Cross-Border Life Sciences Collaborations in China (Part 1)

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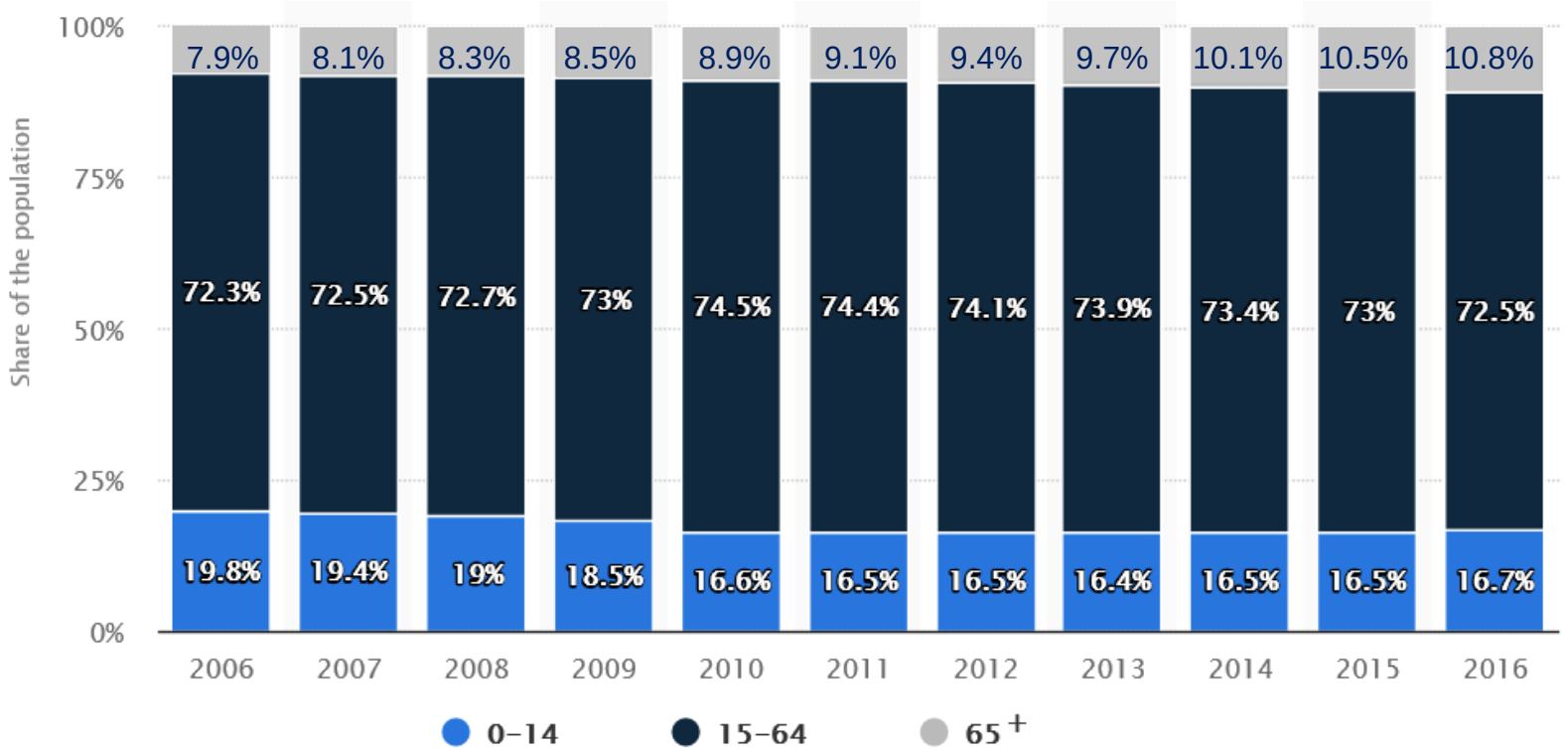
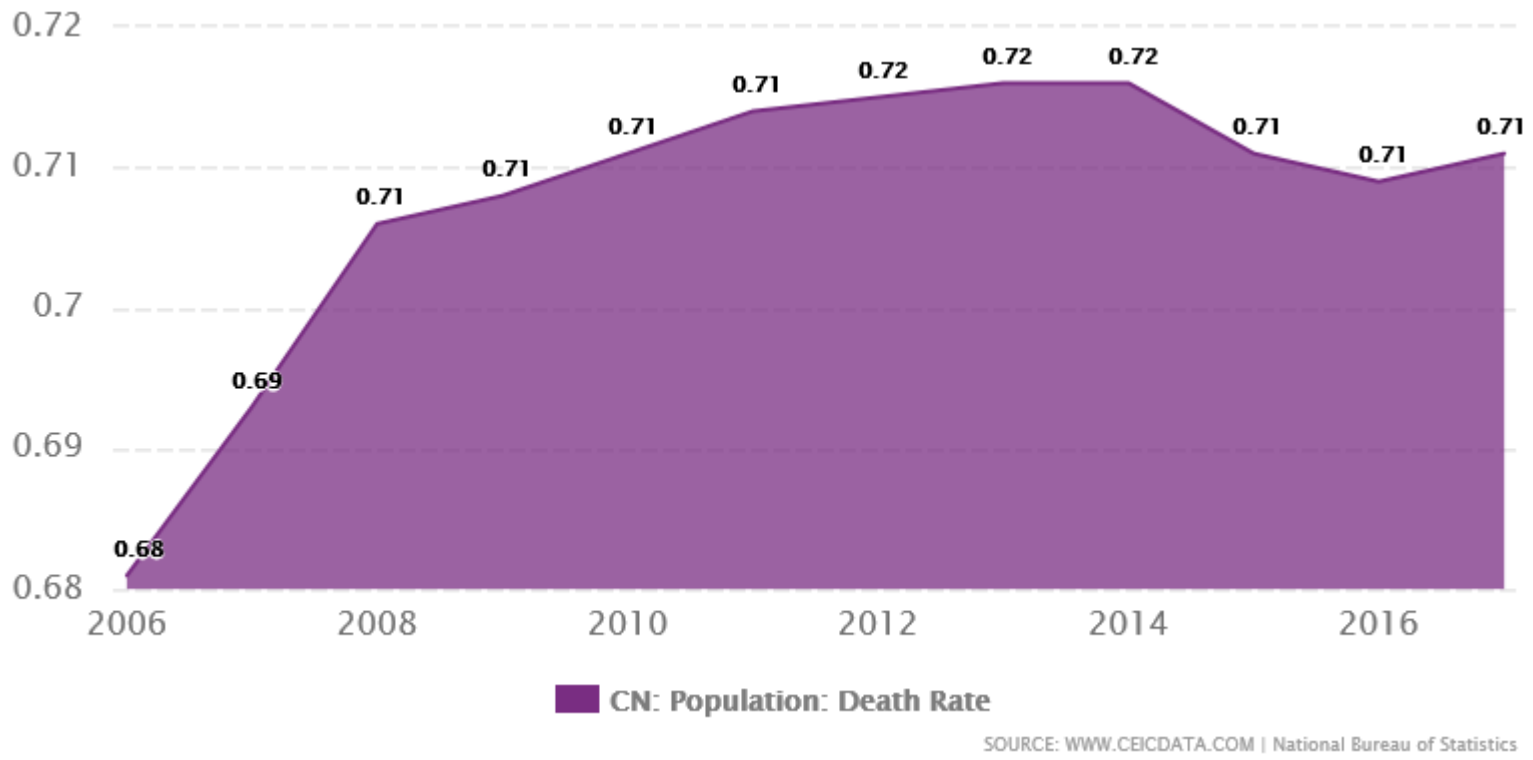
Longitudinal Demographic Profile in China (2006 – 2016)



Source: Statista 2018 (https://www.statista.com/statistics/270163/age-distribution-in-china/)

The 65+ age cohort rose by one-third to 10.6% between 2006 and 2016 and is projected to rise to 15% in years to come in response to improved health, legacy birth control measures, and lifestyle changes, increasing the need for healthcare to address medical needs of the elderly.

