise in the period. Among all, 175 reported higher net profits attributable to shareholders in the quarter vs. the same period in 2016, and 28 and 14 of them witnessed above 50% and above 100% net profit growth attributable to parent companies respectively. On the other hand, 70 listed pharma companies reported falling net profits in the first quarter of 2017 compared with the same period in 2016. The combined operating revenues and net profits of the 245 listed pharmaceutical companies reached CNY 266,698 million and CNY 21,889 million, up 18.00% and 7.64% respectively in Q1/2017.

Meanwhile, Hong Kong-listed Alibaba Health Information Technology (Ali Health) reported a massive 739% year-on-year revenue increase in the past 12 months on the back of its pharmaceutical e-commerce business. In a move to further consolidate and build up Alibaba's health-related assets, Ali Health said it would acquire a nutritional supplement unit of its parent Alibaba Group for HK$3.8 billion (US$490 million).

Major domestic players also continued their expansion overseas, most likely as a move to counter Chinese market risks.

Shanghai Pharmaceutical Holding Co Ltd said on May 17 that it was interested in a possible deal for Germany's Stada Arzneimittel AG, though it had not made any official offer. German drug firm Stada, the target of a takeover bid from buyout firms Bain and Cinven that valued it at about EUR 5.3 billion (US$5.89 billion).

Chinese pharmaceutical equipment supplier Truking Technology Ltd. and other investors have agreed to acquire 75.1% of German pharmaceutical packaging and equipment maker Romaco Group for €150 million (US$164 million).

BGI announced on May 17 a new U.S. West Coast Innovation Center that will be co-located between Seattle and San Jose with the goal of fostering partnerships and innovation between BGI and institutions in the two hubs. It is the first center of its kind, but follows BGI's trend of fostering international collaborations.

In a similar move, Qilu Pharmaceuticals opened Boston's first Chinese pharma-backed innovation center, Qilu Boston Innovation Center (QBIC), on May 19. QBIC is located in a two-story building at 50 Soldiers Field Place that was acquired by Qilu last year for around US$10 million. Along with the incubator, Qilu's first branch company in Massachusetts – QLB Biotherapeutics Inc (QLB Bio) – also set up shop in the new facility on the same day.

Crown Bioscience announces a collaboration to develop a CTLA-4 antibody with Jiangsu Qyun Bio-Pharmaceutical Co. Ltd. As part of the collaboration agreement CrownBio will leverage Jiangsu Qyun Bio-Pharmaceuticals expertise to support the Investigational New Drug Application (IND) and further clinical development of CrownBio's proprietary 10B10 antibody.

Besides, a clearer picture is beginning to emerge of the US$1.4 billion-plus auction for Quadrant Private Equity's Icon Group, with its Chinese operating partner, Yibai Pharmaceuticals, said to be in the mix as a prospective buyer. Icon Group includes radiology centers, a pharmacy supply operation and Australia's largest provider of day oncology and haematology services. In addition, Chinese group CITIC, in conjunction with New Journey Cancer Hospital, which it partly owns, is bidding. So are Baring Private Equity and Luye Pharma.

WuXi AppTec and its affiliates pulled off multiple deals in May. It announced on May 15 that it has completed its acquisition of HD Biosciences (HDB), a leading biology focused preclinical drug discovery CRO. In the meantime, WuXi Healthcare Ventures and Frontline BioVentures, have agreed to merge to form one healthcare investment group named 6 Dimensions Capital. The combined firm will be one of the larger healthcare focused investment firms in China and the U.S., with total asset-under-management of CNY 5.5 billion (US$800 million). WuXi NextCODE recently closed a US$75 million series B financing co-led by Temasek Holdings and Yunfeng Capital. WuXi NextCODE will use the proceeds of the funding round on advancing the commercialization of its consumer solutions for the China market, to further strengthen informatics, and expand its capabilities in artificial intelligence and deep learning. Also, WuXi Biologics has reportedly set the stage for a US$513 million IPO in Hong Kong soon.

Finally, Shanghai-based startup Abbisko Therapeutics has raised US$28 million in a Series A financing that will be used to advance its cancer immunotherapies into clinical trials. The investment round, by Lilly Asia Ventures, Sinopharm Capital, Jianxin Capital and TF Capital, will be used to set up R&D teams and discovery centers that will help it advance its core anticancer programs.

CANbridge Life Sciences, a clinical-stage biopharma company focused on developing Western drug candidates in China and North Asia, announced that it raised US$25 million in a Series B round. Proceeds will be used to fund the clinical trial development of its two lead compounds, CAN008 and CAN017, in China. CAN008, a fully-human fusion onco-immunotherapy, is currently in a Phase I/II for the treatment of glioblastoma multiforme (GBM) in Taiwan.

CFDA jumpstarts reform to beef up support of innovation and IP protection

After the CFDA released a draft new policy, *CFDA Decisions on Adjusting Import Drug Registration Related Matters*, on March 17 which aims to encourage, following IND approvals, synchronized international and domestic clinical trials of non-marketed foreign drugs, the agency published four more proposed policies to boost support of drug innovation and better protect intellectual property rights on May 11 for comments by June 10.

The draft *Relevant Policies for Protection of Innovator Rights to Encourage Drug and Medical Device Innovation* provides: 1) establishing patent linkage system; 2) perfecting drug trial data protection system; 3) facilitating confidentiality obligations of state employees; and 4) introducing the formulary of marketed drugs.

The draft *Relevant Policies for Accelerating Drug and Medical*

Device Evaluation and Approval to Encourage Innovation provid es: 1) accelerating evaluation and approval of drugs and medical devices in urgent clinical need; 2) supporting R&D of orphan drugs and medical devices for orphan diseases; 3) heightening evaluation and approval of injectable drugs; 4) adjusting the management model of APIs, excipients and packaging materials; 5) perfecting the drug and medical device evaluation system; 6) supporting clinical application of new drugs; 7) supporting inheritance and innovation of TCMs; and 8) establishing the priority evaluation and approval system on the basis of patent compulsory licensing.

The draft *Relevant Policies for Implementing Full Product Life Cycle Management of Drugs and Medical Devices to Encourage Innovation* stipulates: 1) facilitating the legal obligations of MAHs; 2) perfecting ADR reporting system of drugs and medical devices; 3) developing re-evaluation of approved injectable drugs; 4) improving the re-evaluation system of medical devices; 5) seriously punishing clinical trial data fraudulent practices; 6) streamlining academic promotion of drug products; 7) strengthening capacity building for evaluation and inspection; 8) reforming drug clinical sampling testing system; 9) facilitating full process (from research to application) inspection obligation; and 10) building a professional inspector force; 11) boosting international cooperation.

The draft *Relevant Policies for Reforming Clinical Trial Manage-ment to Encourage Drug and Medical Device Innovation* calls for: 1) shifting from Designation to Filing Manage-ment of Clinical Trial Institutions; 2) supporting researchers and clinical trial institutions in conducting clinical trials; 3) perfecting ethical committee mechanism; 4) raising ethical review efficiency; 5) optimizing clinical trial review procedures; 6) accepting foreign clinical trial data; and 7) supporting extended clinical trials.

Subsequently, the CFDA announced on May 16 that it has approved the designation of 149 additional medical institutions as designated clinical research institutions and issued relevant certification documents. The move will relieve to some point the current shortage of clinical research resources immediately amid soaring needs of bioequivalence studies. A week later, the agency approved selected specialties in 256 more medical facilities as designated clinical research institutions and expanded the approved medical specialty scope of 95 existing designated clinical research institutions.

Similarly, the CFDA is also working on liberalizing the regulation of health foods. It released on April 28 a draft document, *Opinions for Further Strengthening Health Food Regulation*, which will make a number of important changes to the existing regulatory regime for such products including: 1) formulating a health food raw material list and a healthcare function list control regulation; 2) expanding the health food raw material list on three levels of vitamin & mineral raw material, single raw material formulation and similar formulations; and 3) advancing and liberalizing health food product filing regulation so that most health food products will be subject to filing regulation instead of registration approval.

In other regulatory developments, the CFDA issued the *Technical Guidelines for Extrapolation of Adult Drug Usage Data to Pediatric Population* as an attempt to resolve the urgent clinical needs for pediatric drugs, further encourage R&D of pediatric drugs and maximize the use of existing data to reduce unnecessary pediatric research.

The agency also introduced new and draft documents for generic drug quality and efficacy equivalence. It released on May 25 a new draft document, *Matters Relating to Applications for Quality and Efficacy Equivalence Evaluation of GI Local Acting & Electrolyte Balance Generic Drugs and Bioequivalence Study of Special Drugs*, as well as four new guidelines for onsite inspection of generic drug quality and efficacy equivalence studies including: 1) *Guidelines for R&D Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*; 2) *Guidelines for Production Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*; 3) *Guidelines for Clinical Trial Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*; and 4) *Guidelines for Cause-Triggered Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*. On the last day of May, the Center for Drug Evaluation (CDE) under the CFDA released two draft documents, the *Drug eCTD Composition* and the *Application Guidelines for eCTDs for Chemical Generic Drugs*.

The CFDA also took a few actions to move reviews of selected innovative drugs forward. It issued a new announcement (CFDA Announcement 2017#59) on May 19 about onsite inspection of 44 drug applications which completed clinical studies and are seeking production or import approvals. Among them, 35 are for import drugs from Astellas, Helsinn, Otsuka, Boehringer Ingelheim, Acetolion, Lundbeck, Bayer, GSK, AstraZeneca, Novartis and Cephalon.

The NHFPC, CFDA and MIIT jointly issued a notice on May 15, releasing the second batch of 40 pediatric drug products which are encouraged for development, while the Center for Drug Evaluation (CDE) under the CFDA publicized on May 23 a new list of 11 drug applications (by application number) (17th Batch) which are to be granted priority review status.

Last but not the least, the CFDA released its *2016 Food and Drug Regulatory Statistical Annual Report* on May 23 to report a comprehensive range of drug regulatory information for the year of 2016 which are detailed later in this issue.

State Council Lays Out Major Healthcare Reform Tasks As It Raises Healthcare Spending Budget and Resident BMI Subsidies

The General Office of the State Council issued an official document, *Major Tasks of Deepening Healthcare System Reform in 2017*, on May 2. The document includes a total of 70 major tasks to be implemented this year. The first part of the document includes 14 new policies to be formulated and issued in 2017 by various central government agencies. The rest 56 major healthcare reform tasks are mostly provided in various earlier documents. For details of this comprehensive document with deadlines and responsible agencies for implementation of each reform task, please refer to our full coverage of this story in the latter part of this journal edition issue.

Days later, China's national fiscal budget for healthcare expenditures is set at CNY 1,404.4 billion in 2017, up 5.1% year on year, according to Qichao SONG, Deputy Director General, the Social Security Department of Ministry of Finance. This is 4.4 times of the same figure in 2008 when healthcare reform began. The amount also represents 7.2% of the 2017 fiscal budget of Chinese government, up from 5.0% in 2008. Among the total, CNY 398.2 billion comes from the central government budget, which represents 7.7% of the 2017 fiscal budget of central government, up from 6.1% in 2008.

The MOHRSS and the Ministry of Finance (MOF) issued at the beginning of May a joint notice for urban and rural resident basic medical insurance (BMI) in 2017. It is provided that the Chinese government will increase the government subsidy of urban and rural resident BMI system by CNY 30 per participant to a total

of CNY 450. Besides, the notice requires increase of personal premium contribution to the system by CNY 30 per participant to a total of CNY 180.

According to a recent information release of the MOHRSS, the urban employee BMI program and the urban and rural resident BMI program saw a combined surplus of CNY 1,496.5 billion in 2016. Among the total, the surplus of urban employee BMI in 2016 was CNY 1,297.2 billion, including CNY 777.2 billion BMI fund surplus and CNY 520.0 billion personal BMI account surplus, while the surplus of urban and rural resident BMI was CNY 199.3 billion in the same year.

In a separate development, the Ministry of Finance, the State Taxation General Administration and the China Insurance Regulatory Commission jointly issued a notice on May 2 to expand the trial of personal income tax relief policy for commercial health insurance purchase to nationwide with effect from July 1, 2017. Under the policy, commercial health insurance expenditure incurred by individuals will benefit from tax relief up to a limit of CNY 2,400 per year. Corporate purchase of commercial health insurance is deemed the same as personal purchase.

Following the policy line, Nippon Life Insurance has begun selling health insurance that lets Chinese policyholders receive cancer treatment in Japan as part of their coverage. Insurance policy sales will be handled by Nissay-Greatwall Life Insurance, a joint venture between Nippon Life and the Chinese government. Nippon Life holds a 30% stake. In addition to cancer treatment, other costs such as travel and lodging will be covered by the insurance.

On other fronts, the NHFPC and the SATCM recently issued a new policy document, *Guidance Opinions for Accelerating Electronic Registration Management Reform of Medical Institutions*, Physicians and Nurses. The document requires that full registration management of medical institutions, physicians and nurses should be completed nationwide by June 2018.

China is to issue its first regulation on how the big data from the health sector is collected, stored and used. JIN Xiaotao, Vice Minister of the National Health and Family Planning Commission, said the regulation will be issued soon, as the nation aims to safeguard public security. Big data for the health industry includes patients' basic information and conditions, disease control and prevention, food safety, lifestyles and even genomes.

In close … it is a rare positive moment worth cheering for

We discussed at the beginning of this editorial the possible external backdrop behind the recent progress made by the Chinese government in materializing its commitment for drug innovation. Certainly I should also not discount entirely the internal drive of the Chinese government to change as a part of the so-called "supply side reform", which has been hailed as a national strategy to make Chinese industries more efficient and competitive.

CFDA Minister BI Jingquan delivered a keynote speech at the *24th National Congress of the Chinese Pharmaceutical Association* recently. He pointed to the weak drug R&D innovation capability of the Chinese pharmaceutical industry as a typical supply side problem which needs to be reformed.

Bi called for reform of the following areas to improve China's systemic environment for drug innovation: 1) mobilizing more clinical research resources through regulatory liberalizations; 2) accelerating the review and approval of new drugs through reforms; 3) stimulating market dynamism and social creativity through exploration of new systems including those for data protection, patent linkage and patent term restoration to ensure a predictable marketplace, steady and transparent regulatory environment, and good return on investments; 4) cleaning up the eco-system of scientific research with stringent law enforcement for clinical research; and 5) facilitating full life cycle management obligations of marketing authorization holders on the basis of MAH system trial experiences, including those for product design, clinical research, production and sales, and ADR reporting.

His speech is generally in line with what have been proposed recently by the CFDA. But most notably, Bi cited patent term restoration as an area of reform to encourage drug innovation for the first time. This topic was not brought up in the latest CFDA proposed measures which has been publicized for comments.

Well, we will be witness a very exciting time in the history of Chinese pharmaceutical industry, if what the CFDA is proposing is to become reality. It remains to be seen things will work out in favor of MNC innovators as they are now, in which case these companies can expect more leverage as IP holders, better market access and prospects, as well as improved return on investment for their patented novel drugs.

Despite the encouraging news, MNCs should continue to stay vigilant of various Chinese policy moves designed to substitute import drugs and support indigenous new drugs, as well as an alarming tendency to facilitate compulsory licensing of products in vaguely defined circumstances of public safety through recent policies and policy proposals. It is also possible the latest CFDA proposals will eventually lead nowhere or get castrated as international and domestic politics shift gear or even change direction, so it is by no means time for celebration yet.

Nevertheless, it is a rare positive moment worth cheering and anticipating for. Let's keep our fingers crossed for the better.

News in Focus

State Council Issues Document on Major Healthcare Reform Tasks in 2017

The General Office of the State Council publicized an official document, *Major Tasks of Deepening Healthcare System Reform in 2017*, on May 2.

The document includes a total of 70 major tasks to be implemented this year. The first part of the document includes 14 new policies to be formulated and issued in 2017 by various central government agencies. The policy on advancing infrastructure building and development of medical consortiums was already released and other documents to be introduced and with notable relevance with the pharmaceutical industry are as follows:

- Implementation Opinions for Reform and Perfection of Shortage Drug Supply Security Mechanism (Responsibility of NHFPC to be completed before end of June 2017);
- Guidance Opinions on Establishment of Modern Hospital Management System (Responsibility of NHFPC to be completed before end of June 2017);
- Guidance Opinions on Deepening Reform of Medical Institutions Affiliated to State-owned Enterprises (Responsibility of SASAC to be completed before end of June 2017);
- Opinions for Supporting Social Capital in Multi-layered and Multiple forms of Medical Services (Responsibility of NDRC to be completed before end of June 2017);

- Guidance Opinions for Strengthening Overall Regulation of Medical and Health Industries (Responsibility of NHFPC and MOHRSS to be completed before the end of September 2017);
- Guidance Document for Reform and Perfection of Generic Drug Regulatory Policies (Responsibility of State Council's Healthcare Reform Office to be completed before the end of October 2017);
- Provisions for Registration and Filing of Medical Representatives (Responsibility of CFDA to be completed before the end of December 2017); and
- Drug Procurement and Supply Credit Management System (Responsibility of NHFPC and MOHRSS to be completed before the end of December 2017).

