ACCESTRA
CONSULTING COMPANY

Your Long Term Strategic Partner for Regulatory Compliance in China

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Access Extra

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About Our Company

- Accestra Consulting Company is a professional regulatory consulting firm in Pharmaceutical, Chemical, Food, Feed and Cosmetic industry providing Chinese market access advisory for international enterprises.
- We work with 70% global companies based on multi-language competence, outstanding technical background and extensive experiences of our experts.
- Headquartered in Hangzhou China and 2 offices located in Amsterdam and Shanghai to provide efficient response to our global clients.
- Our core business covers global product registration, regulatory compliance advisory, training, factory audit, and testing agency service. We have in-house database, with capability to customize IT tools for clients to check formula according to regulation requirements.

Why Work with Us

Expert team

10 Years of Experience

Our team has over 10 years of experience in worldwide registration of industrial Pharmaceutical Chemicals, Food, and Cosmetics in China.

Abundant Local Resources

Accestra has real-time channels for regulation updates, close connections with local competent authorities, contract laboratories and local experts to complete and extend our own knowledge network.

Effective & Customized Solutions

We catch the needs of our clients quickly, create more values & reduce risks of failure for our customers according to our past successful experience.

Specialize in Serving International Clients

Extensive experience of serving international customers enables our team to be excellent at cross-cultural communication & project management.

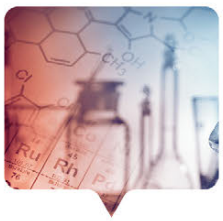
Our team

ACCESTRA is built up of experienced technical experts with multi-language competence and strong technical academic background in areas including pharmacy, chemistry, toxicology, food science, project management.
Our senior management team has 20+ years' experience in regulatory and market access, import/export registration, and established close relationship with governments and associations.

Our Service

Pharmaceutical Regulatory Advisory

- Imported drug application for both innovative drug and generic drug
- IND application/Re-registration/Supplement Application
- Dossier translation
- Generic Drug Quality Consistency Evaluation support
- Production site GMP auditing support before marketing authorization
- Pharmacovigilance, i.e., AE report, post-marketing surveillance, training
- Market access feasibility analysis report
- China regulatory compliance guideline



Chemical Regulatory Advisory

- China New Chemical Substance Notification(China NCSN)
- Taiwan TCSCA Registration
- Korea REACH Registration
- Japan CSCL Registration
- Globally Harmonized System of Classification and Labeling of Chemical(GHS)in China

Food Regulatory Advisory

- Food Importation Compliance Solution
- Infant Formula Registration and Compliance
- Health Food/Dietary Supplement Registration
- New Food Raw Material Registration
- New Food Additives Registration
- Registration of Food for Special Medical Purpose

Cosmetic Regulatory Advisory

- Ingredient check
- Imported “special-use cosmetic” Registration
- Imported “non-special-use cosmetic” Filing

Feed Regulatory Advisory

- Ingredient check and product classification
- GACC and manufacturer registration
- Imported registration license
- New feed and feed additive registration

Our Partners and Clients

EUSME Centre · UK Trade & Investment · USDA · Australian Government, Australian Trade and Investment Commission · New Zealand Trade & Enterprise · Dairy Australia · JETRO Japan External Trade Organization

teva · douglas · The Medicines Company · Takeda · ZMC · IBL · Sanitarium health & wellbeing

Total · Idemitsu · Costco Wholesale · Migros · Reckitt Benckiser · a2 Milk Company · Hero

