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China's Biopharmaceutical Industry in 2026 (and Beyond)

From Emerging Innovator to Global Competitor: Regulatory Reforms, Geopolitical Restrictions, and Implications for U.S. Multinational Companies

Prepared by GRA Advisors | Global Regulatory Affairs

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Executive assessment

China's biopharmaceutical industry has reached a significant turning point in 2026. The country is increasingly recognized as a major originator of innovative drug candidates, a leading location for clinical development, and an important source of assets for multinational pharmaceutical pipelines.

The scale of this transformation is measurable:

31.1%	$139.4B	51%
Global development pipeline involving China	Announced potential outbound licensing value through October 8	China-origin share of specified large-pharma licensing deals through Q3

Figures reflect different measures and reporting periods; they should not be interpreted as China-origin global drug approvals or realized licensing revenue.

The central finding is that China is becoming more attractive as a source of pharmaceutical innovation at the same time that cross-border access to its technologies, companies, clinical evidence, and manufacturing capabilities is becoming more regulated.

Two developments explain this apparent contradiction.

China's government is strengthening the regulatory framework supporting pharmaceutical innovation through revised drug legislation, protection for innovative products, clinical trial modernization, improved manufacturing flexibility, and reimbursement reforms. Its September 2026 pharmaceutical industry plan formalizes ambitious growth targets through 2030.

Meanwhile, the United States is extending biotechnology-related national-security oversight into procurement, outbound investment, imports, and foreign clinical research. China has responded with its own supply-chain protections, counter-extraterritorial measures, and proposed technology-export controls.

For U.S. multinational pharmaceutical companies, the implications differ across four business models: China for domestic commercialization, China for global innovation, China for global clinical development, and China for global manufacturing.

The most consequential issue for regulatory strategy is the increasing possibility that clinical innovation generated in one jurisdiction may not automatically produce evidence that is usable, verifiable, or sufficient for approval in another.

This concern is particularly relevant to State Council Order No. 818, China's human genetic resources framework, FDA scrutiny of foreign clinical studies, and the implementation of ICH E17 principles for multiregional clinical trials.

1. China's Emergence as a Global Biopharmaceutical Innovator

1.1 The evidence of China's progress

The Financial Times' October 2026 analysis, China's drugmakers move into the big league, captures an important structural change in the pharmaceutical industry. Chinese companies are increasingly generating proprietary therapeutic candidates and negotiating global licensing arrangements with major international pharmaceutical companies. [1]

The following indicators illustrate the scale of China's progress.

Indicator	Reported evidence	Interpretation
Global drug pipeline	7,141 drugs, or 31.1%, involved development in China in 2026	China is now a major global development location
Share of innovative-drug clinical trials	Increased approximately sixfold to 30% between 2016 and 2025	Rapid expansion of clinical development capabilities
Outbound licensing	US$139.4 billion in announced potential deal value through October 8, 2026	Exceeded the reported full-year 2025 total of US$138.8 billion
Upfront licensing payments	US$8 billion through Q3 2026, versus US$7.2 billion for all of 2025	Rising committed financial consideration
Major pharmaceutical licensing	China-origin assets represented 51% of specified big-pharma deals with at least US$50 million upfront through Q3	China has become an important source of external pipelines
Licensing stage	27 of 38 major transactions in one 2026 tracker involved discovery, preclinical or Phase I programs	Innovation growth remains exposed to clinical-development risk

Sources: ITIF, Reuters Breakingviews, PharmCube and Vision Life Sciences, citing J.P. Morgan/DealForma. [2–4]

The distinction between deal value and realized revenue is critical. Announced headline values typically include contingent milestones. They should not be interpreted as payments received or guaranteed future sales.

Nevertheless, the growth in upfront payments demonstrates that large pharmaceutical companies are increasingly committing capital to Chinese-origin innovation.

1.2 China is becoming a source of platform innovation, not just individual molecules

Three major agreements illustrate the evolution of China's role.

2026 agreement	Financial terms	Strategic significance
Roche–Hansoh, October	US$400 million upfront; US$110 million first-anniversary payment; more than US$15 billion in potential milestones	Multiple antibody-drug conjugate programs using Hansoh's proprietary platform
Novo Nordisk–Hengrui, September	US$300 million upfront; up to US$2.6 billion total potential value	China-origin Phase I-ready GLP-1/GIP obesity asset
Pfizer–Innovent, May	US$650 million upfront; up to US$9.85 billion in milestones	Twelve-program oncology collaboration, including ADCs and multispecific antibodies

Sources: Company announcements and Pfizer's SEC filing. [5–7]

The Roche–Hansoh agreement is particularly illustrative. Hansoh will conduct early development through global Phase Ia trials before Roche assumes subsequent development responsibilities outside Greater China.