The rest 54 major healthcare reform tasks are provided in various earlier documents which were previously covered in detail by us multiple times and therefore only the most important tasks are spotlighted below again:

- Advancing the reform of military and armed police hospitals as parts of the local urban public hospital reform where they are located (Responsibility of Military Logistics Department's Health Bureau);
- Full implementation of overall reform of public hospitals with elimination of hospital drug purchase margins before the end of September 2017 (Responsibility of NHFPC, SATCM, NDRC, MOF, MOHRSS, MOFCOM, SASAC and Military General Logistics Department's Health Bureau);
- Facilitating medical service price reform with full implementation in urban public hospitals and establishment of regional coordination systems for such prices (Responsibility of NDRC, NHFPC, MOHRSS and SATCM);
- All provincial level governments should set annual healthcare expenditure caps with such growth contained at below 10% (Responsibility of NHFPC, MOF and SATCM);
- Completing merger of urban and rural basic medical insurance systems (Responsibility of MOHRSS, NHFPC and CIRC);
- Fully advancing the hybrid BMI payment model on the basis of disease group-based payment scheme with DRG trials in select areas (Responsibility of MOHRSS, NHFPC and MOF);
- Advancing disease group-based BMI payment scheme with all cities implementing no less than 100 disease groups before the end of 2017 (Responsibility of NDRC, NHFPC, MOHRSS, SATCM and MOF);
- Introducing trial of uniform BMI drug payment standards and exploring the formulation of uniform BMI medical service payment standards. Pushing forward nationwide BMI information connectivity and achieving direct settlement of qualified out-of-area hospitalization expenditures (Responsibility of MOHRSS and NHFPC respectively);
- Drawing up around 200 clinical pathways with a total of 1,200 such pathways in place, and formulating around 100 TCM clinical pathways (Responsibility of NHFPC and SATCM);
- Accelerating generic drug quality and efficacy equivalence evaluation and developing MAH system trials (Responsibility of CFDA);
- Further expanding designated production of shortage drugs and support construction of centralized production center for minor drugs. Building and improving shortage drug early alert and classified response system (Responsibility of MIIT and NHFPC);
- Taking advantage of the National Drug Supply Security Overall Management Information Platform to persist on the principle of centralized purchase with volume and pushing forward classified drug purchase of public hospitals (Responsibility of NHFPC);
- Facilitating the two-invoice policy for public hospital drug procurement. The two-invoice requirement should be fully implemented in provincial level trial sites of overall healthcare reform and the first four batches of 200 public hospital reform trial sites before the end of this year (Responsibility of NHFPC, CFDA, NDRC, MIIT, MOFCOM, STGA, SATCM and MOF);
- Pushing forward the establishment of drug ex-manufacturer price traceability mechanism (Responsibility of CFDA, NDRC, MIIT, STGA and NHFPC);
- Raising the number of drug products subject to national price negotiation and ensure relevant BMI complementary policies (Responsibility of NHFPC and MOHRSS);
- Experimenting classified regulation of retail pharmacies, encouraging the development of retail pharmacy chains, exploring connectivity and real time sharing of medical institution drug prescriptions, BMI settlement information and drug retail consumption information (Responsibility of MOFCOM, MOHRSS, NHFPC and CFDA);
- Launching evaluation of the National Essential Drug List and formulating incentive policies for prioritized use of national essential drugs (Responsibility of NHFPC);
- Conducting trials of hospital chief pharmacist system in selected areas (Responsibility of NHFPC);
- Advancing application of BMI intelligent surveillance and control system with coverage of most BMI funding areas before the end of 2017 so that BMI supervision of medical institutions will be extended to healthcare professionals (Responsibility of MOHRSS and NHFPC);
- The government subsidy of public health services should be raised to CNY 50 per capita with strengthened disease control and chronic disease prevention systems in place (Responsibility of MOF, NDRC and NHFPC respectively); and
- The drug prescription commentary system should be facilitated with guidance, list control and focused surveillance of supplementary and nutritional premium drugs (Responsibility of NHFPC and SATCM).

For full text of this document in Chinese, please visit the following central government weblink: http://www.gov.cn/zhengce/content/2017-05/05/content_5191213.htm

Financial Overview of Urban and Rural BMI Programs in 2016

According to a recent article released by the MOHRSS, the urban employee BMI program and the urban and rural resident BMI program saw a combined surplus of CNY 1,496.5 billion in 2016.

Among the total, the surplus of urban employee BMI in 2016 was CNY 1,297.2 billion, including CNY 777.2 billion BMI fund surplus and CNY 520.0 billion personal BMI account surplus, while the surplus of urban and rural resident BMI was CNY 199.3 billion in the same year.

The fund income of urban employee BMI program in 2016 was CNY 1,027.4 billion with its CAGR between 2012 and 2016 at 14.1%, while fund spending was CNY 828.7 billion with its CAGR between 2012 and 2016 at 14.2%.

The fund income of urban and rural resident BMI program in 2016 was CNY 281.1 billion with its CAGR between 2012 and 2016 at 33.8%, while fund spending was CNY 24.8 billion with its CAGR between 2012 and 2016 at 38.4%.

The number of urban BMI participants reached 743.92 million in 2016, up by 207.51 million compared with that of 2012. Among the total, the number of urban employee BMI participants was 295.32 million (including 217.20 employees and 78.12 million retirees), up by 30.46 million compared with that of 2012, while the number of urban resident BMI participants reached 448.60 million, up by 177.04 million compared with that of 2012.

CFDA Minister Calls for Improved Drug Innovation Environment at CPA Conference

CFDA Minister BI Jingquan delivered a keynote speech at the 24th National Congress of the Chinese Pharmaceutical Association recently. He pointed to the weak drug R&D innovation capability of the Chinese pharmaceutical industry as a typical supply side problem which needs to be reformed.

Bi called for reform of the following areas to improve China's systemic environment for drug innovation.

- Mobilizing more clinical research resources through simplifying regulations, reforming clinical research management model, encouraging social capital in clinical research institutions, enhancing efficiency of ethics review, optimizing review procedures of clinical trials and motivating enthusiasm of medical professionals in clinical research;
- Accelerating the review and approval of new drugs by establishing a technical evaluation system led by review and supported by inspection and testing, as well as capacity building of reviewer force for new drugs and medical devices;
- Stimulating market dynamism and social creativity through exploration of new systems including those for data protection, patent linkage and patent term restoration, so that social capital and researchers can have a predictable marketplace, steady and transparent regulatory environment, and opportunities for good return on investments;
- Cleaning up the eco-system of scientific research with stringent law enforcement for clinical research to ensure truthfulness and traceability of data;
- Facilitating full life cycle management obligations of businesses. On the basis of MAH system trial experiences and the principle of matching rights and obligations, the full legal obligations of marketing authorization holders for product design, clinical research, production and sales, and adverse drug reaction reporting must be facilitated. The manufacturer ADR reporting and monitoring system should be established; and
- Building a professional drug evaluation and inspection force and deepening reform the drug evaluation and approval system to meet the requirements for an innovative country and healthy China building.

Most notably, Bi cited patent term restoration as an area of reform to encourage drug innovation for the first time. This topic was not brought up in the latest CFDA proposed measures which has been publicized for comments.

CFDA Solicits Comments on New Policy on Full Product Life Cycle Management of Drugs and Medical Devices

The CFDA issued a new draft document, *Relevant Policies for Implementing Full Product Life Cycle Management of Drugs and Medical Devices to Encourage Innovation* (CFDA Announcement 2017#54), in the evening of May 11 for public comments.

Feedbacks are "suggested" to be submitted before May 25 to the Drug and Cosmetic Registration Department of CFDA via email yhzcszhc@cfda.gov.cn. However, the announcement also said the deadline for comment seeking is June 10.

Full text of the document in Chinese is available at the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0087/172569.html.

WiCON|*Pharma China* has prepared an exclusive summary of the document for its subscribers:

1. *Facilitating the legal obligations of marketing authorization holders (MAHs)* – Holders of drug approval numbers in the ten provincial level MAH trial sites should hold entire legal obligations of preclinical research, clinical research, contract manufacture, raw material and excipient quality, distribution and delivery, clinical guidance and adverse drug reaction (ADR) reporting, as well as truthfulness, completeness and traceability of clinical data, production process and sample products. CROs and CMOs should shoulder relevant responsibilities provided by law and contracts. On the basis of trial experience, the MAH system will be implemented nationwide.
2. *Perfecting ADR reporting system of drugs and medical devices* – On the basis of existing ADR reporting system which is dominated by medical institution reports, an ADR reporting system with MAHs as the main constituent should be established. All MAHs should conduct continued research and risk assessments of drugs and medical devices on the market.
3. *Developing re-evaluation of approved injectable drugs* – In accordance with relevant provisions of the Drug Administration Law and scientific progress, safety, efficacy and quality control re-evaluation of approved injectable drugs will be conducted. The re-evaluation should be completed between five to ten years with best efforts. Those passing re-evaluation will enjoy the same preferential policies for bioequivalent solid dosage form generic drugs.
4. *Improving the re-evaluation system of medical devices*.
5. *Seriously punishing clinical trial data fraudulent practices* – Party A and B Signers of the clinical research project and relevant researchers are primary responsible parties of clinical trial data. Those responsible for fraudulent and untrue preclinical and clinical research reports, as well as responsible persons of CROs will be penalized severely according to law.
6. *Streamlining academic promotion of drug products* – Medical representatives (MRs) are responsible for academic promotion of new drugs and hearing feedbacks in clinical applications. They are banned from being assigned sales tasks and private contacts with physicians. Medical institutions are banned for providing drug prescription data to MRs and pharmaceutical companies. MAHs (manufacturers) are responsible for registering MRs with websites designated by the food and drug agencies.
7. *Strengthening capacity building for evaluation and inspection* – Drug and medical device evaluation should be included in the government service purchase in order to provide high

efficiency services. IT infrastructure building and introduction of electronic dossier systems should be accelerated.

8. *Reforming drug clinical sampling testing system* – Applicants or MAHs should guarantee their clinical trial sample products to have the same quality and efficacy as the samples provided for application of marketing approvals.
9. *Facilitating full process (from research to application) inspection obligation* – Establishing the clinical trial project inspection model on the basis of risk and evaluation needs, and strengthening onsite and triggered inspections.
10. *Building a professional inspector force*.
11. *Boosting international cooperation* – Deepening bilateral policy and technical exchanges, actively participating in international rule and standard setting, and gradually realizing harmonization/mutual recognition of evaluation, inspection and testing results.

CFDA Solicits Comments on New Policy on Accelerating Drug and Medical Device Evaluation and Approval

The CFDA issued a new draft document, *Relevant Policies for Accelerating Drug and Medical Device Evaluation and Approval to Encourage Innovation* (CFDA Announcement 2017#52), in the evening of May 11 for public comments.

Feedbacks are "suggested" to be submitted before May 25 to the Drug and Cosmetic Registration Department of CFDA via email yhzcszhc@cfda.gov.cn. However, the announcement also said the deadline for comment seeking is June 10.

Full text of the document in Chinese is available at the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0087/172567.html

WiCON|*Pharma China* has prepared an exclusive summary of the document for its subscribers:

1. *Accelerating evaluation and approval of drugs and medical devices in urgent clinical need* – Drugs and medical devices for diseases seriously endangering life with no alternative therapies as well as other drugs and medical devices significant for meeting major clinical demands can be approved conditionally, if their early and mid-term parameters of clinical trials indicate therapeutic efficacy with predictable clinical value. Applicants should formulate risk control plans and conduct verification clinical trials and complete research provided in the conditional approvals. To encourage innovation, priority evaluation and approvals are offered to those listed in the national science and technology major programs as well as those supported by national major R&D research programs.
2. *Supporting R&D of orphan drugs and medical devices for orphan diseases* – The health and family planning department should publish orphan disease list and patient registration system. Applicants of such products can raise applications for clinical trial reduction or exemption. Such products approved in foreign countries can be approved conditionally with makeup research to be conducted later within specified timeframes.
3. *Heightening evaluation and approval of injectable drugs* – Strictly controlling change of oral drug formulations to injectable dosage forms. Whenever oral dosage forms can meet clinical demands, injectable dosage forms will not be approved; strictly controlling change of muscle injections to iv injectable dosage forms. Whenever muscle injection can meet clinical demands, iv injectable dosage forms will not be approved; and applications for changes between large volume, small volume and sterile power injectable dosage forms will not be approved without obvious clinical advantages.
4. *Adjusting the management model of APIs, excipients and packaging materials* – Formulating filing systems and establishing filed information platforms for such products. Such filed information will be reviewed and approved together with linked drug applications. Drug manufacturers are responsible for the quality of such products.
5. *Perfecting the drug and medical device evaluation system* – Building a technical review system led by evaluation and supported by inspection and testing. Meetings between applicants and reviewers should be held before phase I clinical trial application, after phase II is completed and before start of phase III, and after completion of phase III and before submitting production and marketing applications. Establishing the system of expert consultative committee, which will openly debate major technical issues, and hear from both reviewers and applicants.
6. Supporting clinical application of new drugs – Encouraging prioritized purchase and application of new drugs with well-defined therapeutic efficacy and reasonable pricing by medical institutions. NRDL dynamic revision mechanism should be improved, BMI uniform drug payment standards should be explored, and BMI reimbursement of innovative medicines under the regulations is supported. All local l governments can organize centralized purchase of such products at the provincial level.
7. *Supporting inheritance and innovation of TCMs* – A new traditional Chinese medicine registration and evaluation system meeting characteristics of TCMs should be established with a balance of TCM efficacy and modern drug development requirements and a balance of traditional drug application approaches and modern drug consumption needs. Innovative TCMs should be reviewed and approved according "new efficacy" standards; improvement TCMs should demonstrate its clinical advantages; TCMs with classic recipes should be subject to simplified evaluation and approvals; and natural medicines should be reviewed and approved according to modern medical standards. TCM market and resource assessments should be conducted to lead the clinical value-oriented TCM innovation. Encouraging development of formulated TCMs using modern science and technology, supporting development of TCM new drugs on the basis of TCM traditional dosage forms.
8. *Establishing the priority evaluation and approval system on the basis of patent compulsory licensing* – Drug evaluation agency should offer priority evaluation and approval of registration applications for products approved by the IP department for compulsory licensing. The procedures for initiating compulsory licensing when public safety is under major threat should be introduced by the health and family planning department.

CFDA Solicits Comments on New Policy on Reforming Clinical Trial Regulation

The CFDA issued a new draft document, *Relevant Policies for Reforming Clinical Trial Management to Encourage Drug and Medical Device Innovation* (CFDA Announcement 2017#53), in the evening of May 11 for public comments.

Feedbacks are "suggested" to be submitted before May 25 to the Drug and Cosmetic Registration Department of CFDA via email yhzcszhc@cfda.gov.cn. However, the announcement also said the deadline for comment seeking is June 10.

Full text of the document in Chinese is available at the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0087/172568.html

WiCON|*Pharma China* has prepared an exclusive summary of the document for its subscribers:

1. *Shifting from Designation to Filing Management of Clinical Trial Institutions* – The designation system of clinical trial institutions is to be withdrawn. Medical institutions with clinical trial capacities should register and file with the website designated by the food and drug department. Social capital is encouraged to set up clinical trial institutions. Principle clinical trial investigators should possess senior professional ranks and have previously participated in at least three clinical trials.
2. *Supporting researchers and clinical trial institutions in conducting clinical trials* – Medical institutions, medical research institutions and medical/ pharmaceutical academic institutions are supported to participate in clinical trials with such capacity included as a parameter for future medical institution grading. Medical institutions are encouraged to set up specialized clinical trial units with professional clinical researchers. Clinical doctors are encouraged to participate in drug and medical device innovation. Foreign companies and research institutions are allowed to conduct phase I drug clinical trials in China.
3. *Perfecting ethical committee mechanism* – Clinical trials must meet ethical standards with sufficient trial information disclosed to volunteers, who should understand and sign informed consent agreements. Medical institutions conducting clinical trials should establish ethics committees to review and approve clinical protocols. Each area can establish regional ethics committee as needed to review and supervise local clinical trials and qualifications of researchers.
4. *Raising ethical review efficiency* – Before submitting clinical trial applications, applicants should first seek approvals from ethics committees. For those conducting multi-center clinical trials in China, after the ethics committees of lead investigating institutions review and approve their clinical protocols, ethics committees of other member clinical investigating institutions can simply endorse review conclusions of the ethic committees of lead investigating institutions without conducting additional reviews. The National Medical Clinical Research Center and institutions supported by the national science and technology major programs and national major R&D research programs should streamline resources to set up a uniform ethics review platform and gradually achieve mutual recognition of ethics committee reviews.
5. *Optimizing clinical trial review procedures* – The communication mechanism between applicants and reviewers should be established and perfected. Such communications should be held before applying for approvals of phase I and III drug clinical trials. Drug evaluation agency should provide positive or negative review comments within 60 working days and, without such comments from the drug evaluation agency within the timeframe, applications are deemed approved. In case of clinical protocol changes, major pharmaceutic changes or preclinical safety issues in the process of clinical research, applicants should file such incidents with the drug evaluation agency. Applicants should modify clinical protocols or suspend/ terminate clinical research projects in case of safety and other risks.
6. *Accepting foreign clinical trial data* – Clinical research data obtained by applicants outside China can be accepted for Chinese registration applications if relevant requirements of China's drug and medical device registration are met and following onsite inspections. Foreign companies can submit applications for marketing approvals directly after they complete international multi-center drug clinical trials in China and if relevant Chinese registration requirements are met. For drugs and medical devices applying for marketing in China for the first time, applicants should provide clinical trial data without racial differences. Bioequivalence test data for generic drugs approved by the EU, the U.S. and Japan can be used to support Chinese generic drug registration applications if relevant requirements of China's drug and medical device registration are met and following onsite inspections.
7. *Supporting extended clinical trials* – Drugs and medical devices under clinical trials for diseases seriously endangering life and without alternative therapeutics can be used on other patients following informed consent, if initial observations of these clinical trials show possible benefits and meet ethical requirements. Such clinical data on other informed consent patients can be used to support registration applications. Extended use of experimental drugs can only be used in institutions conducting phase II and III clinical trials and the number of people taking such drugs must not exceed the number of volunteers provided by clinical protocols.