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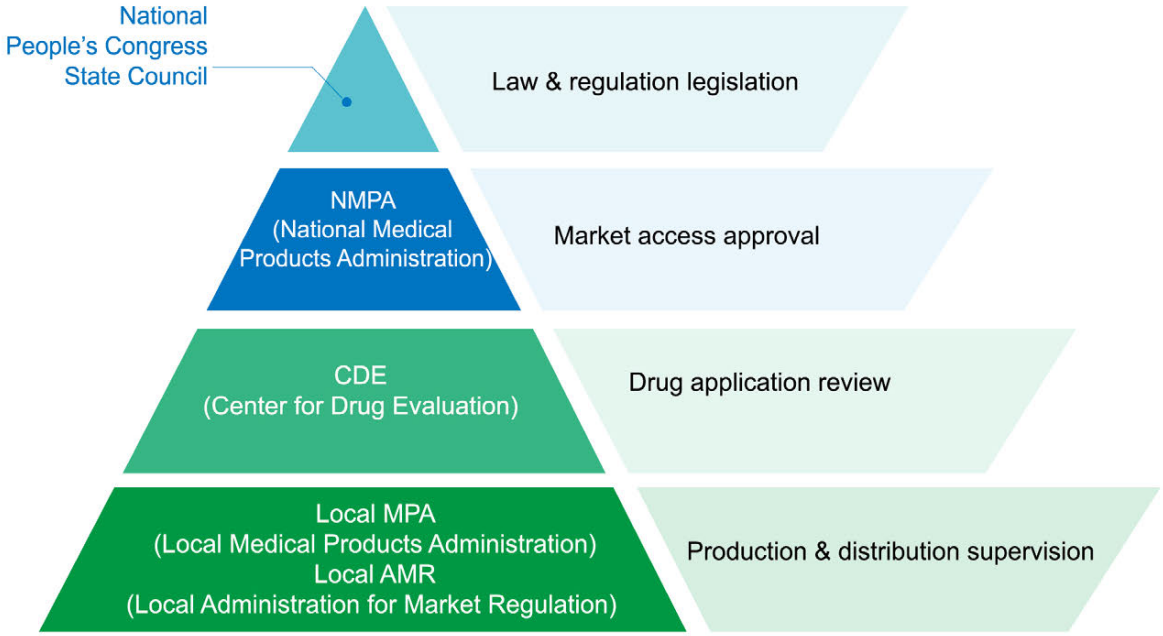
CHINA PHARMACEUTICAL REGULATORY ADVISORY

As the second-largest market of pharmaceuticals in the world, China shows strong growth trend in the next ten years since the government has determined the Healthy China 2030 policy as the core national policy. There's never been a better time for multinational pharmaceutical companies to invest drug business in China. Accestra has been continuously focusing on the ever-changing pharmaceutical environment in China, and assisting clients to successfully move through the regulatory process with thorough regulation knowledge and solid registration experience.

SUPERVISION FRAMEWORK

China has implemented comprehensive pharmaceutical regulatory reform since 2015 and national institutional reform from 2018. The current pharmaceutical supervision organization in China consist of NPC, State council, NMPA, CDE, local MPA and AMR.

