China 2026: Understanding the System Behind the Market

Why China now shapes global drug development.

Stefanie Fasshauer: Business Development Director – Life Sciences

Agenda

- China’s Multi-Year Evolution
- Modern Regulatory Reality
- Market Access Model
- Success Playbook 2026

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The China System Logic

A Different Operating Model

Policy Priorities

National goals shape both regulatory and market access pathways.

Deep Connectedness

Regulation, reimbursement, and procurement are tightly linked into one ecosystem.

Managed Lifecycle

Market entry is a continuous lifecycle process, not a single launch event.

Structural Links

Global and China strategies are now fundamentally and structurally tied together.

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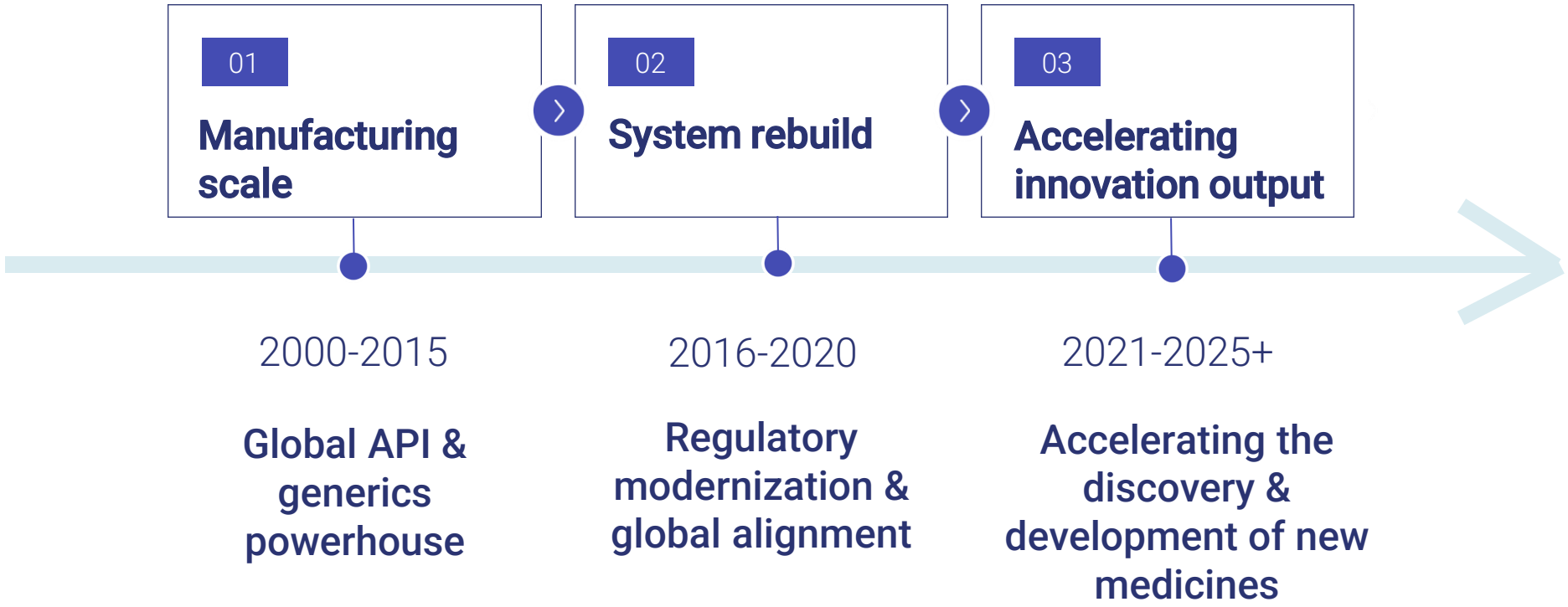
China’s 3-Step Evolution in Pharma

The Structural Ascent: 2000-2026

Sustained leadership followed a clear sequence:



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China’s Pharma Momentum (2025)

China’s role has shifted from a "global pharmacy" (API supplier) to a major hub for high-value, innovative drugs.

- Total trade (imports + exports): $201.7B (+1.18% YoY)
- Exports: $111.3B (+3.14% YoY) → main growth driver
- Imports: $90.4B (-1.14% YoY) → slight decline

Source: China customs via Bloominglobal (Jan 26, 2026).