CFDA Solicits Comments on New Policy on Protecting Innovator Rights

The CFDA issued a new draft document, *Relevant Policies for Protection of Innovator Rights to Encourage Drug and Medical Device Innovation* (CFDA Announcement 2017#55), in the evening of May 11 for public comments.

Feedbacks are "suggested" to be submitted before May 25 to the Drug and Cosmetic Registration Department of CFDA via email yhzcszhc@cfda.gov.cn. However, the announcement also said the deadline for comment seeking is June 10.

Full text of the document in Chinese is available at the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0087/172606.html

WiCON|*Pharma China* has prepared an exclusive summary of the document for its subscribers:

- *Establishing patent linkage system* – When drug registration applicants submit applications, statements relating to relevant rights which are known and should have known must be submitted. If relevant drug patents are challenged, applicants must state that their applications do not constitute infringements and they should inform relevant patent holders within 20 days of submitting their applications. If relevant patent holders believe there are patent infringements, they should litigate with judicial institutions within 20 days of receiving applicant notices and subsequently inform the drug evaluation agency. The drug evaluation agency can set up approval stay periods of no more than 24 months after receiving relevant certifications from the judicial institutions for patent infringement litigation acceptances. During the approval stay period, technical evaluation of relevant products will not stop. During the approval stay period, if both parties reach settlements or judicial judgments are made, the drug evaluation agency will approve or disapprove relevant applications accordingly. If the approval stay period is exceeded without legal judgments, the

drug evaluation agency can approve relevant applications. For applications without statements of relevant patent involvements which are sued by patent holders, the drug evaluation agency should decide on the approval stay period according to judicial litigation acceptance situation. Approved drug products involving intellectual property lawsuits should follow the judicial determinations.

- *Perfecting drug trial data protection system* – Trial data protection applications can be submitted together with the applications for drug marketing. For innovative drugs approved for marketing, six years of data protection is applicable. For innovative drugs for orphan diseases and dedicated pediatric use, ten years of data protection is applicable. For improvement new drugs for orphan diseases and dedicated pediatric use, three years of data protection is applicable. For innovative therapeutic biologics, ten years of data protection is applicable. For drugs which successfully challenges patents and first-to-copy generic drugs which are already marketed abroad, one and half years of data protection is applicable. For new drugs submitting Chinese marketing and data protection applications within one year of approvals in EU, U.S. and Japan, corresponding categories of data protection are applicable. If the above one year timeline is exceeded, data protection period will be reduced by the length of exceeding time until it reaches the minimum of 1.5 years. The clock of data protection period begins from the date of marketing approval. During the data protection period, the drug evaluation agency will not approve marketing applications of other applicants for the same products, excluding data obtained by applicants on their own.
- *Facilitating confidentiality obligations of state employees* – All employees participating in the evaluation and approval of drugs and medical devices, as well as employees participating in relevant inspection, testing and regulation, have the obligation to keep technical know-how and trial data submitted by applicants confidential. Those violating confidentiality duties will be dealt with according to law and regulations, and they will be publicized.
- *Introducing the formulary of marketed drugs* – Drug products approved by China will be included in the China Formulary of Marketed Drug Products, noting their product categories (innovative new drugs, improvement new drugs and generic drugs passing quality and therapeutic equivalence), active pharmaceutical ingredients, dosage forms, specifications, MAH, patent term, surveillance periods, trial data protection period, etc.

The Market

Nicholas Hall Projects Chinese OTC Drug Market to Grow 6% CAGR in the Next Five Years

Nicholas Hall, a leading global OTC drug market research firm, released the following projections of the Chinese OTC drug market to W*i*CON|*Pharma China*.

The market is projected to grow 6.0% CAGR between 2016 and 2021 to US$29,252.34 million. It further forecasts the market to rise at a slightly lower CAGR of 5.9% between 2021 and 2026 to reach an annual size of US$38,990.16 million.

Chinese OTC Drug Market Forecast 2016-2026

Description	2016	2021	2026	2016/2012 CAGR %	2021/2016 CAGR %	2026/2021 CAGR %
Analgesics	2,611.28	3,627.12	4,845.26	8.1	6.8	6
Cough, Cold & Allergy	4,657.91	6,163.97	8,012.56	5	5.8	5.4
Gastrointestinals	3,222.06	4,243.54	5,484.07	6.4	5.7	5.3
Vitamins, Minerals & Supplements	6,421.46	8,457.47	11,096.63	7.6	5.7	5.6
Dermatologicals	2,723.30	3,576.94	4,688.49	5.4	5.6	5.6
Lifestyle OTCs	2,188.70	3,183.29	4,863.14	6.7	7.8	8.8
OTC Sales - China	**21,824.71**	**29,252.34**	**38,990.16**	**6.5**	**6.0**	**5.9**

Source: Nicholas Hall (www.nicholashall.com)

Nicholas Hall Reports 6% Growth for Chinese OTC VMS Market in 2016

Nicholas Hall, a leading market research firm on global OTC drug market, recently reported that Chinese sales of vitamins, minerals & supplements grew by 6% to CNY 44.6 billion (US$6,476.4 million) in 2016 driven by activity in pediatric segment.

A number of factors, Nicholas Hall notes, impacted the sector in the period, including 1) influx of MNC brands via online channels, although regulatory uncertainty hampered sales; and 2) vitamin K2 approved as health food ingredient, leading to several launches.

Chinese consumers have a strong appetite for overseas VMS brands as they tend to believe they are safer than local products, according to Nicholas Hall. As such, there has been a trend for Chinese tourists purchasing VMS products from other countries (particularly Australia and Japan) or entrepreneurs buying brands in bulk abroad and re-selling them online in China. Now, multinational marketers are cutting out the "suitcase traders" by setting up stores on Hong Kong versions of online retailers such as JD and Alibaba-owned TMall, where they can sell products not registered in China to mainland consumers.

However, cross border e-commerce (sales which are excluded from our topline) hit a stumbling block in 2016 when uncertainty about proposed costly changes to taxation led to destocking by some online retailers. In April 2016, a tax of 11.9% was applied to cross border e-commerce sales for one-off personal online purchases on imported goods over CNY 2,000 (US$290) and annual cumulative purchases over CNY 20,000 (US$2,902).

The new arrangement has had minimal impact as the majority of transactions relating to health foods are within the threshold spend.

Chinese OTC VMS Market Facts

OTC VMS sales FY 2016:	US$ 6,476.4 mln
Index 2016/2015 (local currency):	106
Population:	1,378 mn
Per capita spend:	US$4.70
Exchange rate (04/01/2017):	US$1.00 = CNY 6.89

Source: Nicholas Hall (www.nicholashall.com)

OTC VMS Market in China – Full Year 2016

Category	US$ mln	Growth (CNY)
Multivitamins	740	+6%
Eye Health Supplements	n/a	–
Single vitamins	673.0	+5%
Minerals	1,820.5	+6%
Hair & beauty supplements	145.3	–
Herbal & natural supplements	1,199.5	+5%
Probiotics & prebiotics	425.1	+10%
Tonic & cure alls	1,463.7	+4%
Tonic drinks	n/a	–
TOTAL in US$	6,476.4	–
TOTAL in CNY	CNY 44.6B	+6%

Source: Nicholas Hall (www.nicholashall.com)

Top 5 Chinese OTC Multivitamin Brands in 2016

Rank	Brand	Marketer
1	Centrum	Pfizer
2	Yi Ke Xin	Shandong Dyne
3	Elevit	Bayer

Source: Nicholas Hall (www.nicholashall.com)

Top 2 Chinese OTC Single Vitamin Brands in 2016

Rank	Brand	Marketer
1	By-Health	By-Health
2	Yang Sheng Tang VC	Yang Sheng Tang

Source: Nicholas Hall (www.nicholashall.com)

Top 3 Chinese OTC Calcium Brands in 2016

Rank	Brand	Marketer
1	D-Cal	A&Z
2	Caltrate	Pfizer
3	Sanjin Gai	Harbin Pharma Group

Source: Nicholas Hall (www.nicholashall.com)

Top 3 Chinese Probiotics & Prebiotics Brands in 2016

Rank	Brand	Marketer
1	Biostime	Biostime
2	Ma Mi Ai	Hanmi
3	Bifico	Shanghai Pharma

Source: Nicholas Hall (www.nicholashall.com)

Top 4 Chinese Tonic & Cure Alls Brands in 2016

Rank	Brand	Marketer
1	Dong'e Ejiao	Dong'e Ejiao Group
2	Fupai E-Jiao	Shandong Fujiao
3	Hong Mao Medicated Wine	Neimenggu Hong Mao
4	Very Grass	Qinghai Spring

Source: Nicholas Hall (www.nicholashall.com)

Chinese OTC Cough, Cold and Allergy Market Posted 6% Growth in MAT 1Q/2017

Nicholas Hall, a leading market research firm specializing in the global OTC drug market, reported recently that the Chinese OTC cough, cold and allergy (CCA) market grew 6% (on CNY sales) in the 12 month period ending March 2017.

Drivers in the period included: 1) growth of 6% driven by new marketing strategies for key systemic cold & flu and allergy remedies; 2) environmental factors such as smog and H7N9 virus brought publicity for cough, cold & flu; and 3) Sanofi and RB tie-ups with China Resources Sanjiu is expected to impact CCA.

Chinese OTC Cough, Cold & Allergy Market (MAT March 2017)

	MAT March 2017 (MSP US$ mln)
Systemic cold & flu	1,823.5
Topical decongestants	159.5
Allergy remedies	244.1
Cough remedies	1,384.9
Sore throat remedies & medicated confectionery	1,091.0
Asthma remedies	43.2
TOTAL	**4,746.3**
TOTAL in CNY	**32.5 Billion**
Index 2016/2015 (CNY)	106
Population (mn)	1,378.0
Per capita spend (US$)	3.44
Exchange rate	US$1.00 = CNY 6.9

Source: Nicholas Hall (www.nicholashall.com)

Systemic cold & flu remedies grew by 4% in the 12 months to March 2017 owing to safety and innovation being a focus of A+P for top brands. Also, people are likely to be more concerned about influenza as the H7N9 avian flu virus has been highly publicised. The latest epidemic (from October 2016 to spring 2017) has been the worst on record since this strain first hit China in 2013.

Top 5 OTC Systemic Cold and Flu Remedies in China (MAT March 2017)

Rank	Brand	Marketer
1	999 Gan Mao Ling	999 Medical & Pharma
2	Gan Kang	Jilin Wutai Pharma
3	Quike	Hainan Asia
4	Yiling Lianhua Qingwen	ShiJiaZhuang YiLing
5	XiangXue Kang Bing Du Liquid	Guangzhou Xiang Xue

Source: Nicholas Hall (www.nicholashall.com)

Growth of allergy remedies improved to 6% in the 12 months to March 2017 as No.3 brand Dezhong Bi Yan Kang (China Traditional Chinese Medicine Co / Sinopharm) bounced back from a decline.

Top 3 OTC Allergy Remedies in China (MAT March 2017)

Rank	Brand	Marketer
1	Taiji Bi Dou Yan Liquid	Chongqing Taiji
2	Clarityne	Bayer
3	Dezhong Bi Yan Kang	Foshan DeZhong / SinoPharm

Source: Nicholas Hall (www.nicholashall.com)

Cough remedies grew by 8% in the 12 months to March 2017. Sales in this category tend to rise each year, driven in part by the

country's smog problem, which can lead to respiratory illness. Beijing is one of the worst affected areas and, according to the Beijing Municipal Environmental Protection Bureau, pollution was at the second worst recorded level in five years in January 2017 after Chinese New Year fireworks added to the problem. A+P for some brands focuses on this subject.

Top 5 OTC Cough Remedies in China (MAT March 2017)

Rank	Brand	Marketer
1	Nin Jiom Pei Pa Koa	Nin Jiom
2	Taiji Jizhi Syrup	Chongqing Taiji Group
3	Sunflower Xiao Er Feire Kechuan	Sunflower Pharma

Source: Nicholas Hall (www.nicholashall.com)

The category of sore throat remedies & medicated confectionery grew by 7% in the 12 months to March 2017 driven by new marketing efforts for top tier brands. No.1 brand Golden Throat (Golden Throat) grew by 2%. The strongest rise came from the food-registered version of the lozenge, sales of which grew owing to strengthened promotional efforts and a new distribution network.

Top 5 OTC STR&MC Products in China (MAT March 2017)

Rank	Brand	Marketer
1	Golden Throat Sweets	Guangxi Jinsanzi
2	Watermelon Frost	Guilin Sanjin Pharma
3	Man Yan Shu Ning Qing Hou Li Yan	Reckitt Benckiser

Source: Nicholas Hall (www.nicholashall.com)

Chinese MHP Trade Underlined by Strong Import Growth in Q1

Chinese foreign trade of medicines and health products (MHPs) reached US$25.6 billion in the first quarter of 2017, according to the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCIEMHP). Among the total, import surged 15.5% in the period to US$12.2 billion, while export grew only 2% to US$13.4 billion.

Pharmaceutical formulation export managed double digit growth of 11% to reach US$770 million due to sharp growth of antibiotic, vitamin, hormonal and insulin drug formulations.

Chinese import and export of APIs rebounded to grow 9.6%, reaching US$8,882 million in the first quarter. Among the total, export of APIs rose 6.71% to US$6,722 million. The API export growth in the period was facilitated by vitamin C export price increase recently, as well as volume growth on fallen prices of other APIs.

Industry News

Snapshot of Top 17 A-Share Listed Chinese Pharma Firms by Net Profits in 2016

17 A-share listed pharmaceutical companies saw net profits above CNY 1 billion in 2016 with the top five witnessing at least CNY 2.5 billion in net profits, according to public data compiled by SMEI.

Top 17 A-Share Listed Pharma Companies by Net Profits in 2016

Company	Revenue (CNY mln)	+/- (%)	Net Profit (CNY mln)	+/- (%)
Kangmei Pharma	21,642	+19.79	3,340	+21.17
Shanghai Pharma	120,765	+14.45	3,196	+11.10
Yunnan Baiyao	22,411	+8.06	2,920	+5.38
Fosun Pharma	14,629	+16.02	2,806	+14.05
Hengrui Medicine	11,094	+19.08	2,589	+19.22
Shandong Dong'e Ejiao	6,317	+15.92	1,852	+14.00
Buchang Group	12,321	+5.71	1,769	-49.97
Jilin Aodong Pharma Group	2,737	+17.22	1,666	-35.75
Shanghai RAAS	2,326	+15.54	1,613	+11.84
Baiyunshan Pharma	20,036	+4.76	1,508	+15.97
Huadong Medicine	25,380	+16.81	1,447	+31.88
Shenzhen Salubris Pharma	3,833	+10.23	1,396	+10.31
Zhejiang NHU	4,696	+22.86	1,203	+199.11
China Resources Sanjiu	8,982	+13.69	1,198	-4.11
SinoPharm Accord Medicines	41,248	+9.07	1,187	+27.92
Tasly	13,945	+5.47	1,176	-20.43
Er-kang Pharma	2,961	+68.62	1,026	+69.78

Source: SMEI

Performance of Listed Domestic Pharma Companies Improves in Q1/2017

245 of listed Chinese pharmaceutical industry companies released their performance results in the first quarter of 2017. In general, the net income of these companies had been on the rise in the period.

Among all, 175 reported higher net profits attributable to shareholders in the quarter vs. the same period in 2016, and 28 and 14 of them witnessed above 50% and above 100% net profit growth attributable to parent companies respectively.

On the other hand, 70 listed pharmaceutical companies reported falling net profits in the first quarter of 2017 compared with the same period in 2016.

The combined operating revenues and net profits of the 245 listed pharmaceutical companies reached CNY 266,698 million and CNY 21,889 million, up 18.00% and 7.64% respectively in Q1/2017.

By subsectors, the revenues and net profits of chemical drug formulation listed companies rose 17.34% and 20.78% respectively in the quarter; those of biopharmaceutical listed companies surged 13.94% and 17.47% respectively; and those of formulated TCM listed companies increased 11.61% and 17.60% respectively.

Local Company News

Shanghai Pharma Eyes Takeover Bid for Germany's Stada

Shanghai Pharmaceutical Holding Co Ltd said on May 17 that it was interested in a possible deal for Germany's Stada Arzneimittel AG, though it had not made any official offer.

German drug firm Stada, the target of a takeover bid from buyout firms Bain and Cinven that valued it at about 5.3 billion euros (US$5.89 billion), said on Tuesday it had not been notified of any

rival offer, following a Bloomberg report saying Shanghai Pharma was discussing a potential higher bid of about 70 euros a share along with investor Advent International.

"The Company had recently discussed about the possibilities of project Stada with a couple of financial investors," Shanghai Pharma said in a filing to the Hong Kong bourse, in its first public confirmation of an interest in Stada. It added that there was still "a lot of uncertainties" as to any cooperation.

"As at the date of this announcement, the Company has not sent any official offer," Shanghai Pharma said.

Reuters reported on May 15, citing sources, that Stada had not been approached by Advent or Shanghai Pharma with a counter offer.

Bain and Cinven's offer in April of 65.28 euros per share and a dividend of 0.72 euros per Stada share had seemed to end the contest to acquire the generic drug maker.

Shanghai Pharma added the reported offer price was far-fetched. "The bidding price of 70 euro per share that the media mentioned is inconsistent with the reality," it said.

Chinese Pharma Cos in Race for Australian Cancer Care Provider Icon Group

A clearer picture is beginning to emerge of the US$1.4 billion-plus auction for Quadrant Private Equity's Icon Group, with its Chinese operating partner, Yibai Pharmaceuticals, said to be in the mix as a prospective buyer. Icon Group includes radiology centers, a pharmacy supply operation and Australia's largest provider of day oncology and haematology services.