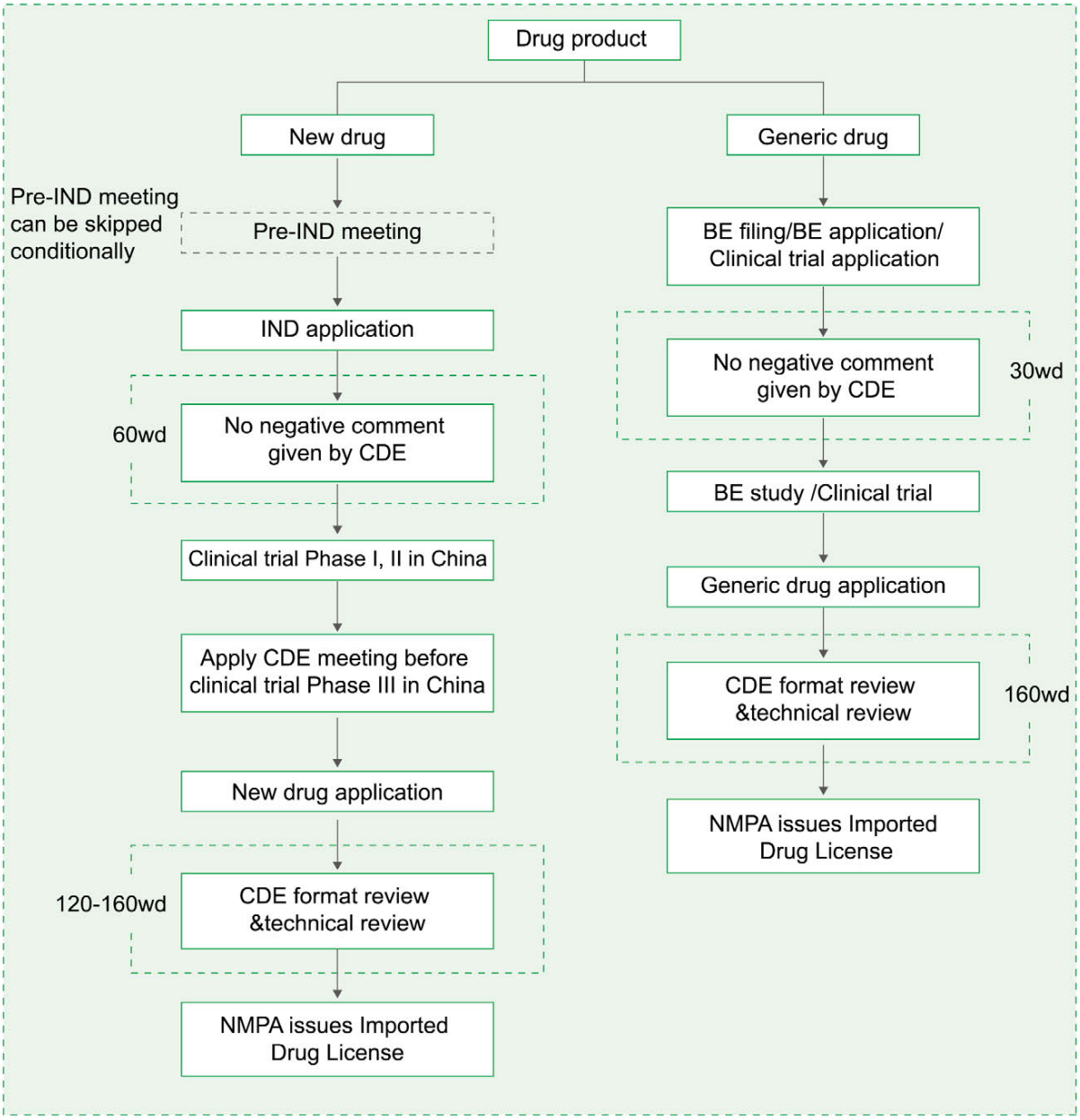


NEW CHEMICAL DRUG CLASSIFICATION

- **Class 1.**
  Innovative new drugs not marketed anywhere in the world
- **Class 2.**
  Improved new drugs not marketed anywhere in the world, e.g., new dosage form, new indication
- **Class 3.**
  Generic drugs, of which the originator drugs have been marketed in other countries, but not yet in China
- **Class 4.**
  Generic drugs, of which the originator drugs have been already marketed in China
- **Class 5.**
  Drugs that have been marketed in other countries, but not yet in China

* the classification of biological products is in revision now

DRUG REGISTRATION PROCEDURE



DRUGS APPLICABLE OF PRIORITY REVIEW IN CHINA

- Innovative drugs
- Drugs demonstrating significant clinical effectiveness from advanced preparation techniques or innovative therapeutic methods
- Drugs for HIV, Tuberculosis, Viral hepatitis, Rare disease, Malignant tumor, Pediatric medicine and Elderly disease
- Fill unmet medical need

SERVICE WE PROVIDE

Pre-marketing Activities

- Pre-IND meeting application;
- IND/CTA/BE application;
- CRO management;
- Clinical trials auditing and quality assurance;
- Innovative drug application/NDA;
- Generic drug application/ANDA;
- Priority reviewing procedure application;
- Dossier translation and preparation;
- Application submission, follow-up and coordination with CDE-NMPA;
- Generic Drug Quality Consistency Evaluation support;
- Production site GMP auditing support before marketing authorization.