This structure reflects a more mature distribution of scientific and commercial responsibilities. Chinese companies contribute discovery expertise, intellectual property and early clinical execution, while multinational partners contribute international development, regulatory capabilities and commercialization infrastructure.

The strategic implications extend beyond traditional in-licensing. Chinese biotechnology companies are increasingly seeking to retain platform rights, domestic commercialization rights and participation in the downstream value of their innovations.

The emerging competition is therefore not simply between Chinese and Western drugs, but between alternative models for creating and capturing pharmaceutical innovation.

1.3 What China's progress does not yet establish

Despite these advances, China has not displaced the United States or Europe across all dimensions of pharmaceutical innovation.

The United States retains substantial advantages in private-sector R&D investment, late-stage global development, financing, regulatory execution and commercial infrastructure. ITIF reports that China accounted for approximately 4% of global pharmaceutical industry R&D expenditure in 2024, compared with approximately 54% for U.S.-headquartered companies. [2]

China's expansion is strongest in development activity, clinical trial participation, early-stage assets and licensing.

Many of these assets have not completed pivotal clinical studies or obtained international marketing authorization.

Therefore, the next test of China's competitiveness will be whether its rapidly growing pipeline produces clinically differentiated products that can achieve regulatory approval, successful manufacturing scale-up and sustainable global sales.

2. China's Pharmaceutical Regulatory Reforms: More Favorable Conditions for Innovation

2.1 State Council Order No. 828: Revised Drug Administration Law Implementing Regulations

Promulgated January 16, 2026 | Effective May 15, 2026

Order No. 828 represents a substantial modernization of China's pharmaceutical regulatory framework.

The revised regulations address pharmaceutical development, regulatory exclusivity, marketing authorization holders, manufacturing, pharmacovigilance and lifecycle oversight. [8]

Key changes include:

Provision	Regulatory impact
Rare-disease medicines	Up to seven years of market exclusivity for qualifying products, subject to applicable conditions
Pediatric medicines	Up to two years of market exclusivity for eligible products
Undisclosed registration data	Protection for qualifying pharmaceutical data for up to six years
MAH responsibilities	Stronger quality management, pharmacovigilance and postmarketing obligations
Segmented manufacturing	Greater flexibility for qualified manufacturing arrangements
Overseas MAHs	Enhanced expectations for designated Chinese legal entities responsible for specified local obligations

NMPA Announcement No. 47, effective May 15, operationalizes the pharmaceutical trial-data protection framework. [9]

Implications for U.S. MNCs

The reforms may improve the commercial attractiveness of registering differentiated innovative medicines in China, particularly rare-disease and pediatric products.

However, exclusivity periods are subject to eligibility and implementing requirements rather than being automatically available to every innovative drug.

For foreign MAHs, the legislation also imposes stronger lifecycle responsibilities. Global companies should review their local representation, pharmacovigilance systems, manufacturing arrangements, product quality agreements and postmarketing governance.

> **Assessment:** Favorable for pharmaceutical innovation and regulatory predictability, but accompanied by increased quality and lifecycle compliance responsibilities.

2.2 Updated Good Clinical Practice

NMPA Announcement No. 50 | Effective September 1, 2026

China's revised GCP framework further aligns its domestic clinical trial requirements with ICH E6(R3), emphasizing risk-based quality management, sponsor oversight, data reliability, participant protection and appropriate use of computerized systems. [10]

For multinational sponsors, this facilitates the potential integration of Chinese sites into global clinical development programs.

However, convergence in GCP principles does not eliminate China-specific requirements governing data transfers, biological specimens, ethics or regulatory classification.

> **Assessment:** Favorable for international regulatory convergence, provided implementation results in verifiable compliance rather than only procedural harmonization.

2.3 Pricing reform and innovative-drug reimbursement

State Council General Office Opinion No. 9 | Published April 14, 2026

China's pharmaceutical pricing reform explicitly recognizes that medicines demonstrating high levels of innovation and substantial clinical value may justify initial prices that reflect the financial risks of their development.

The policy also emphasizes market-based price formation, real-world evidence, reimbursement negotiations, centralized procurement and monitoring of pharmaceutical prices. [11]

A complementary development is the implementation of China's first Commercial Insurance Innovative Drug List on January 1, 2026.