Longitudinal Mortality Profile in China



The crude mortality rate has gradually risen from 0.68 to 0.71 per 1000 persons between 2006 and 2017.

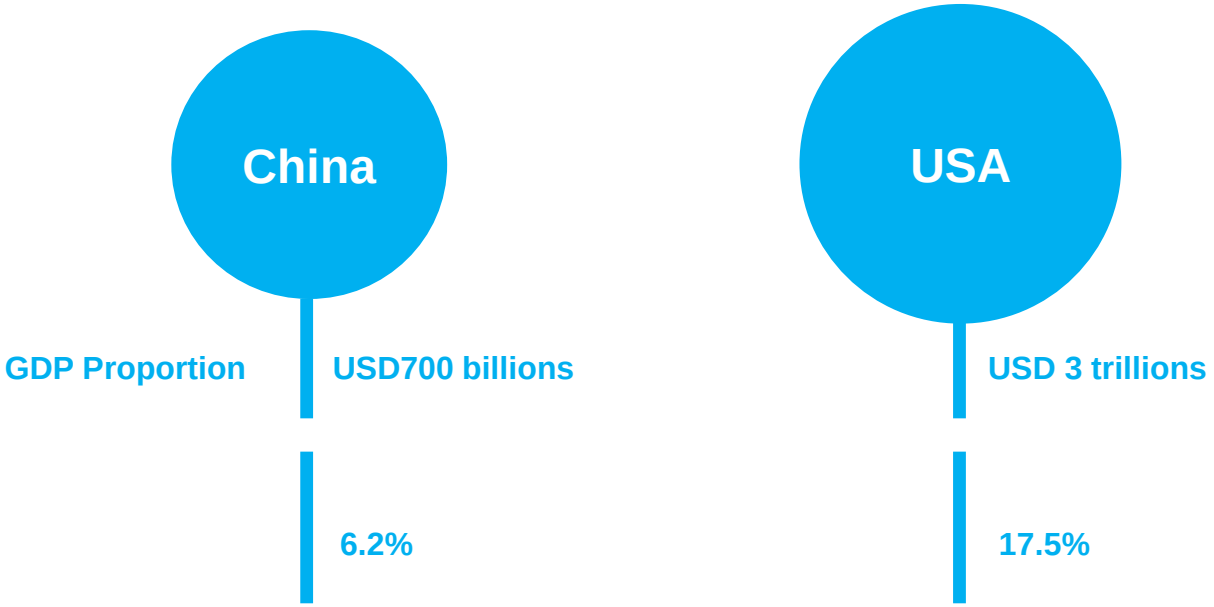
Longitudinal Cancer Incidence and Mortality Profile in China

- About 3,804,000 new cancer cases (2,114,000 male cases; 1,690,000 female cases) were diagnosed in 2014
- The crude incidence rate was 278.07/100,000 (301.67/10,000 in males; 253.29/100,000 in females) in 2014
- The crude mortality rate was 167.89/100,000 (207.24/100,000 in males; 26.54/100,000 in females)

Source: Vol 30, No 1 (February 2018): Chinese Journal of Cancer Research (http://www.cjcrcn.org/issue/418.html)