The Demographic Engine

323 million seniors aged 60+ (23% population) are driving rising demand for innovative medicines.

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China is no longer a “late-stage” emerging market – it is a frontline innovation battleground.

Science is the entry fee.

Execution – regulation, access, and partnerships – determines the winners.

China’s Regulatory Transformation: 2015-2026

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Speed is largely driven by structural efficiency - not lower standards

Fragmented administration → Unified national lifecycle regulator
Centralized authority with end-to-end oversight

Local rules → Global regulatory harmonization
International standards embedded in Chinese law and regulation

Procedural review → Science-based decision making
Evidence-led assessment with expanded scientific capacity

Manual bureaucracy → Digital-first governance
End-to-end digital submission, review, and traceability

Passive gatekeeping → Proactive innovation governance
Priority pathways accelerating breakthrough medicines

The result:

China has evolved from a local “follower”, into a global peer regulator operating at scale, speed, and rigor.

2026: Implementing Regulations updated

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China's Regulatory System: Structure, Speed & Operating Reality 2026

Authorities & Regulatory Architecture

NMPA: National policy authority; final approval

CDE: Scientific review (clinical, CMC, non-clinical)

NIFDC: Quality standards and registration testing

CFDI: GCP / GMP inspections

Core Technical Guidelines Backbone

Clinical

- ICH E6(R3), E17 (MRCT), E8(R1)

Quality / CMC / Manufacturing

- ICH Q8–Q12, Q5A–E, Q7–Q11

Dossier Format

- ICH M4 (CTD format)

Product-Specific

- NMPA Biosimilar Guidelines (WHO/EMA aligned)
- Generic Quality Consistency Evaluation (GQCE)

2026 Shift: Decree 828

- Lifecycle + enforcement upgrade

Review Pathways & Timelines

30-day IND	Eligible Class 1 only
Standard IND	~60 days
Priority NDA	~130 working days (typical)
Standard NDA	~200 working days (typical)

Data Exclusivity Framework

Exclusivity & data protection (2026)

- Data protection: ≤6y (innovative) / ≤3y (improved)
- Reduced term: overseas-first
- Market exclusivity: Rare disease ≤7y / Pediatric ≤2y

Process Essentials & Lifecycle Control

- Language: Simplified Chinese
- Parallel testing and technical review
- Approval validity: 5 years
- Post-approval CMC changes: formal supplements required
- Traceability requirements
- E-label / electronic instructions
- PV + post-market evaluation impacts renewal