The list contains 19 medicines and is intended to complement basic medical insurance for selected innovative, often expensive therapies. [12]

This is relevant to oncology, rare diseases, cell therapies and other specialized treatments.

Implementation indicators are encouraging. In July, China's NHSA reported that products on the commercial innovative-drug list were stocked at 1,486 designated medical or pharmaceutical institutions by the end of May, and more than 100 inclusive commercial insurance products covered medicines on the list. [12]

However, the list is recommendatory. Inclusion does not guarantee coverage by every commercial insurer or adequate reimbursement for every patient.

Assessment: Directionally favorable to innovative products, but the value to MNCs will depend on actual insurance coverage, reimbursement levels and commercial uptake.

2.4 The Pharmaceutical Industry 15th Five-Year Plan

Issued September 2026 | Planning horizon 2026–2030

The pharmaceutical industry plan issued by ten Chinese government departments establishes ambitious industrial and innovation targets.

These include annual growth exceeding 20% for the innovative-drug industry, a 25% global share of first-in-class drugs, pharmaceutical industry revenue exceeding RMB 3.5 trillion among enterprises above the designated scale threshold, and at least five medicines with global annual sales exceeding US$1 billion. [13]

The plan also addresses AI-enabled pharmaceutical development, advanced manufacturing, international collaboration and supply-chain resilience.

These targets should not be confused with accomplished results. They nevertheless demonstrate sustained government support for the industry's transition toward higher-value innovation.

Assessment: Favorable for investment in pharmaceutical innovation, while potentially intensifying international competition.

3. Order No. 818: A New Regulatory Pathway With Global Implications

State Council Order No. 818 | Promulgated September 28, 2025 | Effective May 1, 2026

Order No. 818, the Regulations on the Clinical Research and Translational Application of New Biomedical Technologies, deserves particular emphasis in the report.

The regulation establishes a distinct framework for the clinical investigation and clinical application of qualifying emerging biomedical technologies.

It is especially relevant to certain highly individualized interventions, emerging cell-based approaches and other biomedical technologies that may not fall within conventional drug or medical-device regulatory pathways. [14]

3.1 A dual regulatory framework

China now has two complementary pathways for certain advanced biomedical innovations.

Regulatory feature	NMPA pharmaceutical pathway	NHC biomedical-technology pathway
Principal framework	Drug Administration Law and drug registration regulations	State Council Order No. 818
Oversight	NMPA	National Health Commission
Research authorization	Applicable drug clinical trial authorization	Research filing and associated review and oversight
Intended regulatory outcome	Pharmaceutical marketing authorization	Approval for qualifying clinical translational application
Commercialization	Authorized pharmaceutical product	Approved clinical use in qualified healthcare settings

Regulatory feature	NMPA pharmaceutical pathway	NHC biomedical-technology pathway
Automatic equivalence for FDA submission	No	No

China's April 28, 2026 classification guidance provides important clarification.

It states that data generated through research classified under the biomedical-technology pathway are intended to support clinical translational application. Development of products classified as drugs must follow the applicable pharmaceutical trial authorization and registration requirements. [15]

This is an important point for global regulatory strategy.

Order 818 does not establish an alternative way to obtain an NMPA pharmaceutical marketing authorization. Nor should it be interpreted as establishing a shortcut to FDA or EMA approval.

3.2 Stronger clinical research oversight

Order 818 requires research at eligible tertiary Grade A healthcare institutions and introduces specified obligations concerning scientific and ethics review, informed consent, clinical safety, record retention and regulatory supervision.

Article 20 prohibits charging participants for the biomedical technology research itself.

Article 22 requires clinical research records and original materials to be retained for 30 years after completion. Research involving subsequent generations requires permanent retention.

Following successful research, qualifying technologies may receive NHC approval for clinical application, subject to the specified evaluation and institutional requirements. [14]

These provisions address important concerns concerning oversight of hospital-based biomedical research and the boundaries between experimentation and clinical care.

> **Assessment:** Favorable for formalizing research oversight and potentially supporting responsible innovation, but more demanding for research institutions and companies previously relying on less standardized arrangements.

3.3 Order 818 is not primarily a genetic-data export-control law

This distinction is essential.

Order 818 regulates biomedical research and clinical translational application. The primary legal framework for regulating covered human genetic resources remains China's separate Biosecurity Law and human genetic resources regulations.

Under the existing HGR implementing rules, human genetic information includes human gene and genome data generated from covered genetic materials.

Ordinary clinical data, imaging data, proteomic data and metabolomic data are not, by themselves, defined as human genetic resources information. However, they may remain subject to separate personal-information and data-security requirements. [16]

Order 818 therefore should not be described as a direct legal mechanism for prohibiting genetic-data transfers.