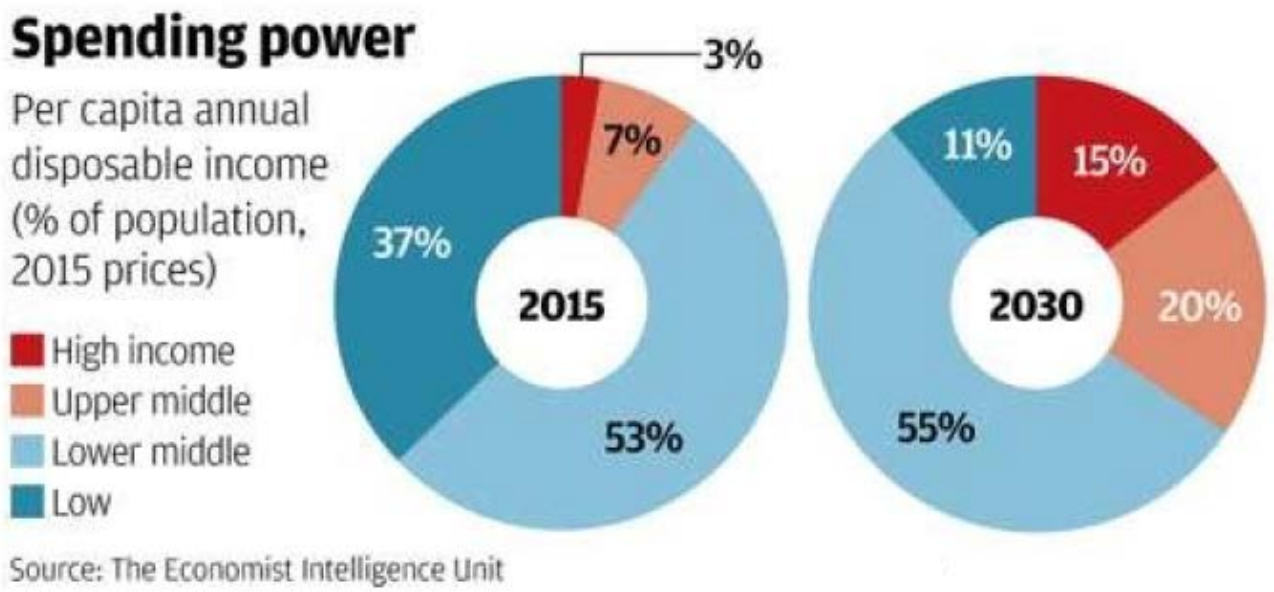
2016 Healthcare Expenses

US v. China

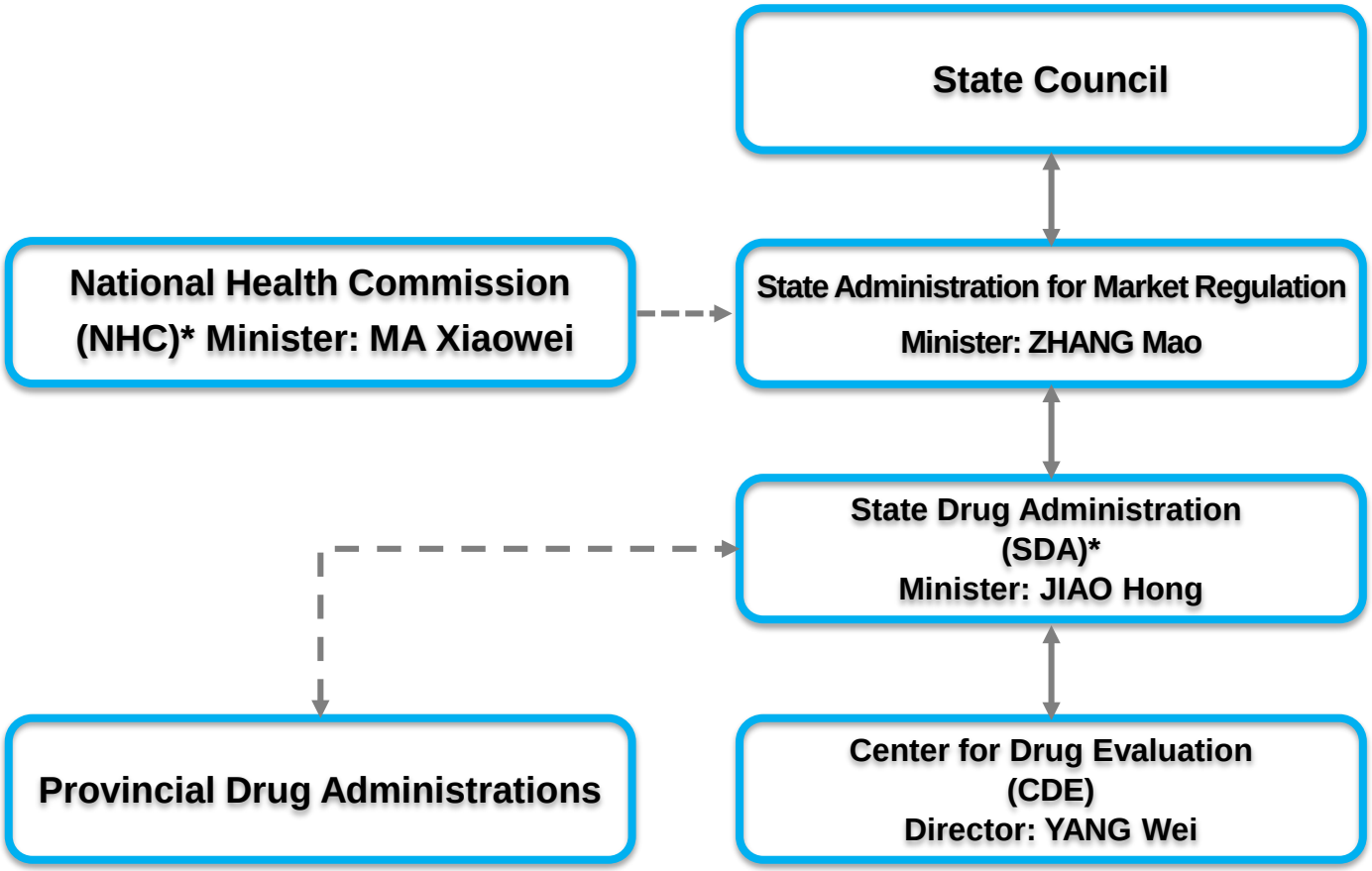


Source: http://www.rdpac.org/UpLoad/UpLoadFileDir/201802/03/201802032252341998.pdf

Growth of the Middle Class in China



Reorganized Organization Structure



*NHC and SDA – Previously known respectively as the National Health and Family Planning Commission and China Food and Drug Administration ("CFDA") before the State Council's institutional reform in March 2018.

Major Laws and Regulations

1. Drug Administration Law (药品管理法, amended April 24, 2015)

2. Regulations for Implementation of Drug Administration Law (药品管理法实施条例, amended February 6, 2016)

3. Measures on the Administration of Drug Registration (药品注册管理办法, amended October 1, 2007)

Key Legislative and Regulatory Developments 2015 – 2018

China has been engaged in comprehensive regulatory reform of drugs and medical devices policy since 2015. Regulatory reforms have been introduced to encourage innovation while reducing costs and regulatory burdens on life sciences companies

1. **Opinions on the Reform of Review and Approval System for Drugs and Medical Devices (关于改革药品医疗器械审评审批制度的意见, State Council August 2015, http://www.sda.gov.cn/WS01/CL0056/126821.html)**

   - initiated the comprehensive and fundamental regulatory reform of drugs and medical devices policy, particularly with respect to registration

2. **Opinions on Resolving the Backlog of Drug Registration Applications and Implementing the Priority Review and Approval Procedure (总局关于解决药品注册申请积压实行优先审评审批的意见, former CFDA February 2016, http://www.sda.gov.cn/WS01/CL0844/145260.html)**