Source: 中华人民共和国药品管理法实施条例_医药管理_中国政府网

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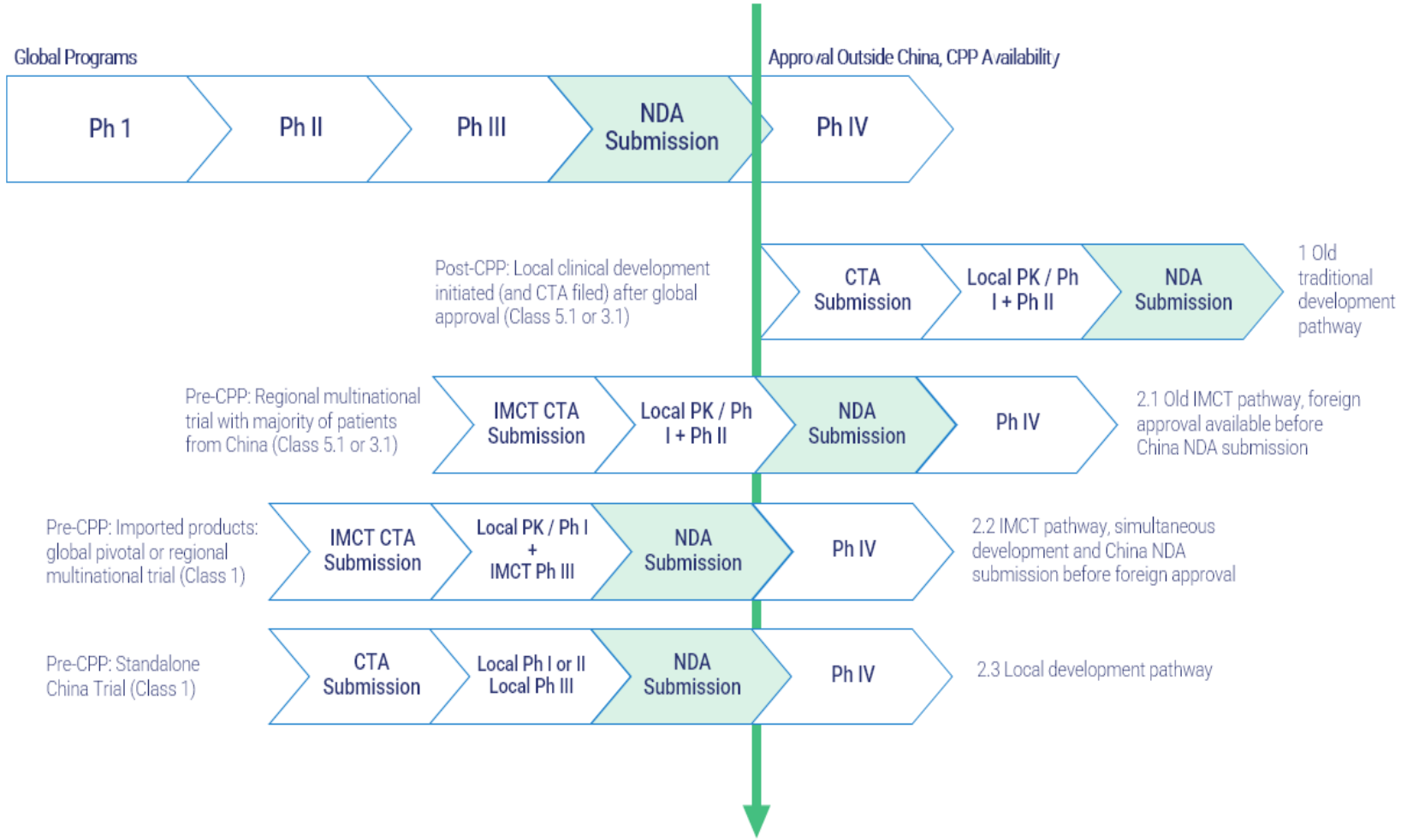
Registration Pathways



Classification

NMPA Registration Types (Chemicals + Biologics)

1) Chemical drugs

Class 1: Innovative (not marketed anywhere)

Class 2: Improved/modified new drug

Class 3: Domestic generic - overseas RLD (not marketed in China (CN))

Class 4: Domestic generic - CN RLD (marketed in CN)

Class 5: Imported drug (marketed overseas)

- 5.1: Originator / Innovative
- 5.2: Generic

2) Biologics

Class 1: Innovative biologic (not marketed anywhere)

Class 2: Improved/ modified biologic

Class 3: Marketed overseas (not yet in China)

- Class 3.3: Biosimilar

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The R&D Machine (2024)

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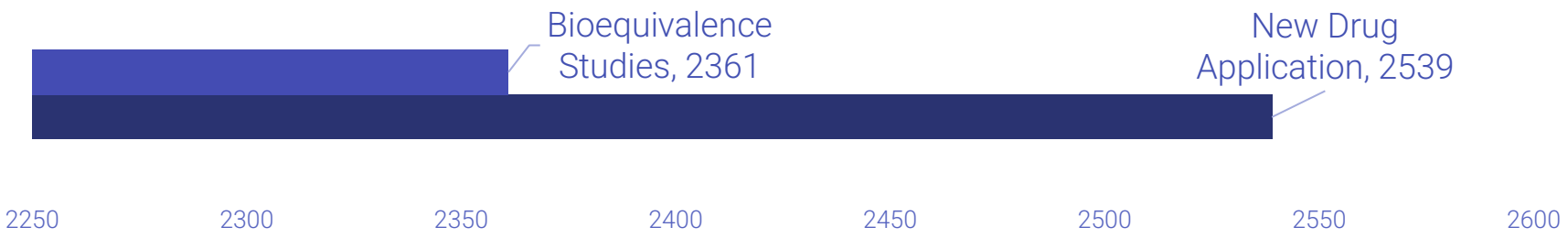
Clinical Trial Application Type