Its significance is the way the new research pathway interacts with China's existing regulatory governance of human genetic resources, biological materials, clinical documentation and cross-border collaboration.

3.4 The global regulatory issue: Can the evidence travel?

This is the most consequential question for multinational pharmaceutical companies.

An innovative therapy developed through a Chinese biomedical research program may have promising safety and efficacy results.

However, the international regulatory value of those findings depends on several separate considerations: whether the studies were appropriately designed; whether source data and supporting records are complete; whether FDA or EMA can verify the results; whether the study population and endpoints are relevant to the intended market; and whether the sponsor can lawfully obtain and provide all required evidence.

The result is a potentially important distinction between scientific innovation and regulatory portability.

China's increasing ability to generate innovative therapeutic candidates may not automatically translate into internationally acceptable clinical evidence.

For companies licensing Chinese-origin assets, this should be addressed during regulatory due diligence rather than after the transaction is completed.

3.5 FDA decisions involving China-generated evidence: Innovent and HUTCHMED

FDA's experience with Chinese-origin oncology products provides a useful historical precedent.

Innovent/Eli Lilly: Sintilimab

In March 2022, FDA issued a Complete Response Letter for sintilimab, which was being developed for first-line nonsquamous non-small cell lung cancer.

The pivotal ORIENT-11 trial was conducted exclusively in China and outside a U.S. IND.

FDA's February 2022 advisory committee briefing identified concerns about the applicability of the results to U.S. patients and clinical practice. These included population diversity, the choice of comparator, progression-free survival as the primary endpoint and differences in contemporary standards of care.

The agency expressly discussed ICH E17 and the preference for appropriately designed multiregional clinical trials. [17,18]

HUTCHMED: Surufatinib

In April 2022, FDA issued a Complete Response Letter for surufatinib, based on an application supported by two positive Phase III studies in China and a U.S. bridging study.

FDA required additional multiregional evidence involving patients more representative of the U.S. population and U.S. medical practice.

HUTCHMED also reported that COVID-19-related difficulties involving inspection scheduling and access contributed to the decision. [19]

These two decisions demonstrate that successful trials conducted in China do not necessarily establish sufficient evidence for U.S. marketing approval.

However, it would be inaccurate to characterize these decisions as a general FDA prohibition on Chinese clinical data or as political retaliation.

Indeed, FDA approved toripalimab for nasopharyngeal carcinoma in October 2023 using clinical evidence that included single-region and single-country studies.

This demonstrates that predominantly Asian clinical evidence may be acceptable where the disease context, unmet medical need, study design and evidence satisfy applicable U.S. requirements. [20]

3.6 ICH E17: Potential divergence between globally coordinated development and national regulation

ICH E17, General Principles for Planning and Design of Multiregional Clinical Trials, provides the international scientific framework for planning development programs intended to support regulatory submissions in multiple regions. [21]

The guideline emphasizes prospective consideration of intrinsic and extrinsic ethnic factors, regional consistency of treatment effects and the applicability of results across different populations.

The objective is to support globally coordinated development and reduce unnecessary duplication of clinical trials.

Importantly, ICH E17 does not require FDA to accept all foreign clinical studies. It does not establish equivalence between a single-country study and a well-designed MRCT.

The Innovent and HUTCHMED decisions therefore do not, by themselves, demonstrate FDA inconsistency with ICH E17.

The more important concern is prospective.

If national rules governing clinical evidence, research classification, genomic information and inspection access evolve in incompatible directions, the practical objectives of ICH E17 may become increasingly difficult to achieve.

This could result in additional clinical studies, delayed global registration, higher development costs and duplication of research.

3.7 Will FDA adopt a reciprocal response to Order 818?

The possibility of reciprocal regulatory measures deserves consideration, particularly given growing U.S. national-security concerns involving biotechnology and genetic information.

However, there is no verified FDA policy establishing a quid pro quo against Order 818.

The chronology is important: FDA's sintilimab and surufatinib decisions occurred in 2022, several years before Order 818 entered into force. They cannot be attributed to that regulation.

What has changed is the broader regulatory environment.