Regulatory Strategy

- China regulatory compliance guideline;
- Market access feasibility analysis report;
- Product registration strategy.

Post-marketing Activities

- Dossier lifecycle management;
- Supplementary submission;
- License renewal;
- Pharmacovigilance, i.e., AE report, post-marketing surveillance, training;
- Efficacy and safety re-evaluation;
- Communication with Health Commission in China.

OUR EXPERIENCE

Dosage Forms

- Tablets, Capsules, Soft capsules, Dry suspension agents, Injections, Patches, Inhalations, etc.

Indications

- Antihypertension, Antilipemic, Diabetes, Arthritis, Antidepressant, Oncology, Respiratory, Anti-infection, Analgesics, Orphan drugs.

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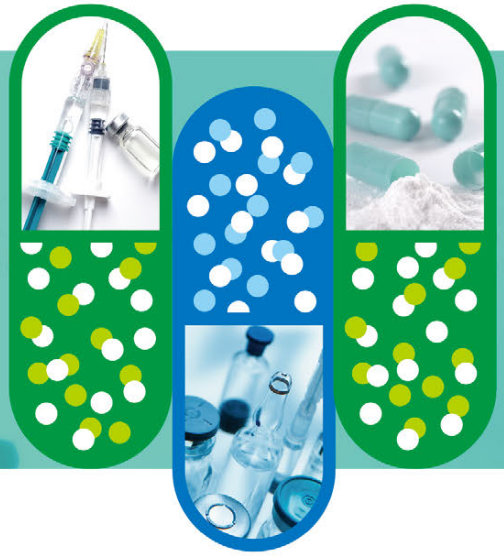