It is understood a Chinese consortium has formed to purchase the company, and the view around the market is that other parties are likely to be off the pace, causing some to question whether they have been scared off by a Chinese powerhouse with deep pockets.

Chinese group CITIC, in conjunction with New Journey Cancer Hospital, which it partly owns, is bidding. So are Baring Private Equity and Luye Pharma, which owns Australian private hospital operator HealtheCare, although it remained unclear yesterday whether all the parties are within the same consortium as Yibai or in fact other consortiums may be taking shape.

Still, while the talk is that a Chinese consortium is in line to deliver a knockout bid for Quadrant, relying on a buyer from the Asian super power always comes with its risks, given the fear that they may not follow through with the deal at the final hour.

The other question mark is whether any Chinese bidding party will get over the line with the Foreign Investment Review Board because GenesisCare, the other major private radiology provider, is owned by another Chinese state-backed group, China Resources.

Icon signed a joint venture with Yibai Healthcare last year to provide world-class radiation therapy services to 50 cancer centres across China, but it is understood that the party does not have enough money to bid for the asset alone.

Credit Suisse is handling the sales process for Quadrant after it helped Kohlberg Kravis Roberts to achieve a knockout US$1.7bn bid for GenesisCare by China Resources last year.

It will be interesting to see what investment banks emerge as advisers to the bidders.

When Luye bought Archer Capital's HealtheCare for close to US$1bn, it was advised by Barclays, which has since left the Australian market, while Baring used Goldman Sachs and UBS when it launched its takeover bid for SAI Global last year.

Other private equity firms such as Archer Capital and The Carlyle Group were earlier discussed as possible bidders.

The business delivers US$100m in earnings before interest, tax, depreciation and amortisation and includes radiology centres, a pharmacy supply operation and Australia's largest private provider of day oncology and haematology services.

Truking Tech To Acquire Germany's Romaco For $164M

Chinese pharmaceutical equipment supplier Truking Technology Ltd. and other investors have agreed to acquire 75.1% of German pharmaceutical packaging and equipment maker Romaco Group for €150 million (US$164 million).

Truking Technology's controlling shareholder, Changsha Truking Investment Co., and Hunan Pengpai Equity Investment Management Services Co., are among the Chinese investors buying the stake from German private equity firm Deutsche Beteiligungs AG. Deutsche Beteiligungs will retain a 24.9% stake, which Truking Technology plans to buy out within the next three years.

Deutsche Beteiligungs AG acquired Romaco from listed U.S. company Robbins & Myers, Inc. in April 2011. Since then, Romaco has increased its annual sales by around 50% to €134.3 million in the 2016 fiscal year. Romaco also opened five sales and service centers in China, France, Russia, Brazil and the U.S.

Uni-Bio Science Launches Best-in-Class Oral Anti-Diabetic Drug Mitiglinide

Uni-Bio Science Group Limited (HKSE: 690) announced on May 4 that, with the exclusive global rights to manufacture and commercialize Mitiglinide acquired from Jiangsu Hansoh Pharmaceutical Co. Ltd (Hansoh) in 2015, it is launching this new oral anti-diabetic drug (OAD) under the registered brand name (Bokangtai) in Fujian province, subsequent to the drug being included in the 2017 NRDL.

The new oral anti-diabetic agent belongs to the glinides class of blood glucose lowering compounds. It is known to improve postprandial hyperglycemia (after meal blood glucose spike) in patients with Type 2 diabetes and has received New Drug Approval from the China Food and Drug Administration as a first and/or second line of treatment for the disease. Mitiglinide has demonstrated strong clinical advantages against other glinides. It acts fast after intake, lowering blood sugar within five minutes compared with other treatments in the same class which can take up to 15 minutes and has lower risks of hypoglycaemia and dyslipidaemia.

Before the end of 2016, the Group's tendering task force began related activity for Bokangtai in several provinces. Following the sales and marketing teams' efforts, Bokangtai was finally launched and shipped to a number of hospitals in Fujian province in April 2017. The Group has also submitted tenders for Bokangtai in Shanghai, Chongqing, Guangdong and Sichuan with a target to sell Bokangtai in at least 10 provinces by the end 2017.

Crown Bioscience, Jiangsu Qyun Biopharma to Co-develop CTLA-4 Antibody

Crown Bioscience, a wholly-owned subsidiary of Crown

Bioscience International (TWSE: ticker 6554) and a global drug discovery and development services company providing translational platforms to advance oncology and metabolic disease research, announces a collaboration to develop a CTLA-4 antibody with Jiangsu Qyun Bio-Pharmaceutical Co. Ltd.

As part of the collaboration agreement CrownBio will leverage Jiangsu Qyun Bio-Pharmaceuticals expertise to support the Investigational New Drug Application (IND) and further clinical development of CrownBio's proprietary 10B10 antibody.

10B10 is a humanized anti-CTLA-4 antibody with higher binding affinity and in vitro T cell stimulation than ipilimumab, the first immune checkpoint blockade antibody targeting CTLA-4 to receive FDA approval for the treatment of melanoma. The two antibodies have equivalent activity in T cell activation and tumor growth suppression but a different binding epitope and pharmacokinetic profile.

The goal of the collaboration between CrownBio and Jiangsu Qyun Bio-Pharmaceutical is to develop a less toxic CTLA-4 antibody and better combination strategies to overcome the immunological adverse effects due to T cell activation and proliferation observed in a minority of patients treated with anti-CTLA-4 immunotherapies.

Qilu Pharma Opens Innovation Center and R&D Unit in Boston

Qilu Pharmaceuticals, a Chinese drug company with more than US$2 billion in annual sales, opened Boston's first China-backed innovation center, Qilu Boston Innovation Center (QBIC), on May 19.

After launching, "QBIC will be serving as an incubator for biotech startups, with the aim of helping biotechnology startups implement their ideas, to sooner transform their research results into medicine to meet clinical needs and improving Qilu's domestic product lines," said Larry Cai, head of business development in New England at Qilu. He said the company's total investment in Boston was about US$40 million.

QBIC is located in a two-story building at 50 Soldiers Field Place that was acquired by Qilu last year for around US$10 million. Along with the incubator, Qilu's first branch company in Massachusetts – QLB Biotherapeutics Inc (QLB Bio) – also set up shop in the new facility on the same day. With the remodeling, the 25,000-square-foot center with lab and office space becomes Qilu's biggest overseas research and development site.

QLB Bio, a startup focusing on discovering and developing biological medicines, is devoted to developing next-generation cancer therapies using the "transformative potential of immuno-therapy", according to its website.

According to a report co-authored by the Rhodium Group and the National Committee on US-China Relations, Chinese companies invested US$46 billion in the US last year, tripling the amount seen in 2015, sending two-way direct investment to a record high.

BGI Establishes Innovation Center in the U.S. West Coast to Foster Collaboration

BGI announced on May 17 a new U.S. West Coast Innovation Center that will be co-located between Seattle and San Jose with the goal of fostering partnerships and innovation between BGI and institutions in the two hubs. It is the first center of its kind, but follows BGI's trend of fostering international collaborations.

Dr. Yiwu He, CEO of BGI Groups USA, said the Seattle center will likely include a lab space one day but, for the moment, the company would work in the labs of partners in the city. The company has an existing lab in San Jose with just over 100 employees.

BGI is one of the largest genomic players in the world. It fuels large-scale human, plant, and animal genomics research through partnering with companies and organizations around the globe, offering research collaborations as well as technology transfer and genetic testing services. The company also pursues its own commercial operations.

BGI announced the opening of a small Seattle office in December to strengthen the partnerships it has with institutions in the area.

The idea really to stimulate the innovative collaboration or partner-ship between BGI and research institutions, universities, and potentially biotech industries in the United States. That includes work on precision medicine with the UW, an ongoing partnership with the Bill and Melinda Gates Foundation and work with the Allen Institute for Brain Science, as well as with Washington State University in Pullman, Wash. The organization's current partnerships in the Pacific Northwest largely focus on health and agricultural research.

The new center will give BGI a strong foothold in the city to continue developing those partnerships and will also allow for easier faculty exchanges between BGI and partner institutions.

Ali Health's Revenue Up Sharply as Online Pharmacy Sales Soar

Alibaba Health Information Technology (Ali Health) reported a massive 739% year-on-year revenue increase in the past 12 months on the back of its pharmaceutical e-commerce business.

For the year ended March 31, Ali Health revenue came in at US$68.9 million, although the company's adjusted net loss increased about 8% over the past year to US$30.1 million. The company said it had higher costs due to higher sales, marketing, administrative and product development costs. Higher sales and marketing, administrative and product development expenses in the year to March led to a wider net loss of CNY 207.6 million, compared with CNY 191.6 million a year earlier.

Ali Health originally relied heavily on business from CFDA, which had hired the company to run an authentication system for medicine sold in China in 2014, the Financial Times reported. The company had swiftly diversified its operations in early 2016 after the CFDA ended the mandatory use by drug trading enterprises of its product identification, authentication and tracking system on the mainland.

Now the medical company relies on its e-commerce business for nearly 83% of its total revenue for the 2017 financial year. In August, Alibaba's online retail platform Tmall.com struck a deal with Ali Health that has provided a "steady and fast-growing source of revenue," Ali Health chief executive Lei Wang said in the earnings call, the South China Morning Post reported.

The business tried to expand its offerings in the past year, but to not much avail. The "immediate relief" platform it launched in June failed to add anything meaningful to its revenue, partly because fees for the platform were considerably higher than the original platform it replaced, according to the Financial Times. In addition, Ali Health Insurance, an Alibaba-controlled joint venture, also failed to contribute to the bottom line. The company said that was because "the newly acquired associates are either at

the initial stage of business development, or under business transformation."

"The ageing Chinese population, increasing public awareness about health issues and the progress of government-backed medical reforms have combined to create huge opportunities in China's pharmaceutical and health care market," Ali Health chief executive Lei Wang said.

Wang said a service agreement with Alibaba's online retail platform Tmall.com also took effect last August, providing "a steady and fast-growing source of revenue" for Ali Health.

The company provides business development, technical support and other value-added services for merchants selling certain pharmaceutical-related goods on Tmall, such as medical devices, contact lenses and family planning products.

Wang said Ali Health also developed a new online service called Ma Shang Fang Xin to assist more than 5,000 enterprises from the drug, food and nutritional supplement industries to track the full life cycle of their products, helping fulfill their regulatory compliance obligations.

Chinese Biotech Startup Abbisko Raises $28M in Series A Financing

Shanghai-based startup Abbisko Therapeutics has raised US$28 million in a Series A financing that will be used to advance its cancer immunotherapies into clinical trials.

The investment round – by Lilly Asia Ventures, Sinopharm Capital, Jianxin Capital and TF Capital – will be used to set up R&D teams and discovery centers that will help it advance its core anticancer programs, currently consisting of three preclinical compounds headed by lead candidate ABSK001, which is at the lead optimization stage.

Abbisko was set up last year and is located in the Zhangjiang biotech cluster in Shanghai. It is led by founder and CEO Yao-Chang Xu, a 25-year industry veteran who was previously general manager at Hansoh BioMedical. Xu's CV includes a six-year stint as executive director of the Novartis Institutes for BioMedical Research in Cambridge, Massachusetts, and a prior role as head of chemistry for Eli Lilly in Indianapolis.

The company's website suggests it will focus on immuno-oncology drugs to treat cancers that have a high incidence among Asian patient populations, such as lung, liver, stomach and esophageal cancers, with a particular emphasis on developing small-molecule drugs. It also has early-stage programs in liver disease, viral infections and central nervous system disorders.

CANbridge Life Sciences Raises $25 Million in Series B Round

CANbridge Life Sciences, a clinical-stage biopharmaceutical company focused on developing Western drug candidates in China and North Asia, announced that it raised US$25 million in a Series B round with lead investor, Lapam Capital, a Beijing-based life science venture capital firm, with a portfolio that includes Betta Pharm. Several other institution investors also participated, including: Qiming Venture Partners, Yuanming Capital, Yanyuan Capital, Biossom Investment Management and Wuxi App Tec. Haoyue Capital provided professional services.

CANbridge will use the proceeds to fund the clinical trial development of its two lead compounds, CAN008 and CAN017, in China.xs CAN008, a fully-human fusion onco-immunotherapy, is currently in a Phase I/II for the treatment of glioblastoma multiforme (GBM), in Taiwan. The company plans to initiate a Phase II CAN008 GBM trial in China in 2018. CAN017, an antibody inhibitory onco-immunotherpy, will target esophageal squamous cell cancer (ESCC), the prevalent form of esophageal cancer in Asia. CANbridge has raised a total of over US$40M in Series A and B financing rounds combined, and has plans for additional strategic transactions in 2017.

InventisBio Raises $19 Million in Series B Financing

InventisBio, a fast-growing biotech company dedicated to the discovery and development of novel medicines, announced on May 30 that it had successfully raised US$19 million in a Series B financing. The investment was led by OrbiMed Asia Partners and joined by Lilly Asia Ventures (LAV).

With headquarter in Shanghai and operations in both China and US, InventisBio has four drug candidates for cancers and gout therapeutic areas. Three of them are expected to enter phase 1 clinical trials in US and China in 2017.

"This new investment will accelerate our product development through phase 1 clinical trials," said Dr. Yaolin Wang, InventisBio Co-Founder, Chairman and CEO. "Our goal is to develop novel medicines that will benefit patients not only in China, but also in the world. The strategic partnership with OrbiMed Asia and Lilly Asia Venture will help us establish a solid foundation for future growth in the global pharmaceutical market."

Financial-related Company News in Brief

A number of recent financial-related news events of the Chinese pharma industry were recorded by WiCON|*Pharma China* in May 2017 as shown in the following table:

Company Financial News Brief May 2017

Announcement Date	Parties	Deal Size	Subject	Description
5/4/2017	Haisco Pharma Group	CNY 200M	Fund raising	It issued the first tranche short-term financing notes in 2017 worth CNY 200 mln with coupon rate of 5.38%.
5/16/2017	Shanghai Fosun Pharma	US$ 304M	Fund raising	It launched an up to $304 million share offering in HK.
5/17/2017	Shanghai Fosun Pharma	HK$ 2.31B	Fund raising	It entered into agreement to place 80.7 mln H shares totaling HK$2.31 bln and intends to use net proceeds to repay interest-bearing debts and finance M&As.
5/19/2017	Tiansheng Pharma Group	CNY 1.2B	IPO	It has completed an IPO on Shenzhen Stock Exchange, raising CNY 1.2 bln.
5/23/2017	Hunan Fangsheng Pharma	CNY 270M	Investment	It plans buyout fund with partners worth CNY 269.7 mln.
5/23/2017	Zhejiang Xianju Pharma	US$ 12M	M&A	It agreed to acquire 36.6% stake in Occulo Holdings for $12 mln.

Source: WiCON|Pharma China

Foreign Company News

AstraZeneca China, PKU's BIBDR to Build Joint Laboratory for Healthcare Big Data

AstraZeneca China and Peking University's Beijing Institute of Big Data Research (BIBDR) signed an agreement on May 26 to form a joint laboratory for healthcare big data research.

The goal of the laboratory is to provide scientific evidence to patients, doctors and government through analysis of medical big data under an innovative collaborative research model between academic institutions and the pharmaceutical industry in China.

AstraZeneca China said the cooperation is only a beginning which will lay the foundation for further collaboration through valuable experience gained in this project. The company has already worked with IBM earlier to conduct similar research of healthcare big data to build disease risk predication models and provide precision medicine solutions to patients. It pledges to continue exploration with partners in different fields in order to establish an innovative and patient-centered medical eco-loop.

Given the high prevalence of COPD among the Chinese (as high as 9.9% among Chinese people of 40 and above), AstraZeneca China and BIBDR plans, with support of the new joint laboratory, to begin with their cooperative project which aims to promote disease perception, diagnosis and management of COPD.

AstraZeneca China will open its internal primary data to the BIBDR conditionally, which is reported to be the first attempt of such information sharing between the pharmaceutical industry and academic research institutions in the country. If successful, it is expected more pharmaceutical companies may follow the suit of AstraZeneca.

Janssen Plans to Step Up R&D and Investment in China

Johnson & Johnson (J&J) subsidiary Janssen will expand its investment in China to drive growth as it races to seize more market shares in lung-related diseases, according to a China Daily report. It will focus on developing medicines, including drugs to fight lung disease, which is a major problem in the country.

"We will launch these drugs in the Chinese market before going global," said William N Hait, global head of Janssen's R&D division.

The company is reported to set up a global research and development center in China. Through innovative approaches, the center aims to lower the cases of lung cancer and increase survival rates among those affected by the disease.

During the next five years, Janssen will launch more than ten new drugs and expand its product fortfolio with 50 generic drugs. In addition, the company will promote sustainable growth through core product mix and innovative measures.

"Johnson & Johnson has witnessed rapid development in the Chinese market. One of the major global strategies of our company is to invest in China constantly. It is estimated that the R&D will continue to play an essential role in the innovative process of Johnson & Johnson," said Alex Gorsky, chairman and chief executive officer of Johnson & Johnson.

"China is one of the most important pharmaceutical markets for us globally. It is the second largest market after the United States." "We have a strong presence, including manufacturing, commercial, as well as research and development," J&J's Executive Vice President and Worldwide Chairman of Pharmaceuticals Joaquin Duato was quoted as saying.

Boehringer Ingelheim Inaugurates World-Class Biopharma Manufacturing Facility in China

Boehringer Ingelheim inaugurated its commercial production site for biopharmaceuticals in Zhang Jiang Hi-tech Park of Shanghai (China) on May 16. The site, with the first-phase investment of more than EUR 70 million, is the first and only biopharmaceutical facility established by a leading multinational active biopharmaceutical manufacturer in China utilizing mammalian cell culture technology. With its global network of biopharmaceutical production sites in Biberach (Germany), Vienna (Austria), Fremont (USA) and now Shanghai, the contract manufacturing business Boehringer Ingelheim BioXcellence is well positioned to fulfil strongly increasing demands of the biopharmaceutical industry for innovative products – both in China and worldwide.