In June 2025, FDA announced increased scrutiny of new clinical trials involving the transfer of living cells from U.S. patients to China and certain other countries for genetic engineering and subsequent administration. [22]

In August 2026, members of Congress requested that FDA reject Chinese trial data from sites not inspected within the preceding 12 months. That request was not enacted as a general FDA requirement. [23]

In September 2026, FDA leadership announced stronger oversight of foreign clinical studies, with particular attention to early-phase and investigator-initiated research performed outside an IND or IDE framework. The agency identified data reliability, informed consent and the ability to inspect clinical research as central concerns. [24]

Existing FDA regulations already establish relevant requirements. Under 21 CFR 312.120, foreign studies not conducted under an IND may support U.S. submissions when applicable GCP and data-validation requirements are met.

Under 21 CFR 314.106, applications relying solely on foreign clinical evidence must demonstrate applicability to U.S. patients and medical practice, appropriate investigator qualifications, and adequate data validation or inspection access. [25]

Thus, FDA's current approach is more accurately characterized as increasing scrutiny of evidence quality and inspectability, rather than an established policy of reciprocal exclusion.

Nevertheless, as biotechnology becomes increasingly linked to national-security policies, the potential for wider regulatory divergence cannot be ignored.

The distinction between reciprocal political action and independently evolving regulatory requirements is important analytically. Both could affect international clinical development, but only the latter is presently supported by the identified FDA policy record.

3.8 Strategic implications of Order 818 and FDA requirements

For U.S. MNCs evaluating Chinese-origin innovations, five considerations follow.

First, regulatory classification must be established before asset acquisition or licensing. Evidence from an NHC biomedical-technology research program should not automatically be treated as equivalent to evidence generated under an NMPA-authorized drug-development program.

Second, clinical data quality, source documentation, informed consent, audit rights and regulatory inspection access should be central elements of scientific and regulatory due diligence.

Third, the international use of genomic data and biological materials should be assessed under China's applicable HGR, privacy and data-security requirements.

Fourth, globally intended products should follow an integrated development plan consistent with ICH E17, including prospective regional representation when scientifically appropriate.

Finally, licensing valuations and milestones should reflect the potential need for additional global studies if the original evidence is insufficient for FDA or EMA submissions.

> **Overall assessment:** Order 818 strengthens China's biomedical research governance. Its interaction with FDA expectations creates additional regulatory planning requirements, but the principal risk is divergence in evidentiary standards and access, not a demonstrated retaliatory response.

4. U.S. Restrictions on China-Linked Biopharmaceutical Activities

4.1 October 2026 action against Chinese genomics companies

U.S. Department of Homeland Security | UFLPA Entity List updated October 29, 2026

The United States added three Chinese genomics companies to the Uyghur Forced Labor Prevention Act Entity List:

- BGI Genomics Co., Ltd.
- MGI Tech Co., Ltd.
- Shenzhen BGI Technology Co., Ltd., also known as BGI Group.

The U.S. government's stated basis concerned the companies' alleged activities involving genetic testing and cooperation with authorities in Xinjiang.

The companies have disputed the allegations. [26]

The legal effect is important.

The UFLPA establishes a rebuttable presumption prohibiting the importation of covered goods associated with listed entities unless the importer satisfies the statutory requirements for an exception.

This is an import restriction, not a blanket prohibition on every commercial transaction with a Chinese genomics company.

Nevertheless, the operational consequences may be substantial.

Genomics equipment, reagents and technologies are important in drug discovery, biomarker development, precision medicine, translational research and companion diagnostics.

U.S. MNCs therefore need to assess supplier exposure, especially where Chinese genomics companies supply equipment, consumables or other goods entering the United States.

The designation also illustrates how biotechnology regulatory risk increasingly extends beyond pharmaceutical products themselves into the research and development infrastructure supporting those products.

4.2 Politico: Proposed U.S. restrictions on biotechnology investment

U.S. Treasury proposal October 22, 2026 | Federal Register October 26, 2026

Politico's October 22 report, Biotech investment is the new front in the U.S.-China trade fight, identifies a potentially significant development affecting cross-border pharmaceutical transactions. [27]

The Treasury Department proposed regulations implementing the Comprehensive Outbound Investment National Security Act, enacted in December 2025.

The proposal would introduce restrictions on certain investments involving covered foreign persons engaged in specified biotechnology activities.

Its scope includes certain pharmaceutical compounds, biological production processes, sequencing technologies, bioinformatics, biomanufacturing equipment and other advanced biotechnology capabilities. [28]

The rules would potentially affect equity investments, certain financing arrangements, joint ventures and other covered investment transactions.

However, a conventional product-level licensing agreement without an investment component is generally distinguishable from a covered investment transaction.

This is a critical distinction for global pharmaceutical business development.

Many China-origin transactions now involve complex arrangements combining licensing, co-development, equity investments, NewCo structures and profit-sharing.