   - announced a new priority review procedure to ease the registration backlog affecting drugs and medical devices
   - encourage innovation in new domestic and international drugs to meet unmet medical needs
   - encourage overseas manufacturers to plan and perform clinical developments in China in parallel with the US, EU and other jurisdictions

Key Legislative and Regulatory Developments 2015 – 2018 (cont'd)

3. Work Plan for Reforming the Chemical Drugs Registration Classification System (former CFDA March 4, 2016, the "New Classification") (化学药品注册分类改革工作方案), an important component of the general reform of the drug and device approval system initiated in the 2015 State Council Opinions:

- redefines "new drugs" and "generics", changing the current chemical drug classification system
- "new drug" eligibility is limited to those drugs that have not been marketed anywhere in the world, as opposed to "not marketed in China" in the previous definition
- This change may incentivize multinational companies wishing to bring innovative drugs to China to start their product development in China earlier than before in order to realize marketing advantages

Key Legislative and Regulatory Developments 2015 – 2018 (cont'd)

Party General Secretary Xi Jinping at the August 2016 National Health Conference called for:

- Promoting healthy lifestyle
- Strengthened health delivery services
- Improved health protection
- Healthier environment
- Development of research-based health industries
- Expanding healthcare delivery capacity at the grassroots level
- Mobilizing societal as well as governmental investment
- Curbing excessive drug prescription and lowering medical costs
- Lowering barriers to foreign investment and expert foreign personnel

Key Legislative and Regulatory Developments 2015 – 2018 (cont'd)

4. Four draft reform policies (former CFDA May 2017):

- 关于鼓励药品医疗器械创新加快新药医疗器械上市审评审批的相关政策 (http://www.sda.gov.cn/WS01/CL0087/172567.html) Circular 52 - to expedite the review and approval of new drug registration applications
- 关于鼓励药品医疗器械创新改革临床试验管理的相关政策 (http://www.sda.gov.cn/WS01/CL0778/172568.html) Circular 53 - to deregulate the conduct of clinical trials to encourage innovation
- 关于鼓励药品医疗器械创新实施药品医疗器械全生命周期管理的相关政策 (http://www.sda.gov.cn/WS01/CL0778/172569.html) Circular 54 – to enhance post-market supervision throughout a product's entire life cycle
- 关于鼓励药品医疗器械创新保护创新者权益的相关政策 (http://www.sda.gov.cn/WS01/CL0087/172606.html) Circular 55 – to protect the rights of drug innovators

Key Legislative and Regulatory Developments 2015 – 2018 (cont'd)

5. **Opinions on Deepening the Reform of the Review and Approval System and Inspiring Innovation of Drugs and Medical Devices (General Office of the Communist Party Central Committee and General Office of the State Council, October 8, 2017, "Innovation Opinions") (关于深化审评审批制度改革鼓励药品医疗器械创新的意见, http://www.gov.cn/xinwen/2017-10/08/content_5230105.htm), which adopted CFDA's four draft reform policies and covered all important regulatory matters relating to drugs and medical devices:**

   - encouraging innovation of drugs and medical devices
   - accelerating drug registration approval process
   - improving and simplifying clinical trial management
   - strengthening intellectual property protection for innovators
   - promoting production of generic drugs
   - establishing the Marketing Authorization Holder ("MAH") system

6. **Decisions to Adjust Relevant Items in the Registration of Imported Drugs (former CFDA October 10, 2017, "Imported Drug Decision") (国家食品药品监督管理总局关于调整进口药品注册管理有关事项的决定, http://www.sda.gov.cn/WS01/CL0053/178363.html)**

   - Implementing changes to facilitate the review and approval process for imported drugs, particularly for innovative imported drugs

Key Legislative and Regulatory Developments 2015 – 2018 (cont'd)

7. **Draft Amendments to the Drug Administration Law (former CFDA October 23, 2017) (中华人民共和国药品管理法修正案 (草案征求意见稿), http://www.sda.gov.cn/WS01/CL0050/178902.html)**