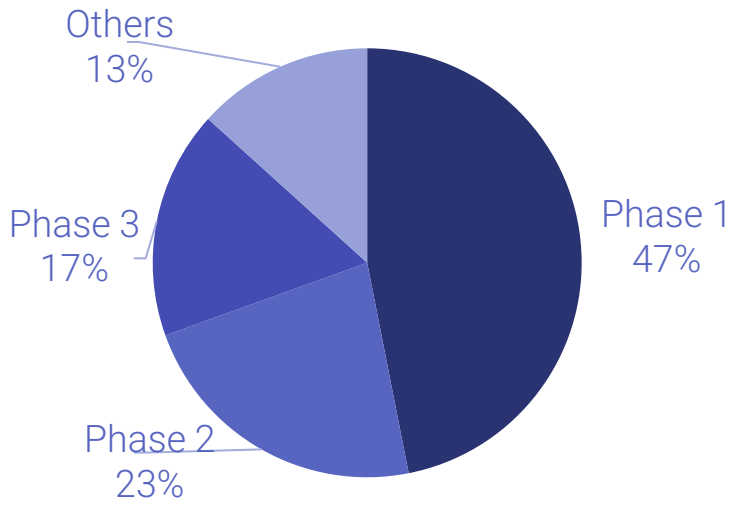


4900

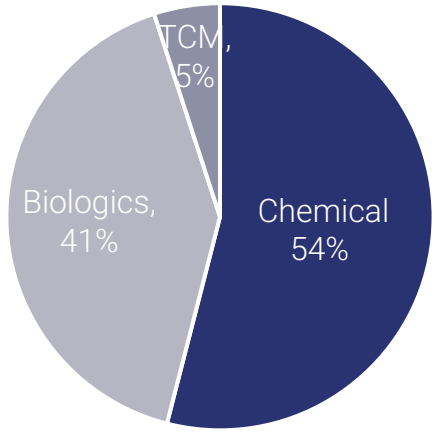
New trials

+13.9%

Applications by Trial Phases



Drug approvals by type (+200 NDA)



3500
Chemical ANDA (Generics)
300+ VBP molecules; price cuts up to 90%

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The Tipping Point: 2025

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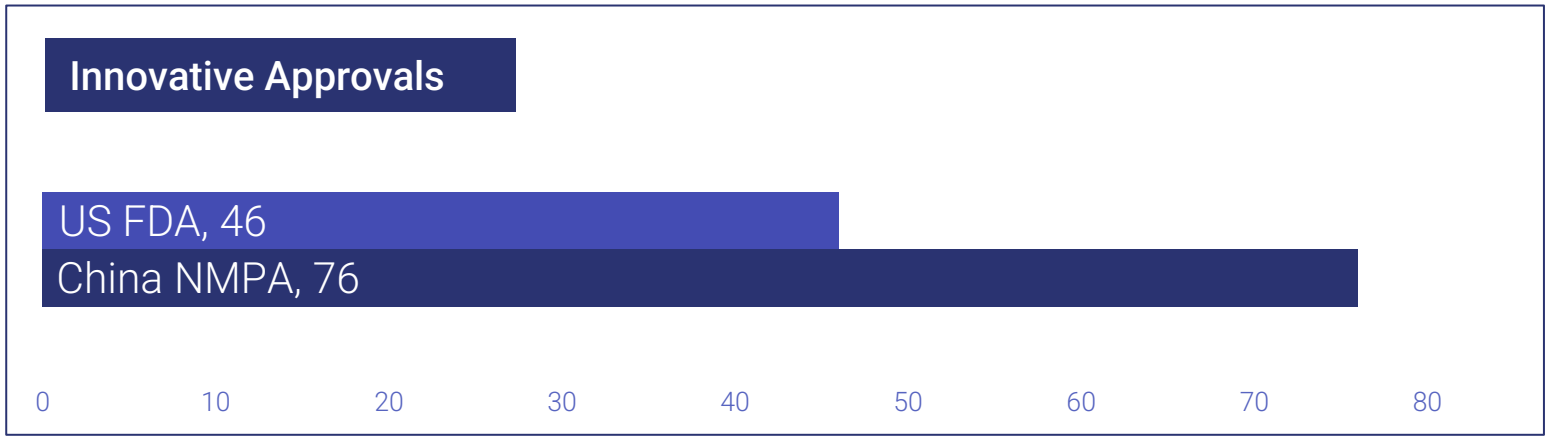
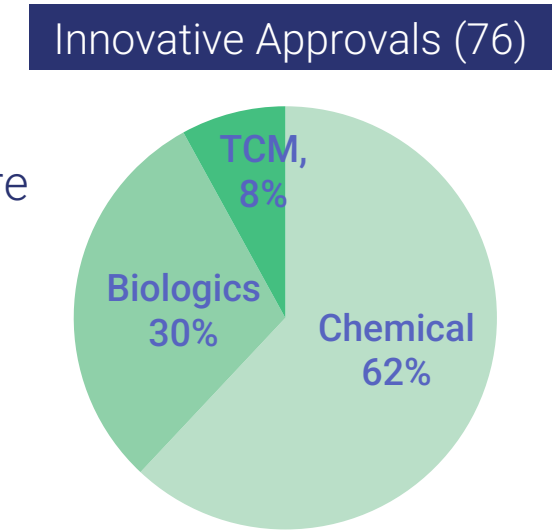