Those structures require transaction-specific legal review.

Transaction type	Implications under proposed Treasury rules
Conventional license with upfront payments and royalties	Generally outside the covered investment categories if it contains no investment-like features

Transaction type	Implications under proposed Treasury rules
Equity investment in a covered biotechnology company	Potential prohibition
Covered joint venture or NewCo investment	Requires close assessment
Acquisition of covered biotechnology companies	Potential prohibition
Co-development with governance or equity rights	Depends on substantive transaction structure
Ordinary CRO or CDMO services without a covered investment	Not automatically prohibited by the investment rules

The Treasury proposal remains open for comments through December 7, 2026. It has not yet become final law.

> **Assessment:** Potentially restrictive for biotechnology investment and complex partnering structures, while conventional product licensing remains distinguishable under the current proposal.

4.3 BIOSECURE Act

Enacted December 18, 2025 | Implementation milestones during 2026 and beyond

The BIOSECURE Act establishes a framework for restricting specified federal procurement and federally supported use of biotechnology equipment or services provided by designated biotechnology companies of concern.

The statute does not automatically ban all Chinese CROs, CDMOs or biotechnology companies.

The first OMB company list is due December 18, 2026.

Subsequent implementation depends on the applicable designation process and Federal Acquisition Regulation changes. The legislation also contains transitional provisions affecting certain existing contracts. [29]

For MNCs, the main issue is identifying suppliers whose services could affect eligibility for covered U.S. government contracts, grants or other federally supported activities.

Supplier changes are not always operationally straightforward. Changing a biological product manufacturer or critical testing laboratory may require technology transfer, comparability assessments, validation and regulatory submissions.

> **Assessment:** Restrictive for covered federal relationships, while the commercial effects will depend heavily on specific company designations and implementation rules.

4.4 Pharmaceutical tariffs

In April 2026, the United States introduced Section 232 tariffs affecting specified patented pharmaceuticals and associated ingredients.

The baseline additional tariff is 100%, with exceptions, alternative rates and company-specific arrangements.

The initial measure excludes generic medicines and biosimilars.

Certain specialty categories, including cell therapies, gene therapies, ADCs and specified orphan drugs, may qualify for zero-tariff treatment under applicable conditions, rather than receiving an unconditional category-wide exemption. [30]

For U.S. MNCs, the implications extend to manufacturing-location decisions, sourcing arrangements, product origin, manufacturing flexibility and supply-chain costs.

> **Assessment:** Restrictive for covered imports, with product-specific effects that cannot be inferred from the country of manufacture alone.

5. China's Countermeasures and Strategic Technology Controls

5.1 Order No. 834: Industrial and Supply-Chain Security

Promulgated March 31, 2026 | Published April 8, 2026 | Effective upon promulgation

Order No. 834 establishes a regulatory framework for protecting the security and resilience of China's industrial supply chains.

Article 13 addresses supply-chain investigations and information-gathering activities conducted within China in violation of applicable Chinese laws and regulations.

It does not impose a blanket ban on foreign supplier audits or due diligence.

Articles 14 and 15 provide mechanisms for responding to specified foreign measures and commercial conduct that China considers harmful to its supply-chain security. [31]

For U.S. MNCs, the issue is the interaction with requirements arising under U.S. biotechnology restrictions.

Supplier screening, ownership investigations, subcontractor assessments and other due diligence must be structured to comply with the applicable laws of both jurisdictions.

5.2 Order No. 835: Countering Foreign Extraterritorial Jurisdiction

Promulgated April 7, 2026 | Effective upon promulgation

Order No. 835 establishes mechanisms through which China may respond to specified foreign extraterritorial measures it considers improper.

The regulation provides for governmental determinations and countermeasures, including a framework for identifying relevant persons and organizations. [32]

For U.S. MNCs, the principal concern is the possibility that compliance actions required under U.S. law could create separate legal consequences in China.

This should not be interpreted as an automatic conflict arising whenever a company complies with U.S. regulations.

Rather, it creates an additional legal risk requiring transaction-specific assessment.

5.3 October 2026 technology-export controls

MOFCOM/MOST Announcement No. 48 | October 16, 2026

China proposed adding 40 technologies to its catalogue of prohibited or restricted technology exports.

Five involve biopharmaceutical technologies, including selected cell and gene therapy, small interfering RNA and pathogen-related technologies.

The proposed additions include three biopharmaceutical technology categories designated for prohibition and two designated for restriction, subject to final adoption.

The proposed list distinguishes certain transfers of proprietary platform technology from many product-specific licensing and services arrangements.