Boehringer Ingelheim has made this strategic move with the long-term goal to become a leader for contract development and manufacturing of monoclonal antibodies and recombinant proteins in China. Since 2014, Boehringer Ingelheim China Biopharmaceuticals has been operating its Good Manufacturing Practice (GMP) clinical material supply at 100L and 500L scales. After its inauguration, the facility will operate for clinical and commercial supply on a 2000L single-use bioreactor scale. It is designed to flexibly add additional 2000L single-use bioreactors and fill/finish capabilities to meet increasing market demand.

Eli Lilly, 3SBio Enters Strategic Alliance for Insulin Products

Eli Lilly China and 3SBio's subsidiaries and entered into a strategic alliance agreement on May 16 for distribution and promotion of insulin products. Under the agreement 3SBio has been granted exclusive rights in China of distribution and promotion of Humulin, an insulin product of Lilly, as of July 1, 2017.

Leveraging on its nationwide sales network and its existing metabolism products segment resources, 3SBio will establish a marketing and promotion team which will cover a wide array of diabetes products (including Humulin). Lilly China will be responsible for the production and supply of the Humulin products produced in accordance with its global quality standards. Currently, both parties are cooperating closely to ensure a smooth transition.

Humulin, formulated in 1982, was the first bio-synthetic insulin product in the worldand was also the first medical product for human produced by recombinant DNA techniques. Since its launch in China in 1997, Humulin has in aggregate served millions of Chinese diabetic patients.

In 2013, Eli Lilly was drawn into allegations of corruption in China, with media reports that it paid CNY 30 million (US$4.9 million) in kickbacks to doctors to prescribe its products for diabetics. The *21st Century Business Herald* newspaper quoted a former Chinese sales manager for the US drug company as saying it had paid hospital doctors for each new patient placed on Humulin and Byetta, as it fought for market share.

MSD's HPV Vaccine Gardasil Finally Approved in China

Following 11 years of regulatory efforts, the CFDA finally approved MSD's HPV vaccine Gardasil for use by women aged between 20 and 45.

Gardasil, also known as Gardisil or Silgard or recombinant human papillomavirus vaccine [types 6, 11, 16, 18], is a vaccine for use in the prevention of certain strains of human papillomavirus (HPV), specifically HPV types 6, 11, 16 and 18. HPV types 16 and 18 cause an estimated 70% of cervical cancers, and are responsible for most HPV-induced anal, vulvar, vaginal, and penile cancer cases. HPV types 6 and 11 cause an estimated 90% of genital warts cases. Though it does not treat existing infection, vaccination is still recommended for HPV positive individuals, as it may protect against one or more different strains of the disease. The HPV strains that Gardasil protects against are sexually transmitted.

The vaccine was approved in the US on June 8, 2006 by the U.S. Food and Drug Administration (FDA). In 2008, Gardasil was approved in 41 of U.S. states. The Gardasil vaccine has also been approved in 120 other countries. The FDA recommends vaccination before adolescence and potential sexual activity.

Merck's latest nine-valent HPV vaccine Gardasil 9, which was U.S. FDA approved on December 11, 2014, has not yet been approved by the CFDA. It protects against infection with the strains covered by the first generation of Gardasil as well as five other HPV strains responsible for 20% of cervical cancers (HPV-31, HPV-33, HPV-45, HPV-52, and HPV-58).

In July 2016, China approved its first HPV vaccine, GSK's Cervarix which the company said would be available in China at the beginning of 2017. No other HPV vaccines have ever been available on the Chinese market. The approval came eight years after trials of the drug began in China – and a decade after it was widely available elsewhere around the world. China has more than a quarter of the world's cervical cancer patients, and over the years many women have opted to travel to places like Hong Kong to obtain the HPV vaccine.

Celltrion Granted China's First Approval for Biosimilar Clinical Trial

South Korea's Celltrion Inc. announced the China Food and Drug Administration (CFDA) has approved a clinical trial for Remsima, its biosimilar drug to treat autoimmune diseases such as rheumatoid arthritis, making it the first foreign antibody biosimilar approved for an efficacy and safety test in the world's most populated country. The drug is already marketed in Europe and the U.S.

Celltrion filed for approval of the clinical study with Chinese health authorities in January 2014. The company said it will use the momentum to submit an application seeking clinical research approval for two more biosimilars: Truxima to treat blood cancer and Hurzuma to treat breast cancer.

The approval is credited to Celltrion chairman Seo Jung-jin who has visited China many times to push for the approval. He also vowed to set up a joint venture with its Chinese partner and to consider establishing a local plant to better meet patient needs across China.

China is a leading "pharmerging" market, which indicates the most promising emerging market in the pharmaceutical domain. In particular, the antibody biopharmaceutical market in China is estimated to grow at an average annual rate of 30 percent or higher to take leadership in the global biopharma market, according to analysts. Demands for biopharmaceuticals will increase explosively when the country of 1.3 billion population enters an aging stage.

Sorrento Announces the Completion of GMP Facility in Suzhou to Support its Growing ADC Pipeline and Service Business

Sorrento Therapeutics, Inc. (NASDAQ: SRNE), announced May 4 that its subsidiary, Levena Biopharma Co., Ltd., has completed construction and put into operation a 25,000 square foot Good Manufacturing Practice (GMP) manufacturing facility in Suzhou, China. The facility will be fully dedicated to supporting Sorrento's antibody drug conjugate (ADC) pipeline and growing service business.

Sorrento currently has a dozen pre-clinical cancer focused ADCs that are partnered with biopharmaceutical companies worldwide, under the Levena brand. These partnerships have ADC candidates at various stages of development, including a HER2-targeting ADC which has an expected IND filing with the China Food and Drug Administration (CFDA) in 2017. Sorrento expects to receive service revenue and royalties on its partnered ADC programs. Additionally, Sorrento is advancing two proprietary anti-cancer ADC product candidates into IND enabling studies, including its proprietary anti-CD38 ADC and an anti-c-MET ADC. Both proprietary anti-cancer ADC programs were generated from Sorrento's fully human GMAB™ library and leverage on Levena's proprietary site-specific conjugation chemistry (K-Lock™ and C-Lock™) and proprietary novel toxin payloads.

Pharnext, Tasly Enter Drug Development Partnership

Pharnext SA (Paris:ALPHA), a biopharmaceutical company pioneering a new approach to the development of innovative drugs based on the combination and repositioning of known drugs, announced on May 10 the signature of a strategic agreement with Tasly Pharmaceutical (Shanghai: 600535), a group ranked amongst China's top 10 listed pharmaceutical companies. This partnership includes three axes: a financial investment by Tasly in Pharnext; the development of a new pipeline of synergistic combinations through a shared platform; and the license of Pharnext's lead product for the Chinese market.

The agreement is composed as follows:

- An investment of €20 million by Tasly in Pharnext at a substantial premium over the current stock price, including: €5 million in shares at a price of €12.5 per share and €15 million in convertible bonds with a conversion price of €13 per share.
- The creation of a research and development Joint-Venture (JV), owned 30% by Pharnext, to develop new combinations of molecules. Programs will be pursued in several indications, primarily in cardiovascular and oncology therapeutic areas. Both companies will share their expertise: Pharnext in the development of synergistic combinations of drugs and Tasly in the use of traditional Chinese medicine wealth. Once the combination of molecules proof of concept is established in humans, commercialization rights will either be allocated to Pharnext and Tasly or licensed to third parties.
- A licensing agreement for the development and commercialization by the JV of the drug candidate PXT3003 for

Charcot-Marie-Tooth type 1A disease on the Chinese market.

Service Provider News

WuXi NextCODE Completes Series B Financing, Raising $75M

WuXi NextCODE, a contract genomics organization and a unit under Wuxi AppTec, has closed a US$75 million series B financing co-led by Temasek Holdings and Yunfeng Capital.

Other investors, including Amgen Ventures, a corporate venture capital fund established by Amgen Inc., and 3W Partners, a Greater China and cross-border focused private equity firm, also participated in the round.

WuXi NextCODE, with offices in Shanghai, Cambridge, Massachusetts and Iceland, provides contract genomics services to precision medicine, diagnostics enterprises using the genome to improve health.

Its capabilities span study design, sequencing, secondary analysis, storage, and interpretation and scalable analytics. It is also applying the same capabilities to advance a growing range of sequence-based tests and scans in China.

WuXi NextCODE will use the proceeds of the funding round on advancing the commercialization of its consumer solutions for the China market, to further strengthen informatics, and expand its capabilities in artificial intelligence and deep learning.

Shanghai-headquartered WuXi AppTec is a contract research organization providing services to pharmaceutical, biopharmaceutical, and medical device organizations globally.

WuXi AppTec Completes Acquisition of HD Biosciences

WuXi AppTec, a leading global pharmaceutical, biotechnology and medical device open-access capability and technology platform, announced on May 15 that it has completed its acquisition of HD Biosciences (HDB), a leading biology focused preclinical drug discovery contract research organization (CRO).

Headquartered in Shanghai, HD Biosciences is a leading biology and preclinical service provider. Its plate-based pharmacology & screening capability and AGMTM based target validation are industry leading platforms with great reputation. The company also provides hit identification, lead discovery, in vivo pharmacology and other related services. The acquisition will further strengthen WuXi's R&D capability from target validation to lead discovery and optimization, improving and expanding WuXi's open-access enabling service platform.

WuXi Biologics Sets Stage for $513M IPO in Hong Kong

WuXi Biologics, a big one-stop shop for drug discovery, development and manufacturing in China, has reportedly set its eyes on a US$513 million IPO.

According to a report in Reuters, the company plans to sell 193 million shares at HK$18.60 to HK$20.60 each, valuing the total deal at up to HK$3.98 billion.

Just a few months ago, the company was talking about raising US$200 million to US$300 million through the IPO on the Hong Kong market. This latest report doubles that amount, highlighting the oversized role that company founder Ge Li has in the country's biotech industry.

Ge LI runs the parent company, WuXi AppTec, in Shanghai. And over the years he's built a large R&D/manufacturing operation that spans the globe. According to WuXi Biologics IPO filing, the company had recruited 678 scientists as of the end of Q3, 2016 – most leaning toward animal studies. They were engaged in 140 preclinical drug projects, 32 early-stage development efforts and three Phase III programs for clients.

Ge LI took WuXi AppTec private two years ago when it had a valuation of US$3.3 billion. The biologics R&D/manufacturing arm that's going public now has been building new manufacturing facilities, including new cGMP manufacturing operations. Its clientele includes close connections with AstraZeneca, J&J, Genentech and Amicus.

The Chinese government has had ambitious plans to expand biotech and drug R&D work, often subsidizing the construction of new facilities.

Certara Partners with PUMC to Deliver PBPK Modeling and Simulation Support for Drug Development in China

Certara, the leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes, announced on May 31 that it is partnering with Phase I Unit, Peking Union Medical College (PUMC) Hospital's Clinical Pharmacology Research Center (PUMCH-CPRC) in Beijing to help Chinese pharmaceutical companies enhance their drug development processes.

Phase I Unit at PUMCH-CPRC will employ Certara's Simcyp Population-based Simulator to develop physiologically-based pharmacokinetic (PBPK) models in support of Chinese new and generic drug applications to the Chinese Food and Drug Administration (CFDA).

Certara and Phase I Unit at PUMCH-CPRC already have a great partnership track record. The two organizations have been working together for several years to increase PBPK modeling and simulation education and training in China and have co-hosted several national workshops.

Phase I Unit at PUMCH-CPRC uses Certara's modeling and simulation technology for first-in-human, point-of-care, and late-phase clinical trials. It has many years' experience using both Certara's Simcyp Simulator and Phoenix® software and has published numerous peer-reviewed papers based on research conducted using those platforms. Phase I Unit at PUMCH-CPRC is a Phoenix Center of Excellence.

CFDA also employs Certara's Phoenix software and is a regulatory affiliate member of the Simcyp Consortium.

Certara's Simcyp Simulator is the pharmaceutical industry's most sophisticated platform for determining first-in-human dose selection, designing more efficient and effective clinical studies, evaluating new drug formulations, and predicting drug-drug interactions and PK outcomes in clinical populations. These include vulnerable populations such as pediatric patients, pregnant women, and patients with impaired organ function.

Regulatory News

CFDA Issues 2016 Food and Drug Regulatory Statistics Annual Report

The China Food and Drug Administration (CFDA) released its *2016 Food and Drug Regulatory Statistical Annual Report* on May 23, 2017. The publication contains the following drug regulatory information for the year of 2016:

Drug registration

In 2016, CFDA issued a total of 4,011 clinical trial approvals (CTAs), zero new drug certificate (NDCs), 13 new drug production approvals (NDAs) and five NDCs+NDAs. The agency also granted 328 CTAs under the new drug approval process.

CFDA issued a total of 2,949 clinical trial approvals and 207 production approvals of generic drugs respectively in 2016. It also issued 513 clinical trial approvals and 28 marketing approvals of imported drugs in the same year.

The agency approved a total of 2,560 supplemental drug registration applications and accepted 578 filings last year. Provincial level food and drug agencies approved a total of 5,202 supplemental applications and accepted 16,039 filings.

It also approved 782 registration applications, 924 re-registration applications and 280 supplemental applications for packaging and containers in direct contact with drugs, in the year. Besides, provincial level food and drug agencies approved 201 domestic supplemental registrations for such products.

CFDA also approved 312 initial registration, 738 change, 143 technology transfer and 118 registration renewal applications for health food products in 2016.

Pharmaceutical manufacturers/distributors

There were a total of 4,176 manufacturers of APIs and drug formulations in China at the end of November 2016, down considerably from 5,056 in 2015 due to many manufacturer license withdrawals after they fail to comply with GMP requirements.

Number of Pharma Manufacturers 2013-2016

Year	# of Manufacturers	+/- (%)
2011	4,629	–
2012	4,747	+2.55
2013	4,875	+2.70
2014	5,000	+2.56
2015	5,056	+1.12
2016	4,176	-17.41%

Source: Pharmadl/CFDA

465,618 businesses held pharmaceutical distribution licenses at the end of November 2016 (down from 466,546 in 2015) including 12,975 wholesalers (down from 13,508 in 2015), 5,609 retail pharmacy chains (up from 4,981 in 2015) with 220,703 outlets (up from 204,895 in 2015), and 226,331 independent retail pharmacy stores (down from 243,162 in 2015).

Number of Pharma Distribution License Holders 2013-2016

Year	# of License Holders	+/- (%)
2013	451,129	+1.81
2014	452,460	+0.30
2015	466,546	+3.11
2016	465,618	-0.20

Source: Pharmadl/CFDA

Number of Retail Pharmacy Chain Companies 2011 – 2016

Year	# of Companies	+/- (%)
2011	2,607	–
2012	3,107	+19.18
2013	3,570	+14.90
2014	4,266	+19.50
2015	4,981	+16.76
2016	5,609	+12.61

Source: CFDA

Number of Retail Pharmacy Stores 2011 – 2016

Year	# of Chained Stores	+/- (%)	# of Independent Stores	+/- (%)	Total	+/- (%)
2011	146,703	–	277,085	–	423,788	–
2012	152,580	+4.01	271,143	-2.14	423,723	-0.02
2013	158,244	+3.71	274,415	+1.21	432,659	+2.11
2014	171,431	+8.33	263,489	-3.98	434,920	+0.52
2015	204,895	+19.52	243,162	-7.71	448,057	+3.02
2016	220,703	+7.72	226,331	-6.93	447,034	-0.23

Source: CFDA

Administrative protection

By the end of November 2016, there were 267 traditional Chinese medicine products under protection (down from 317 in 2015). Among the total, 120 are initial protection approvals, 15 are for duplicate products and 132 are protection extensions.

Number of Protected TCM Products 2013- 2016

Year	# of Products	+/- (%)
2013	504	-44.80
2014	376	-25.40
2015	317	-15.69
2016	267	-15.77

Source: Pharmadl/CFDA

Administrative enforcements

CFDA (SFDA) approved a total of 30,027 drug advertisements, penalized 7,067 drug advertising violations and withdrew 29 drug advertising approvals in 2016.

The agency received a total of 577,915 drug related complaints, among them 22,479 were officially investigated and 20,988 were concluded in the period.

It also dealt with 96,825 illegal drug cases involving goods worth CNY 634 million, fines of CNY 458 million and confiscated illegal income of CNY 132 million in total. 1,401 unlicensed drug distribution violators were removed, 188 counterfeit drug production sites were eliminated, 1,702 businesses were suspended and 153 licenses were withdrawn. 1,655 cases were transferred to law enforcement agencies were prosecuted criminally.

Please visit the following CFDA weblink for full text of this report in Chinese: http://www.sda.gov.cn/WS01/CL0108/172895.html

CFDA Reforms Regulatory Framework for Health Foods with Proposed and New Documents

The CFDA released on April 28 a draft document, *Opinions for Further Strengthening Health Food Regulation*, for public

comments before May 12 via the following means:

Contact: JIN Fabin, YUAN Chao Email: jinfb@cfda.gov.cn
For full text of the draft document and the accompanying official notice in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0847/172242.html

According to the document, the CFDA will make a number of important changes to the regulation of health food products. Such changes include:

- Formulating a health food raw material list and a healthcare function list control regulation;
- Expanding the health food raw material list on three levels of 1) vitamin & mineral raw material, 2) single raw material formulation and 3) similar formulations;
- Advancing and liberalizing health food product filing regulation so that most health food products will be subject to filing regulation instead of registration approval;
- Defining the basic positioning of health foods as a category of special food products which can supplement nutrition provided from food with claims to promote human health functions. They should not substitute food intake and are not oriented to treat diseases or substitute drugs;
- In principle, any healthcare claims of such products should be validated by human intake. Descriptions of such healthcare claims should use restrictive language;
- Such products should be marked specially and must not be named after its healthcare functions;
- Relevant health food advertising regulations need to be revised and perfected; and
- Health food filing refers to the process of manufacturers filing, publicizing and preparing for evaluation with food and drug agencies relevant dossiers containing product safety, healthcare functions and quality control information.