China's innovative approvals are heavily concentrated in:

- Oncology
- Cardiometabolic
- Rare diseases



US$130bn

150+

Out-Licensing Deals

China is a net exporter of high-value pharmaceutical innovation to the global market.

11 FIC

2024 approval mix: Nature Reviews Drug Discovery (Feb 14, 2025)

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China Regulatory Reality (2026)

Higher bar; faster payoff

What Makes China Hard

- **Strict enforcement, no margin for weak filings**
  Poor-quality dossiers fail fast
- **Global-level evidence is mandatory**
  Clinical, CMC, & manufacturing standards match US/EU
- **Speed depends on submission quality**
  Delays come from weak dossiers, not the regulator
- **Traceability + lifecycle inspections increasing**
  End-to-end accountability across the supply chain
- **Structural price pressure**
  Undifferentiated products face rapid margin erosion
- **Late China entry is penalized**
  Lost time, protection, and strategic leverage

What Makes China Attractive

- **Approval speed now matches global standards**
  Priority programs can move as fast as US or EU
- **One global development plan can include China**
  Harmonization reduces China-only development
- **Predictable, rules-based regulation**
  Stable policy enables long-term planning
- **Innovation is rewarded**
  Differentiated drugs are prioritized over commodities
- **Lifecycle compliance is rewarded**
  Clean records unlock faster pathways
- **Early China inclusion creates advantage**
  Parallel development unlocks speed and access benefits

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China’s Market Access Model (2026)

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Faster Access to Innovation

- NMPA-to-NRDL inclusion time has shortened significantly (often ~12-18 months in recent cycles).
- High negotiation success rates are reported for innovative / globally new therapies.
- 50 innovative drugs included in the latest NRDL update (effective 2026).

Strong Cost Control on Mature Products

- National VBP now covers ~490 medicines (11 batches).
- Average price cuts are often ~50% overall, with some products seeing steeper reductions (occasionally >90%).

Reinvestment into High-Value Therapies

- ~60% of VBP savings redirected to fund innovative NRDL listings.
- 114 new drugs added in the latest NRDL update (effective 2026), focused on oncology and rare disease.
- Dual track: NRDL + commercial insurance list

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China Pricing & Reimbursement Lifecycle

Lifecycle stage	NMPA approval	1-2 years after launch	Contract update every 2 years	Generic launch & contract expires	4 generics pass GQCE
Pricing & policy logic	▪ Initial free pricing window ▪ Market-based pricing (no formal price control at launch)	▪ Stage 1: Clinical & economic value assessment (HTA-style review) ▪ Stage 2: National price negotiation with NHSA	▪ Mandatory price cut if sales exceed Budget Impact Analysis commitment	▪ Generic entry triggers contract exit ▪ Hospital/GPO bidding drives price erosion	▪ Lowest bid wins national volume contract ▪ Tiered price cuts (-10% to -30%) for non-winners
Strategic implications	▪ Global price corridor must be set here ▪ Leave space for NRDL cut	▪ IRP benchmarking ▪ PAP strategy design ▪ NRDL comparator price anchoring ▪ BIA modelling (volume–price trade-off)	▪ BIA overspend penalty risk ▪ NRDL comparator repricing pressure ▪ Prepare next NRDL cycle defense	NA	NA