Importantly, the export-control catalogue amendments are not final, but interim pre-export registration requirements for covered technologies already took effect on October 16, 2026. [33]

This is particularly consequential for international licensing transactions involving complex technology rights.

A product license may involve not only rights to a drug candidate but also the transfer of manufacturing know-how, platform technology, process documentation, intellectual property or contingent ownership rights.

Each element may require separate regulatory analysis.

The overlapping U.S. and Chinese restrictions create an important strategic distinction:

A transaction may be permissible as a pharmaceutical license but still require analysis under investment, technology-export or cross-border regulatory requirements.

> **Assessment:** Potentially restrictive for platform ownership and technology transfer, while still leaving room for many international pharmaceutical collaborations.

6. Is the Regulatory Environment Becoming Better or Worse for U.S. MNCs?

The answer depends on the activity being assessed.

China's pharmaceutical regulatory reforms are generally moving toward stronger support for innovation, greater formalization of clinical research and increased international alignment in conventional drug development.

At the same time, the cross-border regulatory environment is becoming more restrictive in areas involving investment, technology ownership, sensitive biological information and national security.

These developments should not be assigned a single positive or negative assessment.

Regulatory development	Direction for U.S. MNCs	Principal implication
Order 828: Drug regulatory reform	Favorable, with added obligations	Stronger innovation incentives and MAH accountability
NMPA data exclusivity	Favorable	Potentially stronger protection for qualifying innovative products
Updated GCP	Favorable, with added obligations	International harmonization and data-quality expectations
Order 818	Mixed	Clearer biomedical research pathway but additional regulatory classification issues
Pharmaceutical pricing reform	Mixed, potentially favorable	Recognition of innovation value alongside reimbursement constraints
Commercial innovative-drug insurance	Favorable	Additional potential market-access pathway
Pharmaceutical industry plan	Favorable for industry investment	Stronger innovation ecosystem and greater competition
Orders 834 and 835	More restrictive	Cross-border due diligence and conflict-of-laws exposure

Regulatory development	Direction for U.S. MNCs	Principal implication
Chinese technology-export controls	More restrictive for covered technologies	Limits on platform transfers and additional registration requirements
U.S. genomics import restrictions	Restrictive for affected suppliers	Import and research supply-chain exposure
BIOSECURE Act	Restrictive for covered relationships	Supplier and federal procurement compliance
Proposed U.S. outbound-investment rules	Potentially restrictive	Constraints on investments and certain partnerships
FDA foreign clinical data scrutiny	Mixed	Higher oversight expectations but stronger data confidence
U.S. pharmaceutical tariffs	Restrictive for covered imports	Manufacturing and global supply-chain implications

6.1 Drug development is becoming more internationally integrated, but regulatory evidence remains jurisdiction-specific

Increasing Chinese participation in global clinical development is a significant opportunity.

However, the divergence between national biomedical research pathways and international drug registration requirements creates uncertainty.

Order 818 is the clearest example.

The regulation may support faster and more structured development of certain medical technologies. Nevertheless, data generated within this framework must be evaluated independently against the requirements of the intended global regulatory authorities.

For companies pursuing international approval, the distinction between generating scientific evidence and generating regulatory-acceptable evidence is fundamental.

6.2 Product licensing may become more attractive than certain equity-based transactions

The combined effect of the U.S. Treasury proposal and China's technology-export controls could change international pharmaceutical deal structures.

Straightforward licensing of individual products may remain commercially feasible, while acquisitions of Chinese biotechnology platforms, certain equity investments and joint ventures could become more difficult.

However, this is a potential structural consequence of the proposed measures, not an established requirement that all future transactions take the form of product licenses.

Companies should evaluate each transaction according to its substantive rights and obligations rather than relying solely on contractual labels.

6.3 China market access is improving structurally, but commercial economics remain uncertain

Innovation incentives, data protection, pricing reforms and commercial insurance provide a more sophisticated environment for differentiated therapies.

Yet commercialization will continue to depend on local competition, purchasing power, reimbursement, institutional access and the value of the product relative to alternatives.

For U.S. MNCs, China launch strategies need to reflect global pricing implications as well as domestic commercial conditions.

6.4 Global manufacturing decisions are becoming more complex

China's support for segmented manufacturing and foreign-invested pharmaceutical projects may create additional operational flexibility.

Shanghai's July 2026 measures, for example, support qualifying foreign-invested biopharmaceutical development, manufacturing and headquarters activities. [34]

However, multinational manufacturing decisions must now account for tariff exposure, supplier designations, technology transfers, regulatory comparability and relevant cross-border restrictions.