In the meantime, the CFDA issued three more health food documents on May 2. The first document is the *Guidelines for Health Food Filing (Interim)* which went into effect on the date of issuance.

For full text of the document and the accompanying official notice in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0847/172243.html

The subsequent documents CFDA issued on May 2 are the *Rules for Allowable Excipients of Filed Health Foods and Their Use (Interim)* and the *Major Production Processes of Filed Health Foods (Interim)*.

It is provided that the allowable excipients and major production processes of file health foods can be adjusted and supplemented as deemed necessary.

For full text of the documents and the accompanying official notice in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0847/172242.html.

Roundup of CFDA New and Draft Regulations/Documents

CFDA Issues Four Guidelines for Onsite Inspection of Generic Drug Quality and Efficacy Equivalence Studies

Following comment seeking in January, CFDA issued an announcement (2017 #77) on May 18 to introduce four guidelines for onsite inspection of generic drug quality and efficacy equivalence studies.

The issued guidelines are as follows:

1. Guidelines for R&D Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies
2. *Guidelines for Production Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*
3. *Guidelines for Clinical Trial Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*
4. *Guidelines for Cause-Triggered Onsite Inspection of Generic Drug Quality And Efficacy Equivalence Studies*

For full text of these documents in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0087/172736.html

CFDA Issues Technical Guidelines on Extrapolation of Adult Drug Usage Data to Pediatric Population

In an attempt to resolve the urgent clinical needs for pediatric drugs, further encourage R&D of pediatric drugs and maximize the use of existing data to reduce unnecessary pediatric research, the CFDA issued an announcement (2017 #79) on May 18 to introduce the *Technical Guidelines for Extrapolation of Adult Drug Usage Data to Pediatric Population*.

For full text of these documents in Chinese, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0087/172743.html

The guideline document is applicable to extrapolation of Chinese adult drug usage data to Chinese pediatric population and does not cover extrapolation of non-Chinese adult drug usage data.

Considering the dynamics and flexibility of data extrapolation in different target population groups, therapeutic areas and drug characteristics, the guideline only provides the general requirements for data extrapolation. Pediatric drug developers are encouraged to communicate with drug regulatory authority in the early stage of R&D.

The guideline only represents the current view and understanding of the drug regulatory authority and is for reference to developers only without compulsory legal power. It will be updated in future.

GCP, ICH and other relevant international and domestic technical guidelines (e.g. *Technical Guidelines for Clinical Trials of Pediatric Drugs* and *Technical Guidelines for Pharmacokinetic Research of Pediatric Drugs*) should be referenced at the same time when using this document.

CDE Solicits Public Comments on Draft eCTD Application Dossier Guidelines

The Center for Drug Evaluation (CDE) under the CFDA released two draft documents, the *Drug eCTD Composition* and the *Application Guidelines for eCTDs for Chemical Generic Drugs*, on May 31.

Public feedbacks need to be submitted to the following email address before June 30, 2017.

Contact: LI Hailing
Email: lihl@cde.org.cn Tel: +86 10 68921209

For full text of the two draft documents in English, please visit the following CFDA weblink: http://www.cde.org.cn/news.do?method=viewInfoCommon&id=313618

CFDA Solicits Comments on Measures Relating to Equivalence Studies of GI Local Acting and Electrolyte Balance Generic Drugs

The CFDA re-issued on May 25 a new draft document, *Matters Relating to Applications for Quality and Efficacy Equivalence Evaluation of GI Local Acting & Electrolyte Balance Generic Drugs and Bioequivalence Study of Special Drugs*.

It is now seeking public comments on the document which need to be submitted to the following email address before June 15, 2017.

Email: fzy@nifdc.org.cn

Full text of the draft document in Chinese can be downloaded from the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0778/172966.html

CFDA Issues Announcement for Handling of Relevant Issues Related to Clinical Data Inspection

The CFDA issued a document, *Announcement on Handling of Relevant Issues Relating to Drug Clinical Trial Data* (2017#63), on May 24.

After the CFDA initiated clinical trial data self-inspection and inspection in July 2015 in accordance with CFDA Announcement 2015#117, the agency has discovered a range of issues relating to clinical trial data truthfulness and fraud. Subsequently it rejected 30 drug applications from 29 pharmaceutical companies in three announcements (2015#229, 2015#260 and 2016#92).

The CFDA summarized the range of issues it has discovered in clinical data inspections so far in this document under the following six categories:

- Issues related to obligations of applicants, clinical research institutions and CROs;
- Violations of the articles 6, 20, 26, 27, 40, 48, 49 and 62 of GCP are deemed as data frauds;
- Above clinical data frauds by applicants or by directly responsible parties or principle investigators of clinical research institutions and CROs will be penalized by the CFDA following principles provided. Those involved with crimes will be transferred to judicial departments;
- Clinical research institutions involved with volunteer information consent and safety violations, improper handling, storage and use of experimental drugs, as well as other violations affecting volunteer rights and trial quality will be suspended for correction, during which time no new trials should be initiated;
- Specific situations, where penalties should be increased, decreased or exempted, are also provided; and
- Punishment handling procedures and rights of violators.

For full text of this document in Chinese, which contains details of these provisions, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0087/172936.html

CFDA Issues New Announcement (2017#59) for Clinical Data Self-Inspection

The CFDA issued a new announcement (CFDA Announcement 2017#59) on May 19 about onsite inspection of 44 drug applications which completed clinical studies and are seeking production or import approvals. Among them, 35 are for import drugs from Astellas, Helsinn, Otsuka, Boehringer Ingelheim, Acetolion, Lundbeck, Bayer, GSK, AstraZeneca, Novartis and Cephalon.

The CFDA said that it had decided to conduct onsite inspection of clinical data for all these registration applications. The agency noted that: 1) after self-inspections uncover issues with clinical data, voluntary withdrawals by applicants before the CFDA inspections will not be pursued for violations; 2) CFDA will no long accept application withdrawals ten days after the CFDA's Center for Food and Drug Inspection publicizes the inspection plan on its website; and 3) applicants, responsible parties and managers of clinical trials and responsible personnel of CROs involved in clinical data frauds, as well as CFDA inspectors not fulfilling duties effectively will be penalized.

Please click on the following CFDA weblink for full text of this announcement in Chinese and a list of the above-mentioned 44 drug applications with more details: http://www.sda.gov.cn/WS01/CL0087/172784.html

China Introduces Second Batch of Encouraged Pediatric Drug Products

The NHFPC, CFDA and MIIT jointly issued a notice on May 15, releasing the second batch of 40 pediatric drug products which are encouraged for development. The list was developed by relevant experts following principles of evidence-based medicine and in accordance with pediatric disease spectrum, clinical demands and domestic R&D capacity.

The list is now on a five-day publication period, during which timeframe, feedbacks can be submitted via phone or email below:

Tel: +86 10 68797753 Email: ertongyongyao@126.com

The first batch of 32 pediatric drug products encouraged for development were introduced by the three agencies in June 2016.

For full text of the notice and the list of 40 second batch pediatric drugs supported for development in Chinese, please visit the following NHFPC weblink: http://www.nhfpc.gov.cn/yaozs/s3578m/201705/b1fe01a5c8fc4e0983a04696ae2b753f.shtml

A NHFPC official in charge of the matter told the Chinese press after release of the first batch of pediatric drug products encouraged for development in June 2016 that a special drug approval path will be established for drugs on the list. Besides, urgently needed pediatric drugs which are not on the mainland Chinese market but have been used for years in Hong Kong, Macau and Taiwan (HMT) can be imported for clinical use on a trial basis. In order to accelerate review of encouraged pediatric drugs, relevant pediatric clinical data in HMT can be used directly to support registration of their mainland Chinese drug applications.

CDE Publicizes Batch 17 of Drug Applications To Be Granted Priority Review Status

The Center for Drug Evaluation (CDE) under the CFDA publicized on May 23 a new list of 11 drug applications (by application number) (17th Batch) which are to be granted priority review status.

Ten of the 11 applications are for new drugs from foreign companies including Novartis, Takeda, Astellas, Gilead, Actelion, Pfizer and Bayer, while the only domestic application is from Jiangsu Hengrui Medicine.

Disputes to priority review status for any of these applications should be submitted via the following CDE weblink within five days from the date of publication: http://www.cde.org.cn/news.do

?method=changePage&pageName=service#

For a full list of these applications in Chinese, please visit the following CDE weblink: http://www.cde.org.cn/news.do?method=viewInfoCommon&id=313875

CFDA Approves 149 More Medical Institutions as Designated Clinical Research Institutions

Following dossier reviews and onsite inspections, the CFDA announced on May 16 that it has approved the designation of 149 additional medical institutions as designated clinical research institutions and issued relevant certification documents.

For a full list of these newly designated clinical research institutions, including the International Hospital Affiliated to the Peking University, with more details on their scope of designation, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0069/172689.html

CFDA Designates 256 More Institutions for Clinical Research and Expands Approved Specialties of Others

Following dossier reviews and onsite inspections, the CFDA announced (2017#61) on May 24 that it has approved selected specialties in 256 additional medical facilities as designated clinical research institutions. One application for such designation, however, was rejected.

For a full list and details of these newly designated clinical research institutions and their approved specialties, as well as more information on the rejected application, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0069/172934.html

On the same date, the CFDA also announced (2017#62) approval of 95 existing designated clinical research institutions to expand their designated medical specialty scope.

For more details in Chinese of the approved specialty scope expansion in these designated clinical research institutions, please visit the following CFDA weblink: http://www.sda.gov.cn/WS01/CL0069/172935.html

China-Denmark Food and Drug Regulatory Cooperation Center Officially Launched

On May 3, 2017, Chinese Premier Li Keqiang and Danish Prime Minister Lars Løkke Rasmussen who is making an official visit to China witnessed the signing of the Memorandum of Understanding between the China Food and Drug Administration of the People's Republic of China and the Ministry of Environment and Food of the Kingdom of Denmark and the Ministry of Health of the Kingdom of Denmark on the Establishment of the China-Denmark Food and Drug Regulatory Cooperation Center.

The center is the first such bilateral cooperation center of the CFDA and it is dedicated to joint symposium hosting, personnel training, exchanges and visits, technical cooperation in drug evaluation, enforcement and testing, research on laboratory testing technologies and methodologies, and mutual references of drug regulatory policies of the two countries.

CFDA Minister Meets Senior Delegation of the USFDA CDER and ICH

BI Jingquan, Minister of China Food and Drug Administration (CFDA), met with the delegation led by Dr. Theresa Mullin, Director of the Office of Strategic Programs of the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA), and chair of the Management Committee of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) on May 19, 2017.

Both sides exchanged opinions on promoting drug innovation through regulatory reform, China joining ICH etc. BI Jingquan delivered to Dr. Theresa Mullin a letter of congratulation to convey to the newly appointed FDA Commissioner Scott Gottlieb, while Dr. Theresa Mullin hand over a greeting letter from Scott Gottlieb to BI Jingquan.

CFDA Vice Minister WU Zhen and relevant directors of CFDA's related departments attended the meeting.

Legal/IPR News

China, India Named and Shamed by USTR on Lax IP

US President Donald Trump's "America First" slogan has come out strong in the latest Special 301 report, which slams several countries including China, India, Canada and Mexico for lax intellectual property and enforcement that hinders US trade.

The annual review is compiled by the United States Trade Representative and details the state of IP enforcement in countries that trade with the US. The latest version has reiterated Trump's campaign pledge for fair trade that does not disadvantage the US and its companies, and "reflects the resolve of this Administration to call out foreign countries and expose the laws, policies, and practices that fail to provide adequate and effective IP protection and enforcement for US inventors, creators, brands, manufacturers, and service providers".

Thirty-four trading partners were singled out with concerns over their IP protections for US goods and companies, with 11 of those listed as priority countries to watch.

China continues to be placed on the USTR priority watch list for its part in "widespread infringing activity" that includes "rampant online piracy and counterfeiting" and the export of these fake goods. The report also notes the requirements imposed on US firms who want to access the Chinese market such as the need to develop their IP in China or transfer their IP to Chinese entities. India has also been called out "for lack of sufficient measurable improvements to its IP framework", which have "negatively affected US right holders". Both countries are criticised for their "inadequate protection for trade secrets", which "puts US trade secrets at unnecessary risk".

The "troubling trends" in the proliferation of counterfeits highlights that there are issues with IP protection and enforcement, the report notes. "Many countries do not provide penalties that deter criminal enterprises engaged in global trademark counterfeiting operations," the report says.

Meanwhile, the report is also particularly scathing about the

"growing problem" of counterfeit drugs, which are "manufactured, sold, and/or distributed in numerous trading partners, including China, Guatemala, India, Indonesia, Lebanon, Peru, and Russia". It further notes that IP protection issues and other trade issues, such as tariffs, in many countries hinders market access of the US pharma and medical device market, which can raise healthcare costs and encourage local growth in counterfeits.

In response to the report, PhRMA released a statement saying that IP protection and access to overseas markets was essential for the continued success of the US pharma industry, while naming and shaming several countries for lax IP protection and enforcement.

The BIO also welcomed the report, saying its members "rely heavily on the strength and scope of their IP" while noting the raft of IP-related challenges including inadequate legal protections and enforcement issues that needed to be addressed.

The countries on the priority watch list include: Algeria, Argentina, Chile, China, India, Indonesia, Kuwait, Russia, Thailand, Ukraine and Venezuela.

I-MAK Challenges Gilead's Remaining Patents of HCV Drug Sofosbuvir

In a move that could strike down barriers to treatment for the exploding hepatitis C epidemic, attorneys and scientists from the Initiative for Medicines, Access & Knowledge (I-MAK) filed a legal challenge against Gilead's remaining patent for the hepatitis C medicine sofosbuvir in China.

Branded as Sovaldi, this patent covers the sofosbuvir base compound and is founded on previously published techniques, and does not meet the legal criteria for a patent. This new filing follows another legal challenge filed by I-MAK in 2015, which helped result in a rejection in June 2015 by China's SIPO on the other critical patent application on sofosbuvir. SIPO found that this patent, covering the prodrug that activates the otherwise inactive base compound in the body, did not deserve a patent under the law.

While the rejection on the prodrug patent application in 2015 in China significantly weakens Gilead's reliance on unjustified patents, removing the unmerited base compound patent will open the market to lower-cost generic versions that could help as many as 8.9 million people in China receive the treatment they need to survive and lead healthy lives.

"When presented with the facts, patent offices around the globe are increasingly recognizing that patents must be reserved for drugs that are proven to be novel, non-obvious and useful," said Tahir Amin, I-MAK co-founder and director of intellectual property. "We hope that the Chinese patent office does the right thing and ends Gilead's manipulation of the law, so that millions of people can have affordable access to the medicine they need."

I-MAK's legal challenges could have a far-reaching impact on the market for affordable medicines in China and around the world. In China, freeing sofosbuvir of its unmerited patents would open the door to affordable generic treatment, saving government health programs and consumers billions of dollars. Affordable treatment for just four million people – or just 46% of those living with hepatitis C in the country – would save at least US$26.8 billion. If every person in China with hepatitis C was treated, the total potential savings of using generic sofosbuvir is at minimum US$59.0 billion, over half of China's annual spending on prescription drugs.

China serves an essential role in the global pharmaceutical drug supply chain, manufacturing more than 800,000 tons of pharmaceutical ingredients each year – more than any other country. More than 70% of all active drug materials consumed in the U.S. and Europe are imported from China and India. China provides roughly 43% of the raw materials used to produce anti-infective medicine for the world, according to the World Bank's Human Development Network. Removing all unjustified patents for sofosbuvir in China will help open the supply of raw materials to manufacturers around the country and get the drug to millions of people with hepatitis C worldwide who currently cannot get the medicine they need to get well.

To date, I-MAK has worked with partner organizations to remove patent barriers against sofosbuvir in 46 countries, including Argentina, Brazil, China, Egypt, India, Russia, Thailand, and Ukraine, and in Europe (covering 38 countries). On the heels of China's prodrug rejection, Ukraine's patent office followed suit and rejected a patent application for sofosbuvir by Gilead; other countries such as Egypt have also rejected key patents on sofosbuvir.

API/Bulk Drug News

U.S. FDA Warns Chinese API Producer for Absence of Written Procedures

The US Food and Drug Administration (FDA) on May 23 released a warning letter sent to China-based API manufacturer Changzhou Jintan Qianyao Pharmaceutical Raw Material Factory for, among other issues, failing to have written procedures on its handling of raw materials.

FDA noted, "When our investigator asked for a list of your critical raw materials and your sampling requirements, you told our investigator that you had no written procedures for testing and sampling incoming materials. Instead, you explained, your warehouse employees accounted for incoming raw material handling, sampling, and testing 'in their heads.'"

The warning letter also revealed that the company "did not have any quality-related procedures in place" before August 2016 "even though you were manufacturing and shipping drugs to the United States."

And though some quality-related procedures were drafted ahead of FDA's February inspection, the agency said that the company had not yet implemented them.

In addition to recommending the firm find a CGMP consultant to help meet the agency's regulations, FDA also pointed the company to expectations outlined in ICH Q7 in determining whether APIs are manufactured in conformance with CGMP and FDA's guidance on Q7.