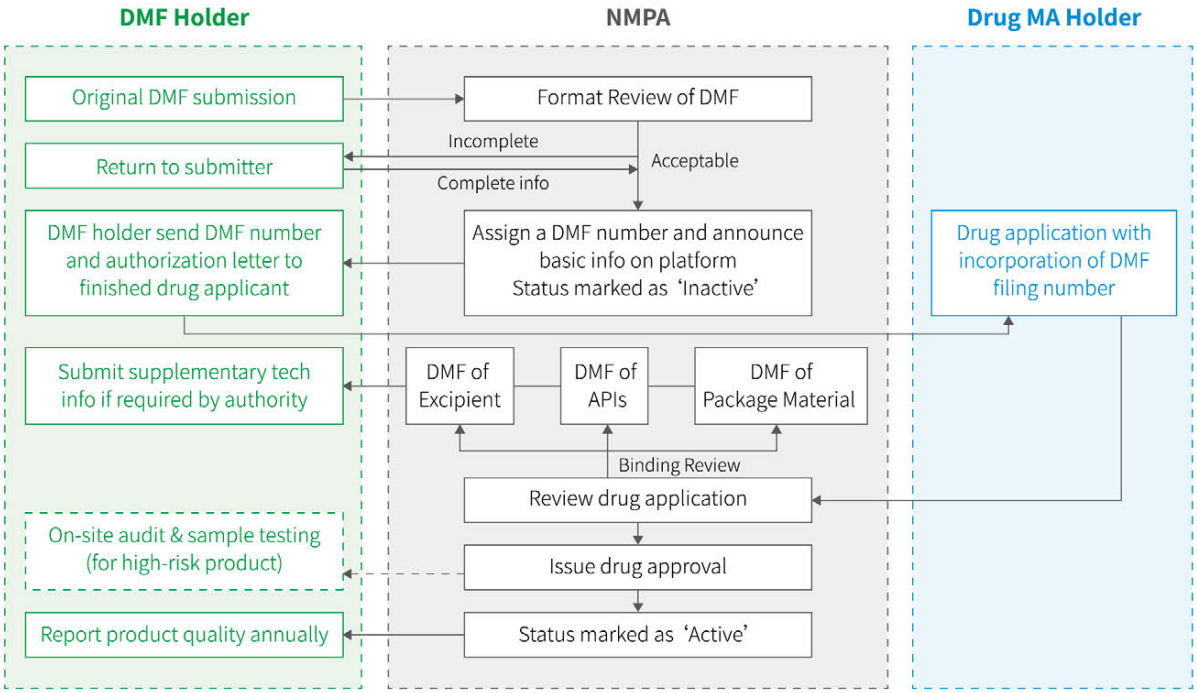
CHINA DMF ––PHARMACEUTICAL API, EXCIPIENT AND PACKAGE MATERIAL FILING

The pre-market approval system of Active Pharmaceutical Ingredients (APIs), Pharmaceutical Excipients and Pharmaceutical Packaging Materials which has lasted for more than ten years in China was ended and switched to the new filing system since Jan 1st, 2018. The current management way became much more similar to the DMF (Drug Master Files) submission now, which means a faster process and a lower cost.

TYPES OF DMF/FILING WORK

- Type I. Drug substance/APIs;
- Type II. Excipient (Colorant, Flavor, Essence and pH Regulator are also included except the exemption category published by China National Medical Products Administration, NMPA);
- Type III. Packaging Material.

FILING SUBMISSION AND REVIEWING PROCEDURE



* It' s also workable the drug applicant submit the APIs, Excipients and Packaging Materials file package together with the drug application dossier.

DMF PUBLIC INFORMATION

After the format review is finished, the basic information of APIs/Excipients/Packaging Materials will be announced on China CDE-NMPA (Center for Drug Evaluation) website, including DMF filing number, APIs/Excipients/Packaging Material name, company name, company address, packing specification, announcement date and approval status. The status 'Inactive' means such products are allowed to be used for pharmaceutical study purpose, and only after the status changing to 'Active', it's legal to use those products in the finished drugs.

DMF PROCEDURE TIME & COST

	Previous License System (Before 2018-1-1)	Current Filing System (After 2018-1-1)
Approval Type	License for APIs/Excipients /Packaging Materials	DMF filing number
Procedure Time	APIs: 3-8 years Excipients: 2-5 years Packaging Materials: 1-3 years	6-12 months
Administration Fee charged by China NMPA	Yes	APIs: 14,000-54,000 USD Excipients: Free Packaging Materials: Free

CUSTOMS CLEARANCE PROCEDURE FOR IMPORTED APIS/EXCIPIENTS/ PACKAGING MATERIAL

Importation license obtained before DMF system enforcement? (2017-11-30)

- Yes → Related Imported Drug License
- No → Active DMF No.+ search result of CDE website announcement
- No → Inactive DMF No.+ search result of CDE website announcement
- No → Related Imported Drug License

→ Local MPA → Customs clearance form → Customs

SERVICE WE PROVIDE

Pre-registration

- China regulatory compliance guideline;
- China Representative Agent service;
- APIs filing;
- Excipient filing;
- Packaging Material filing;
- Dossier translation and preparation;
- DMF submission, follow-up and coordination with CDE-NMPA.

Binding registration

- Technical review follow-up and coordination with CDE-NMPA.

Post-registration

- Production site auditing support;
- Sample testing support;
- DMF dossier lifecycle management;
- Importation license management;
- Annual report.

Accestra Consulting Company

Headquarters

Address: Room 816, Building 5, Xixi Central Plaza,
Hua Jiang Road, West Lake District,
Hangzhou, China (310012)
E-mail: info@accestra.com
Phone: +86 571 8819 3966

Accestra Netherland

Address: World Trade Center Rotterdam,
Beursplein 37, Postbus 30006, 3001DA
Rotterdam ,Netherlands

http://www.accestra.com
https://www.linkedin.com/company/35665094/admin/