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How China Unlocks Reimbursement and Volume

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	Access pathways	How reimbursement and volume are actually unlocked in China
Affordability	List into NRDL and get reimbursement	• Newly marketed innovative drugs must undergo NRDL price negotiation to obtain national reimbursement • NRDL is updated annually and centrally managed by NHSA • Entry requires comprehensive evaluation of clinical value, safety, and health economics • Negotiated price must meet national affordability thresholds to secure access to the mass market
	Other pathways (commercial insurance, PAP)	• High-cost innovative drugs (oncology, rare disease, gene therapy) may obtain supplementary coverage via commercial insurance and PAPs • These mechanisms are used to improve affordability prior to or alongside NRDL inclusion • Since 2025, NHSA increasingly coordinates basic and commercial insurance coverage for innovative drugs
	Self-paid in private market	• Drugs not eligible for reimbursement are primarily sold in the self-paid private market • Typically applies to early launch phase or products failing NRDL negotiation
Accessibility	Purchase and settled in hospital and get reimbursement	• Over 60% of drug sales occur in hospitals, making this the primary volume channel • Drugs must be listed in hospital formularies after NRDL inclusion • Hospital formulary quotas remain tight, reinforcing the central role of national reimbursement listing • Newly launched products must first enter the national reimbursement list before they can be included in hospital formularies and reimbursed.
	Dual-channel / DTP pharmacies	• Many regions have implemented dual-channel policies to improve access to innovative outpatient medicines• • Allows NRDL-listed drugs to be dispensed via designated pharmacies in addition to hospitals
	Purchased and settled in hospital or pharmacy in private market	• Non-reimbursed drugs require full out-of-pocket payment by patients • These products are mainly distributed through retail and online pharmacies

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How to Win in China (2026)

China succeeds when it is designed in, not bolted on

1. Design China in Parallel

China must be part of global development from day one

- Include China in pivotal MRCTs
- Align clinical, regulatory, access, and manufacturing timelines

2. Structure Partnerships for Risk Sharing

China deals are execution partnerships, not just funding

- Flexible China / ex-China rights structures
- Milestones tied to regulatory and clinical inflections

3. Localize Value-Creation Functions

China cannot be run remotely from global HQ

- Local clinical and regulatory leadership
- China-specific go-to-market strategy
- Local manufacturing and supply chain where needed

4. Manage Market Entry as a System

China access is system, not a single launch

- Launch → NRDL → Renewals → Post-generic pressure
- Continuous lifecycle and price management

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Your 2026 China Playbook

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Three Truths for Global Pharma in 2026

- China is now a core global innovation engine, not an emerging market
- Parallel global development is the only viable model
- Master the system logic, and you master the market.

If you leave today with nothing else, remember this:

China is complex, but it is not chaotic.
If you understand the logic, you can dominate the market.

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Thank you!

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Abbreviations

BIA — Budget Impact Analysis
CDE — Center for Drug Evaluation
CFDI — Center for Food and Drug Inspection
CMC — Chemistry, Manufacturing & Controls
CPP — Certificate of Pharmaceutical Product
CTA — Clinical Trial Application
CTD — Common Technical Document
DTP — Direct-to-Patient
EMA — European Medicines Agency
GBA — Greater Bay Area
GPO — Group Purchasing Organization
GQCE — Generic Quality Consistency Evaluation
HQ — Headquarters
HTA — Health Technology Assessment
ICH — International Council for Harmonisation
IMCT — International Multicenter Trial
IND — Investigational New Drug
IRP — International Reference Pricing
MRCT — Multi-Regional Clinical Trial
NDA — New Drug Application
NHSA — National Healthcare Security Administration
NIFDC — National Institutes for Food and Drug Control
NMPA — National Medical Products Administration
NRDL — National Reimbursement Drug List
PAP — Patient Assistance Program
PH — Phase
PK — Pharmacokinetics
PV — Pharmacovigilance
RWE — Real-World Evidence
TCM — Traditional Chinese Medicine
VBP — Volume-Based Procurement
WHO — World Health Organization

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