DSM Sinochem Wins Indian Patent Lawsuit against Sinopharm Weiqida Pharma

DSM Sinochem Pharmaceuticals (DSP), the global leader in production and commercialization of sustainable, enzymatic

antibiotics, next generation statins and anti-fungals, announced on May 23 that the High Court of Delhi has granted a permanent injunction against Sinopharm Weiqida Pharmaceutical for patent infringement in India.

According to DSP, the High Court of Delhi, India, has granted a permanent injunction against Sinopharm Weiqida Pharmaceutical Co., LTD for patent infringement of Indian Patent Number 247,301. This patent, which is owned by DSP, relates to amoxicillin trihydrate having a low free water content and processes for the manufacture thereof.

The permanent injunction prevents the manufacture, use, importation, offering for sale and sale of Weiqida's amoxicillin trihydrate active pharmaceutical ingredient in India, as well as any drug product that utilizes the active pharmaceutical ingredient.

Product and R&D News

Sirnaomics Granted Chinese IND Approval for siRNA Drug for Hypertrophic Scar

Sirnaomics, Inc., a leading biopharmaceutical company in discovery and development of RNAi therapeutics, announced on May 2 that its subsidiary company, Suzhou Sirnaomics Pharmaceuticals, Co. Ltd, China, has received an approval from China Food and Drug Administration (CFDA) for an IND application of STP705 (Cotsiranib), an siRNA (small interfering RNA) therapeutic for treatment of hypertrophic scar. The IND was filed through a chemo-drug category 1.1 application based on CFDA requirement. The approval represents a milestone event for the company and, more importantly, it marks the first in the country allowing innovative siRNA therapeutics to enter clinical study, with the IND filed from a domestic company.

Suzhou Sirnaomics' lead product candidate, STP705, is an anti-fibrosis siRNA therapeutics taking advantage of a dual-targeted inhibitory property and polypeptide nanoparticle (PNP)-enhanced delivery, to directly diminish both fibrotic activity and inflammatory activity allowing for application in many disease states. This initial clinical study is designed to evaluate safety and tolerance of STP705 through healthy volunteers with both single dose escalation and multiple dose escalations.

This approved clinical study is staged into 2 parts: a randomized, double-blind placebo controlled study to evaluate the safety of STP705 administered as subcutaneous injection into healthy volunteers with either single dose escalation or multiple dose escalation. Both pharmacokinetics and pharmacodynamics of STP705 will be evaluated throughout this study.

IMPACT Therapeutics Received Chinese IND Approval for Novel PARP Inhibitor

IMPACT Therapeutics, Inc. (IMPACT) announced that CFDA granted approval to its IND application of IMP4297, a potential best-in-class PARP inhibitor, in January 2017. The company dosed the first patient in its Australian Phase I trial in February 2017, and has since initiated IMP4297 Phase I clinical trial in China.

Dr. Edward Tian, CEO of IMPACT, is looking forward to the IMP4297 clinical trials in China. He said: "It took us about one year to obtain the CFDA approval from the time of our IND submission. The reforms within CFDA have shortened R&D cycle and reduced R&D cost. More importantly, given the CFDA's accelerated efforts to bring new drugs to market, Chinese patients should have access to innovative drugs in a more timely manner."

Dr. Sui Xiong Cai, SVP and CTO of IMPACT, is optimistic about the company's projects. He stated: "IMPACT has a highly experienced management team, which is important for the successful development of our products. IMP4297 is a high potency PARP inhibitor discovered and developed in China. It has the potential to demonstrate better clinical efficacies than the currently marketed PARP inhibitors, and to be developed into a best-in-class new drug."

Athenex Announces CFDA IND Approval for KX-02 Tablet for Glioblastoma

Athenex, Inc., Buffalo, NY, a global specialty oncology pharmaceutical company focusing on the development and commercialization of next generation therapies for cancers and supportive therapies, announced on May 24 that its partner, Guangzhou Xiangxue Pharmaceutical Co. Ltd., (Xiangxue) has received the Chinese FDA IND approval to begin clinical trials for KX-02 tablet for glioblastoma in May 2017 as a Class 1 New Drug in China. Athenex also received the US FDA allowance for KX-02 IND in 2014.

KX-02 is a new Src protein tyrosine kinase (PTK) inhibitor and tubulin polymerization inhibitor designed and developed by Athenex. It can disrupt cancer cell division, induce cell cycle arrest, apoptosis and cancer cell death. KX-02 can also cross the blood-brain-barrier and has induced durable complete remissions of glioblastoma in human xenograft animal models without sustained therapy.

Hengrui's Breast Cancer Candidate Shows Promise in an Early Trial

Early results for a new agent, pyrotinib (HTI-1001) of Hengrui Therapeutics (the U.S. R&D subsidiary of Jiangsu Hengrui Medicines), are showing promise for the treatment of HER2-positive breast cancer, according to phase 1 results from China published in the *Journal of Clinical Oncology*, which showed that the drug was well-tolerated and showed anti-tumor activity. Incidence of diarrhea was relatively high (44%), but that was the only grade 3 toxicity observed and there were no grade 4 ot higher toxicities reported. Maximum-tolerated dose was 400 mg daily.

"All pyrotinib-related diarrhea events were effectively controlled by use of antidiarrheal agents, and only 1 patient experienced dose interruption for one day because of diarrhea," wrote the researchers, who were all from the National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China. "Pyrotinib is well-tolerated at a dose of 400 mg once per day, and its encouraging antitumor activity in patients with HER2-positive breast cancer warrants further evaluation in HER2-positive metastatic breast cancer phase 2 trials with a dose of 400 mg once per day."

Pyrotinib is an oral, irreversible pan-ErbB receptor tyrosine kinase inhibitor with activity against EGFR/HER1, HER2, and HER4.

TaiGen Announces NDA Submission for Taigexyn IV Formulation to the CFDA

TaiGen Biotechnology Co, Limited ("TaiGen") announced on May 31 that it has submitted a New Drug Application (NDA) for the intravenous formulation of Taigexyn (Nemonoxacin), a novel non-fluorinated quinolone antibiotic, to the China Food and Drug Administration (CFDA).

Taigexyn is The NDA submission is supported by a pivotal Phase 3 trial comparing intravenous formulations of Taigexyn 500 mg to levofloxacin 500 mg in 518 patients with moderate to severe community-acquired pneumonia. The clinical success rates were 91.8% for Taigexyn vs. 85.7% for levofloxacin and Taigexyn was shown to be non-inferior to levofloxacin meeting the primary endpoint of the pivotal trial.

Taigexyn is a novel broad spectrum antibiotic with excellent efficacy against drug-resistant bacteria available in both oral and intravenous formulations. The oral formulation is already approved for marketing and launched in Taiwan and mainland China. In addition, Taigexyn is also partnered in Russia, Commonwealth Independent States, Turkey, Mexico, Brazil and the Latin American territory for a total 32 countries worldwide.

China Creates New Kinase-Based Whole-Cell Screening Library for High-Throughput Drug Assay

After five years of hard work, China has completed the world's largest kinase-based whole-cell screening library for high-throughput drug assay.

The cell library is located in Hefei, capital of Anhui Province, and includes over 150 cell lines. The library covers more than 70 different kinases and mutations that are involved in human tumorigenesis and have been targeted through clinical treatment.

Targeted Therapy

The kinase-specific screening library, which is the first of its type for drug screening in China, will provide enormous support for anti-cancer drug development in the country, due to the nature of many types of cancer.

Specifically, many cancers are induced by mutations that activate aberrant cell proliferation, resulting in uncontrolled cell growth. Many of these mutations involve kinases and can be inhibited through well-designed small molecule inhibitors.

Targeted therapy against these kinases has an advantage over traditional treatment methods since it is highly specific for oncogenic targets and cells. As a result, it spares normal cells, thus causing fewer side effects and toxicity.

After more than a decade of effort, targeted therapy has made significant progress with more than 30 drugs in clinical use. However, these drugs cover less than 10 cancer subtypes and are not available for most cancers. Even worse, the rapid appearance of drug resistance has dramatically increased the difficulty of new drug development.

"Patients in Test Tubes"

To address these problems, Dr. LIU Qingsong's research team at the High Magnetic Field Laboratory of the Chinese Academy of Sciences (CHMFL) set up the library, which was built "from scratch" using genetic engineering and a mouse prototype cell line.

Since the library's cell lines depend on a single active kinase mutation, they are extremely sensitive to compounds targeting these specific kinases and ideal for high-throughput drug screening.

Dr. WANG Wenchao, a leading researcher on the project and CHMFL scientist, likened the cell library to "patients in test tubes" since the cell lines can "mimic clinical patients in drug sensitivity evaluation at the cellular level."

To further improve the efficiency of cells in drug screening, LIU's team also set up a state-of-the-art high-throughput platform with automatic sample handling and data processing capabilities in 2013.

With the platform now in place, the team can finish over 10,000 drug assays in just one day and has already served more than 100 industrial and academic groups involved in drug research.

General Health

MOF: Chinese Fiscal Budget for Health-care Spending to Reach CNY 1.4T in 2017

China's national fiscal budget for healthcare expenditures is set at CNY 1,404.4 billion in 2017, up 5.1% year on year, according to Qichao SONG, Deputy Director General, the Social Security Department of Ministry of Finance.

This is 4.4 times of the same figure in 2008 when healthcare reform began. The amount also represents 7.2% of the 2017 fiscal budget of Chinese government, up from 5.0% in 2008.

Among the total, CNY 398.2 billion comes from the central government budget, which represents 7.7% of the 2017 fiscal budget of central government, up from 6.1% in 2008.

Specifically, the Chinese government will raise per capita subsidy of urban resident BMI and NRCMS to CNY 450 in 2017, an increase of CNY 30. The central government will continue to subsidize CNY 3 million and CNY 20 million respectively to each public hospital reform trial site county and city. Besides, the annual per capita essential public health spending is raised to CNY 50 in 2017 from CNY 45 last year.

China Raises Government Subsidy of Urban and Rural Resident BMI Again in 2017

The MOHRSS and the Ministry of Finance (MOF) recently issued a joint notice for urban and rural resident basic medical insurance (BMI) in 2017. It is provided that the Chinese government will increase the government subsidy of urban and rural resident BMI system by CNY 30 per participant to a total of CNY 450. Besides, the notice requires increase of personal premium contribution to the system by CNY 30 per participant to a total of CNY 180.

Besides, the notice includes the following provisions:

- Building a uniform urban and rural resident BMI system with strengthened integration of urban BMI program and NRCMS in all localities;
- Raising synergies and impacts from integration of resident BMI program and NRCMS through uniform management, balanced BMI benefits of urban and rural participants and

higher BMI funding pool;

- Introducing precision BMI payments with lower deductibles, higher reimbursement level and improved contracts with commercial health insurers for critical illness programs;
- Perfecting integration of critical illness and medical assistance programs;
- Enhancing supervision of medical services through compounded BMI payment schemes, such as disease group-based and headcount-based schemes, on the basis of advanced lump sum advance payment scheme;
- Boosting early alert of BMI funding with refined financial budgetary control, sound financial operation analysis system and deficit risk surveillance; and
- Building a healthy publicity environment for resident BMI in 2017 to ensure social stability.

For full text of this notice in Chinese, please visit the following MOHRSS weblink: http://www.mohrss.gov.cn/gkml/xxgk/201704/t20170428_270179.html

China to Implement Tax Relief Policy for Commercial Health Insurance Nationwide

The Ministry of Finance, the State Taxation General Administration and the China Insurance Regulatory Commission jointly issued a notice on May 2 to expand the trial of personal income tax relief policy for commercial health insurance purchase to nationwide with effect from July 1, 2017.

Under the policy, commercial health insurance expenditure incurred by individuals will benefit from tax relief up to a limit of CNY 2,400 per year. Corporate purchase of commercial health insurance is deemed the same as personal purchase and therefore is applicable for such tax relief.

Taxpayers including salary and continuous labor service wage earners, self-employed people, proprietors of sole-owner companies, partners in partnership companies and independent contractors are eligible for such tax relief when they purchase commercial health insurance.

Three categories of health insurance products are qualified for such tax relief, they are: 1) commercial health insurance schemes oriented for personal out-of-pocket expenditures beyond coverage of the state basic medical insurance programs and the civil servant free medical care program; 2) commercial health insurance schemes oriented for major medical expenditures beyond coverage of the state basic medical insurance programs and the civil servant free medical care program; and 3) commercial health insurance schemes oriented for people who are not covered by the state basic medical insurance programs and the civil servant free medical care program.

NHFPC, SATCM Issue Joint Policy for Electronic Registration of Medical Institutions and Professionals

The NHFPC and the SATCM recently issued a new policy document, Guidance Opinions for Accelerating Electronic Registration Management Reform of Medical Institutions, Physicians and Nurses.

The document requires that full registration management of medical institutions, physicians and nurses should be completed nationwide by June 2018. Besides, issuance of electronic certificates should be finished by 2020.

Trials of such electronic registration management reform are required for initiation by all provincial level governments before June 2017 and at least 40% of all municipalities across the country should implement such reform before the end of this year, the document provides.

It is reported such reform trials have already been conducted in recent years in Beijing, Tianjin and Hebei.

China's Big Data Regulation to Boost Healthcare, Security

China is to issue its first regulation on how the big data from the health sector is collected, stored and used. JIN Xiaotao, Vice Minister of the National Health and Family Planning Commission, said the regulation will be issued soon, as the nation aims to safeguard public security. Big data for the health industry includes patients' basic information and conditions, disease control and prevention, food safety, lifestyles and even genomes.

"This data concerns public health and national biological security," Jin said. "The new regulation is necessary, especially given that China seeks to develop healthcare data as an asset."

He said an independent management committee will be set up to ensure data security and that the regulation will define the basic rules on ownership, collection and usage. The move comes after the State Council issued a multidepartment guideline in June to promote and regulate the use of big data in healthcare.

The guideline states that a centralized, uniform big data platform for healthcare is expected to be established by 2020 to standardize data collection, storage, reporting and security management.

"A central goal of the guideline is to improve people's health," said Jin, whose commission was among the departments that produced the document.

The guideline is also expected to play an important role in building a new economic pillar for China involving the application of big data. Jin said the State-level strategy includes setting up a national healthcare big data center and seven regional centers as well as data research and innovation centers, which will be established with partner institutions from home and abroad.

China Introduces Cardiovascular Health Index

The Chinese cardiovascular health index (2017), the world's first national-level index on cardiovascular (CV) disease prevention and control, was released on May 26 in Shangha. It established national level big data in CV health index for the first time, outlining CV health prevention and control in China.

"The index will provide scientific basis for the policy makers and strive to reduce the illness," said Ge Junbo, chairman of Asia-Pacific Society of Interventional Cardiology.

Chronic diseases have become one of the biggest challenges in China's public health sector partially due to the aging population. More than 40% of Chinese die of CV disease – the No.1 cause of death in China.

"With the increasing number of CV diseases year-by-year, CV

health index, as a comprehensive evaluation system, is very necessary," said WANG Honglin, director of chronic disease center at Chinese Center for Disease Control and Prevention.

"It will help reflect overall CV health conditions and its development trends. It also measures the development status, development pattern and governance structure of CV diseases from prevention to treatment," Ge said.

The report is not only the most authoritative large-scale integrated CV health index, but also the world's first national level index evaluation on CV disease prevention and control.

Eight institutions, including the Chinese Center for Disease Control and Prevention, and more than 40 experts participated in creating the health index.

Nippon Life Offers Cancer Insurance in China

Nippon Life Insurance has begun selling health insurance that lets Chinese policyholders receive cancer treatment in Japan as part of their coverage.

As the number of Chinese cancer patients grows, more are said to be seeking high-quality treatment in Japan. The Osaka-based insurer hopes to tap into rising demand for medical tourism among affluent Chinese consumers.

Insurance policy sales will be handled by Nissay-Greatwall Life Insurance, a joint venture between Nippon Life and the Chinese government. Nippon Life holds a 30% stake. In addition to cancer treatment, other costs such as travel and lodging will be covered by the insurance.

Emergency Assistance Japan, a medical intermediary company, will obtain medical treatment visas and select hospitals that fits patients' wishes and needs out of a roster of 1,000 partner institutions in Japan. Nippon Life will pay the hospital fees, alleviating any concerns the medical facilities may have regarding payment.

Nippon Life aims to sign up around 20,000 policyholders in the first fiscal year, earning CNY 50 million (US$7.25 million) in premium income. The company hopes to write about 100,000 policies in the next three years.

Cancer is the leading cause of death in China, according to data from 2010, with the percentage apparently on the rise in recent years. Just 30% of patients live five years after diagnosis, a result of an outdated health care system. In Japan, the survival rate is 70%.

China's life insurance market ranks fourth in the world by revenue, trailing the U.S., Japan and the U.K. But most policies sold in the country are whole life or annuities. Japanese providers Meiji Yasuda Life Insurance and Sumitomo Life Insurance also operate in China.

People in the News

Former Senior CFDA Official Handed Ten Years Prison Sentence for Corruption

TONG Min, formerly Director General of the Medical Device Supervision Department of the CFDA, was sentenced to ten years imprisonment and a fine of CNY 500,000 for receiving bribes in exchange for administrative favors relating to health food and drug registration.

Between 2000 and 2015, Tong had held various important positions including Assistant Mayor of Nanchang City (capital of Jiangxi Province), Deputy Director General of Jiangxi Provincial Economic and Trade Commission, as well as Director General of CFDA's Food Licensing Department, Health Food and Cosmetics Supervision Department and Medical Device Supervision Department.

The court found that he received bribes totaling CNY 3.16 million in the forms of cash, bank cards and automobiles through his ex-marital girlfriend from eight parties. In exchange, he offered help to these parties in business development, health food approval and drug evaluation.