   - most of the proposed amendments focus on full implementation of the marketing authorization regime, an important item in the Innovation Opinions

8. **Draft Amendments to the Measures on the Administration of Drug Registration (药品注册管理办法 (修订稿), http://www.sda.gov.cn/WS01/CL0778/178900.html)**

   - would amend the regulatory review and approval process relating to clinical trials, marketing authorization and approval

9. **Notice Concerning Publication of the China Marketed Drugs Catalogue (former CFDA December 28, 2017, "Drug Catalogue Notice") (总局关于发布《中国上市药品目录集》的公告 (2017年第172号), http://www.sda.gov.cn/WS01/CL1757/220786.html)**

   - similar to the "Orange Book" in the U.S.
   - formulated to encourage drug R&D and innovation in China

Key Legislative and Regulatory Developments 2015 – 2018 (cont'd)

10. State Council Opinions on Promoting Internet Plus Medical Treatment and Healthcare (关于促进"互联网+医疗健康"发展的意见, April 25, 2018)

- Medical institutions are encouraged to use Internet to expand the space and content of healthcare service;
  - It allows the development of online hospitals based on physical medical institutions
- Healthcare institutions also are encouraged to cooperate with internet companies to enhance the integration of regional healthcare information
- Construction and utilization of the information platform will be accelerated so that patients can sign up online with a family doctor
  - Online evaluation and reward mechanism will be explored to improve the services of family doctors
  - Ping An Healthcare and Technology Co Ltd. which operates China's largest online healthcare platform (Ping An Good Doctor Online Platform) has raised $1.12 billion in its IPO on Hong Kong Exchange at the end of April
- Interconnection of prescription information of healthcare institutions and medicine retail information will be further explored
  - This may help promote the development of online medicine sales and the logistics of medical supplies
- The integration of medical insurance information will be accelerated, and online payments will be gradually expanded to provide more convenient service for insured people

Priority Review Procedure for Innovative Drugs

- Pursuant to the Opinions on Resolving the Backlog of Drug Registration Applications and Implementing the Priority Review and Approval Procedure (总局关于解决药品注册申请积压实行优先审评审批的意见, http://www.sda.gov.cn/WS01/CL0844/145260.html), a new priority review procedure has been promulgated to:

  1. encourage innovation in domestic and international drugs to meet unmet medical needs
  2. encourage overseas manufacturers to plan and perform clinical developments in China in parallel with the US, EU and other jurisdictions

- Priority review status may be requested based on the following criteria:

  1. Registration applications for drugs with apparent clinical value including:
     - innovative drugs not marketed anywhere else in the world
     - innovative drugs for which manufacturing is transferred to China
     - drugs with advanced formulation technologies, innovative treatment methods and apparent treatment advantages
  2. Parallel clinical trial applications for new drugs approved for clinical trials in the U.S. or the EU
  3. Parallel registration applications for drugs with the same production line and which have passed on-site inspections in the U.S. or the EU
  4. Registration applications for drugs to prevent or treat HIV, tuberculosis, viral hepatitis, rare diseases, malignant tumors, pediatric drugs and drugs for diseases of the elderly

Conditional/Accelerated Marketing Approval

Pursuant to the Innovation Opinions:

1. Drugs that offer new solutions for treating life-threatening diseases or address critical unmet medical needs may be eligible for conditional approval before completion of Phase III confirmatory trials, so long as early and mid-stage study data indicates their efficacy and predicts their clinical value

2. Companies receiving conditional approvals must develop a risk management plan and initiate confirmatory post-approval study as per the requirements in the conditional approvals. Innovative drugs sponsored by the National Science and Technology Major Project may also be eligible for priority review and approval

3. Similar approval will be given to treatments for rare diseases if such therapy has already been approved elsewhere, under the condition that post-approval commitment studies are required

Questions

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***Join us on May 30 for Part 2.**