The eight parties involved in bribing Tong included the boss of Hangzhou Disheng Pharma and the Vice President of China Health Product Association.

Tong's crimes were discovered by the Party Disciplinary Group at the CFDA and arrested in August 2015.

Recent Executive Moves

AstraZeneca promoted ***Jo Feng*** to the position of General Manager China from her prior position as TA VP – INA (Infection/ Neuroscience/ Autoimmunity) GPPS and earlier VP, CV Business Unit, China. Before joining AstraZeneca China in 2003, she had been Brand manager with Aventis China for three years.

Pfizer China reported announced internally that ***SHAN Guohong***, China Lead of Pfizer Innovative Health, will leave the company in June, only one year after his appointment of this position. Shan has also held the position of Regional President, Greater China, Pfizer Oncology for the past two and half years and had earlier been General Manager, Specialty Care BU of Pfizer China for two and half years. Before joining Pfizer in 2011, he had been Vice President Sales & Marketing BU GRA with AstraZeneca China for three and half years.

MSD China announced appointment of ***SHI Wang*** to the position of Managing Director, Regional Operations. He will be leading ten business regions, retail business and female health business of the company. Shi was previously Senior Vice President, Cardiovascular and Metabolism Business with AstraZeneca China, where he had worked for 15 years. Besides, ***XU Peng***, formerly Senior National Sales Director of Sanofi Pasteur China, joined MSD China as General Manager of the company's vaccine business division. Xu worked at MSD China for nine years as SFE Head before joining Sanofi. Also, MSD China promoted ***ZHANG Cheng***, previously Vice President in charge of south China business to Managing Director, Commercial Operations. Finally, ***TANG Xingbin***, previously Vice President in charge of Northeast China business, will relocate to Merck's global vaccine business headquarters in the U.S. to hold a position in business development.

YANG Weiping is now Co-founder and **Chief Executive Officer of** ApolloBio Corp. He was previously Chairman & President of Fresenius Kabi China Holding Co. Ltd between 2005 and 2011. After leaving Fresenius in 2011, he founded and was **Chairman of** Ranhou Investment Management Co. Ltd.

Roche promoted ***Rachel Deng*** to the position of APAC Disease Area Director (Pipeline Strategic Planning) from her prior position of Associate Disease Area Director. Before joining Roche China

as Strategic Planning Manager in 2010, she had been Consultant and Senior Analyst with IMS Health China for three and half years as well as Marketing Specialist with Shanghai Pharmaceutical Group for two years.

GAO Yan joined AbbVie as Global Brand Leader, Oncology Marketing. She had previously been Global Marketing Director with AstraZeneca for more than one year. Before that she worked with Novartis for ten years, most recently as Breast Cancer Franchise / Disease Director – Emerging Markets with Novartis Oncology.

Andrew Zhu joined Sanofi China as Business Head. He had previously been Marketing Director with AstraZeneca China for more than two years, Marketing Leader (Diabetes), Associate Marketing Director and Regional Sales Manager with BMS China for more than three years, Senior Product Manager with Novartis for nearly six years.

Bayer Healthcare China promoted ***Michelle Han*** to the new position of Franchise Head Oncology from previously Franchise Head Specialty Therapeutics. Before joining Bayer in 2011, she had been Senior Product Manager / Product Manager (Osteoporosis/ CV Anti-hypertension) with Sevier China for more than three years, Regional Brand Manager (Insulin & OAD in Diabetes) with Sanofi China for three years, and MR/ Local Marketing Executive (Dermatology) with Novartis China for more than two years.

Roche China promoted ***Johnson Li*** to the new position of Director of Training & Development and Head of Roche China Academy from previously Director of Commercial Training & Development. Before joining Roche in 2010, he had been Senior Director, Sales Training and Head of Sales Operation with Beijing Novartis Pharmaceuticals for six years.

LIU Xuezheng joined MSD China as Associate Director, IT Account Management. He had previously been with AstraZeneca for nearly eight years, most recently as AsiaPac Regional Collaboration Lead and Commercial Capability Team Leader.

GSK China promoted ***WANG Jianfei*** to the new position of Senior GSK Fellow and Head of Integrated Biological Platform Sciences from his prior position of Head, Integrated Biological Platform Sciences. Before joining GSK in 2009, Jianfei had been Assistant Professor with University of Alberta for three and half years, and Veterinarian/Assistant Professor with Shanghai Laboratory Animal Center, Chinese Academy of Sciences for six and half years.

CUI Li joined Allergan China as Associate SFE Director. He had previously been Engagement Manager with IMS Health China for three and half years, Sr Sales Force Effectiveness Manager and sales representative with Eli Lilly China for more than four years, and Consultant, Strategic Communications with APCO Worldwide for less than two years.

John Sun is now Project Manager, Process Improvements, Process and Technology Optimization, Global Dev Operations with Novartis where he has worked for ten years. He was Global Program Team Director, Established Medicines and Associate Director, Respiratory Franchise for six years. Before joining Novartis in 2007, John had been Sr Project Manager with sanofi-aventis for nearly four years and Project Manager with Schering-Plough Research Institute for two and half years.

David Fan joined Gilead Sciences China as a business innovation executive. He had previously been Co-founder and Head of Strategic Alliance with Xinshulin IT (Beijing) Co. Ltd. for nearly three years, Business Development Manager with Wiley-Blackwell for one and half years, and General Manager of Haoyisheng's Shanghai Branch for six years.

GAO Bing joined LEO Pharma China as National Sales Director. He had previously been Head of Hospital Customer Marketing and National Sales Director with Bayer Healthcare (Consumer Care) for nearly three years.

LU Hongbo is now Partner with Lilly Asia Ventures. She has been Board Members of Echosens and CrownBio. Lu had been Managing Director, Asia, Public Equity with OrbiMed Advisors for more than five years and Senior Equity Analyst and Principal with Piper Jaffray for nearly six years.

Bruce Boulanger joined Permobil as President Business Region Asia. He was previously General Manager China with URGO Group. Before joining Urgo in 2010, he had been Director Global Sales Force Effectiveness with Abbott for less than a year, Director Global Sales Force Effectiveness with Solvay Pharma for four years, and Global Sales Force Effectiveness Manager, Area Business Manager and hospital sales executive with Fournier Pharma for nearly eight years.

BEN Yong is now Chief Medical Officer of BioAtla LLC and he has also been Global Clinical Leader, Immuno-Oncology Clinical Development with AstraZeneca since 2014. Before that, he had been Clinical Lead/Medical Director with Millennium Pharmaceuticals for two and half years, and Clinical Lead/Global Medical Monitor with Pfizer for nearly six years.

Tobias P. Dreesman joined Weber Shandwick as Senior Vice President, Healthcare Communications. He had previously been Global Business Director with M3 USA for two years, Chief Engagement Officer with Omnicom/DAS Healthcare for two years, Group Research Director with WPP/Kantar Health for nearly two years and Business Intelligence Director with Dentsu for ten years.

ZHANG Kingga joined Wuxi PharmaTech as Senior Director, Project Management. She had been Study Management Team Leader with Boehringer Ingelheim China for three years, Clinical Research Manager with Roche China for more than seven years, and Project Leader with PAREXEL-APEX China for one and half years.

CHEN Zhi joined Slate Run Pharmaceuticals as Senior Director, International Business Development. He had previously been Director/Associate Director, Business Development with Cardinal Health Specialty Solutions for more than seven years.

Scarsin Corporation promoted ***Neil Liu*** to the position of Life Science Practice Lead from previously Account Director. Before joining Scarsin in 2016, he had been Engagement Manager with IMS Health for five years.

DING Ding is understood to be heading to Credit Suisse to take up a senior position under Mervyn Chow and Edwin Low, co-heads of Asia Pacific Investment Banking and Capital Markets. He has been Executive Director and Head of Healthcare for Greater China with Nomura's Investment Banking Division in Asia ex-Japan.

David Shen has been promoted to the position of SVP, Global Client Unit – Asia Pacific with McCann Healthcare from his prior position of President, McCann Health Greater China. Before rejoining McCann in 2012, he had been CEO of China Health Media for less than a year. Before that he had worked with McCann Healthcare for 12 years, most recently as Managing Director and Associate General Manager in China.

PJ Chen joined United Neuroscience Taiwan as VP of global clinical development and President. He had previously been Executive Director, Area Head, North Asia Clinical Management with PPD for two years; Executive Director, Head of Project Management and Commercial Operation with WuXiPRA for half

a year; Portfolio Project Lead, Respiratory & GI, Global Medicines Development and Group Manager, Study Management & Operations Leadership with AstraZeneca for more than two years; and Project Leader with PAREXEL China for nearly three years.

Dr. Jason Yang joined CStone Pharmaceuticals as Chief Medical Officer. He had previously been Senior Vice President and Head of Clinical Development with BeiGene for two and half years, Medical Director, Oncology with Covance for three years, Senior Principal Scientist with Pfizer for seven years, and Research Scientist with Tularik/Amgen for six years.

Dr. Wenkai Vincent Xiang joined 6 Dimensions Capital (formed after merger of Frontline BioVentures and Wuxi Healthcare Ventures) as Partner. He is also an Advisor with The Stanford SPARK Translational Research Program and Co-Founders of Aeon Pharmaceuticals and LDX Prognostics. He had previously been Managing Director, Head of International Investments and Business Development of Humanwell Healthcare Group for three and half years, Managing Director China with Burrill& Company for more than a year, and VP, Portfolio Manager and Analyst with Franklin Templeton Group for seven and half years.

Tom Wu rejoined ChinaBio Group as Vice President, Corporate Development. He had previously been Senior Director of Marketing and Communication with Centrillion Biosciences, Inc. for more than two years; Vice President, Corporate Development with ChinaBio Group for over seven years; Marketing Manager with Red Gate International Inc. for one year and Marketing Manager with Aust-China Business Connection for one year.

WANG Minghui, Chairman of Yunnan Baiyao Group, is appointed General Manager of Yunnan Baiyao Holding.

Kanghong Pharma appointed ***CHEN Su*** to the position of Vice President.

ZHENG Yuling is appointed Executive Director of China Biological Products Inc.

ZHAO Jing is appointed Vice Chairman of Buchang Pharma.

Jointown Pharma named ***LIU Yichang*** President of Business Operations and ***WANG Qibing*** Deputy General Manager.

Zhejiang Yatai Pharma announced the election of ***CHEN Yaogen*** as Chairman and General Manager and appointment of ***HE Zhen*** as CFO.

Shenzhen Hepalink Pharma elected ***LI Li*** as Chairman of BOD and appointed ***SHAN Yu*** as General Manager.

WANG Shunlong retired from office as executive director of CSPC Pharmaceutical Group Ltd.

Other News

Upcoming Events

Event: Risk Management in Clinical Practice: Tools and Techniques
Dates: July 31 – August 1, 2017
Venue: Grand Copthorne Waterfront Hotel, Singapore
Weblink: http://openforum.com.sg/event/risk-management-in-clinical-practice-tools-and-techniques/
Contact: Katie
Tel: +65 6635 8835 ***Email***: dm1@openforum.sg

Event: International Pharma Regulatory Summit
Dates: July 27 – 28, 2017
Venue: TBD, Singapore
Weblink: www.wplgroup.com/aci/event/pharma-regulatory-asia
Contact: Priyesh Waghmare
Tel: +91 (0) 20 6527 2803 ***Email***: pwaghmare@acieu.net

Event1: ISPE Conference and Exhibition 2017
Dates: August 23 – 26, 2017
Venue: Suntec Singapore Convention & Exhibition Centre, Singapore
Weblink: www.ispesingapore.org

Event2: 4th Annual PharmaCon Asia
Dates: September 19 – 22, 2017
Venue: TBD, Singapore
Weblink: www.pharmaconasia.com

Event3: Biopharma Development & Production Asia Pacific 2017
Dates: November 6 – 9, 2017
Venue: Hilton, Singapore
Weblink: www.biopharmaproduction-asia.com
Tel: +65 6508 2401 ***Email***: register@ibcasia.com.sg

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This percentage is the highest among oncology and rheumatology physicians at 78% and 89% respectively. By comparison, neurology and cardiology doctors spent less than 50% of their internet medical information searches on specific drug information. Besides, advertising links are found to be rather ineffective, attracting only 6% of physicians who conduct medical information searches. 59.3% of their searches were recommended by medical representatives.

32.8% and 21.9% of physicians who conduct internet medical searches obtain information from websites of pharmaceutical companies and their products. But less than half of physicians found these websites very useful but most of them (above 90%) view them somewhat useful.

98.5% of physicians find online medical journals and mobile phone APPs somewhat or very useful. 57.6% of physicians rank online medical journals as very useful, the highest among all channels.

Among physicians who focus their internet medical information searches on specific drug products, 56% of them say their prescription frequency of given drugs will increase. 72% of high prescribing frequency doctors are more likely to increase their prescription after such information searches.

While physicians are found to favor mobile phone APPs, such tools are unlikely to change the prescription behaviors of doctors with 76% of physicians say they will not be affected and only 24.5% say they will increase or begin prescriptions.

58% of physicians find online physician communities very informative and 74% of them will increase prescription frequency.

Feature Articles

SMEI Release Data Set on Chinese Drug Terminal Market 2010-2016

The following data set on the Chinese drug terminal market was released by the Southern Medicine Economic Institute (SMEI) under the CFDA through its information portal MENET.

Chinese Drug Terminal Markets 2010-2016

Year	Public Hospitals (1st Terminal)			Retail Pharmacies (2nd Terminal)			Public Primary Healthcare Facilities (3rd Terminal)			Total		
	Sales Value (CNY bln)	+/- (%)	Share (%)	Sales Value (CNY bln)	+/- (%)	Share (%)	Sales Value (CNY bln)	+/- (%)	Share (%)	Sales Value (CNY bln)	+/- (%)	Share (%)
2010	457.0	+22.90	67.7	173.9	+16.90	25.8	44.1	+34.0	6.5	675.0	+21.90	100.0
2011	556.2	+21.71	68.7	200.0	+15.01	24.7	53.5	+21.32	6.6	809.7	+19.96	100.0
2012	658.4	+18.37	68.9	226.8	+13.40	23.7	70.3	+31.40	7.4	955.5	+18.01	100.0
2013	755.8	+14.79	68.8	255.8	+12.79	23.3	86.8	+23.47	7.9	1,098.4	+14.96	100.0
2014	859.6	+13.73	69.0	282.8	+10.56	22.7	103.3	+19.01	8.3	1,245.7	+13.41	100.0
2015	951.7	+10.71	68.8	311.1	+10.01	22.5	120.1	+16.26	8.7	1,382.9	+11.01	100.0
2016	1,024.0	+7.60	68.4	337.5	+8.49	22.5	135.9	+13.16	9.1	1,497.4	+8.28	100.0

Source: SMEI

Medical Institution Drug Consumption by Facility Type 2010-2016

Year	Urban Public Hospitals		County Level Public Hospitals		Community Health Service Centers (CHCs)		Township Health Centers (THCs)	
	Sales Value (CNY bln)	+/- (%)	Sales Value (CNY bln)	+/- (%)	Sales Value (CNY bln)	+/- (%)	Sales Value (CNY bln)	+/- (%)
2010	371.4	+22.41	85.6	+24.96	16.8	+31.25	27.3	+35.82
2011	439.8	+18.42	116.4	+35.98	18.4	+9.52	35.1	+28.57
2012	518.5	+17.89	139.9	+20.19	23.9	+29.89	46.4	+32.19
2013	589.3	+13.65	166.5	+19.01	31.0	+29.71	55.8	+20.26
2014	663.4	+12.57	196.2	+17.84	37.3	+20.32	66.0	+18.28
2015	723.3	+9.03	228.4	+16.41	43.8	+17.43	76.3	+15.61
2016	767.5	+6.11	256.5	+12.30	50.1	+14.38	85.9	+12.58

Source: SMEI

Retail Drug Consumption by Facility Type 2010-2016

Year	Total Retail		Retail Pharmacies		Online Pharmacies	
	Sales Value (CNY bln)	+/- (%)	Sales Value (CNY bln)	+/- (%)	Sales Value (CNY bln)	+/- (%)
2010	173.9	+16.9	173.9	+16.9	0.02	–
2011	200.0	+15.01	199.9	+14.95	0.12	+300.00
2012	226.8	+13.39	226.3	+13.21	0.5	+316.67
2013	255.8	+12.79	254.5	+12.46	1.3	+160.00
2014	282.8	+10.56	280.7	+10.29	2.1	+61.54
2015	311.1	+10.01	307.9	+9.69	3.2	+52.38
2016	337.5	+8.49	332.7	+8.05	4.8	+50.00

Source: SMEI

Review of Chinese Pharmaceutical Marketing and Digital Communications in 2016

The total marketing and sales expenditure of the Chinese pharmaceutical industry rose 8.1% year on year in 2016 to US$17.8 billion, according to QuintilesIMS.

Such expenditures were used primarily (87.7%) to fund physician visits by medical representatives or medical liaison officers of pharmaceutical companies, followed by conference expenditures (11.1%).

Major Pharma Marketing Channels in China 2016

Channels	Marketing Expense (CNY mln)	Share (%)	+/- (%)
Physician visits	15,690	87.90	+8.4
Conferences	1,986	11.13	+6.8
Samples	44	0.25	+5.5
Product Presentations	5	0.03	+12.6
Advertising	58	0.32	-9.6
Clinical Trials	44	0.25	-21.7
Others	23	0.13	+18.6
Total	17,849	100.00	+8.1

Source: QuintilesIMS

Among total physician visits, 14.3% and 8.7% are done through phone calls and internet/emails respectively. Among all conference activities, nearly 17% are facilitated online.

QuintilesIMS found that doctors spend 57.4% of their internet medical information searches on specific drug information.

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