The result is greater need for integrated CMC, regulatory, trade-compliance and financial planning.

7. Strategic Priorities for U.S. Multinational Pharmaceutical Companies

The developments of 2026 support a differentiated approach to China's pharmaceutical industry.

China for China: Commercialization and market access

Companies should evaluate opportunities created by strengthened exclusivity, pricing reform, commercial insurance and local innovation incentives.

They should also reassess local MAH representation, quality systems, pharmacovigilance and manufacturing compliance under Order 828.

China for Global Innovation: Licensing and business development

China-origin assets should be evaluated through integrated scientific, regulatory, intellectual property and legal due diligence.

Special attention is warranted for early-stage assets, proprietary biotechnology platforms and transactions involving investment or cross-border technology transfer.

Companies should distinguish headline milestone values from committed upfront payments and account for the possibility of additional international clinical development.

China for Global Clinical Development: Order 818, FDA and ICH E17

The regulatory classification of Chinese clinical research should become a formal component of licensing and development decisions.

Sponsors should establish whether studies were performed under the NMPA pharmaceutical framework or the NHC biomedical-technology framework.

They should determine whether source records, clinical data, genetic information, safety documentation and investigator oversight will meet the requirements of FDA and other intended regulatory authorities.

Early multinational development planning, including application of ICH E17 principles, may reduce the need to repeat studies.

China for Global Manufacturing: Supply-chain resilience

Companies should map Chinese manufacturing, laboratory, genomics and technology suppliers against applicable U.S. restrictions.

They should evaluate product origin, tariffs, alternate manufacturing sites, validation requirements and potential restrictions on technology transfers.

Integrated regulatory governance

A broader organizational change may be necessary.

China strategy can no longer be managed exclusively through regulatory affairs, business development or country commercial leadership.

The increasingly interconnected requirements demand coordination among regulatory affairs, clinical development, CMC, pharmacovigilance, intellectual property, government affairs, business development, finance and trade compliance.

8. Key Regulatory Developments to Monitor

Date or period	Development	Strategic relevance
November 15, 2026	Comments due on China's proposed technology-export catalogue	May determine the final scope of biotechnology platform restrictions
December 7, 2026	Comments due on Treasury's proposed outbound-investment rules	Important for biotechnology investment and partnership structures
December 18, 2026	Deadline for initial BIOSECURE OMB company list	Supplier mapping and procurement exposure
Late 2026	Further Chinese reimbursement-list decisions	Innovative-drug commercialization planning
2027	Continued implementation of China's exclusivity framework	Product-specific registration strategies
2027	Further implementation of Order 818	Clinical research classification and translational application
2027	Additional FDA oversight and possible policy changes concerning foreign clinical data	Global study design and evidence acceptability
2027	Potential finalization of Chinese technology-export and U.S. investment measures	Cross-border transaction planning
Through 2030	Pharmaceutical Industry 15th Five-Year Plan	Long-term innovation, industrial investment and competition

9. Conclusions

China's biopharmaceutical industry is becoming a major contributor to global pharmaceutical innovation.

The expansion of China-origin licensing, large development pipelines, clinical trial capabilities and strategic partnerships demonstrates that the country has moved beyond its historical position as principally a large pharmaceutical market and manufacturing base.

At the same time, China's regulatory environment is evolving in two directions.

Domestic pharmaceutical regulations increasingly support innovation through stronger exclusivity, modernized clinical development, improved manufacturing flexibility and evolving market-access mechanisms.

Conversely, national-security and technology policies in both China and the United States are introducing additional restrictions affecting biotechnology investments, supplier relationships, technology transfers and sensitive biological information.

The emerging regulatory environment is therefore more supportive of developing innovative medicines, but potentially less permissive of certain forms of international biotechnology integration.

For U.S. MNCs, one of the most important concerns is the relationship between China's expanding biomedical research capabilities and the international acceptability of the resulting clinical evidence.

Order 818 illustrates this issue particularly well.

Although it establishes a more formal pathway for qualifying biomedical technologies, it also creates a regulatory distinction between research intended for domestic clinical application and pharmaceutical studies conducted to support international marketing authorization.

FDA's previous decisions concerning sintilimab and surufatinib demonstrate the importance of population applicability, clinical practice, study design and data verification. They do not establish a blanket rejection of Chinese clinical evidence.

Similarly, recent FDA scrutiny and congressional concerns do not demonstrate a retaliatory response to Order 818.

Nevertheless, as national restrictions on biotechnology and sensitive research information expand, the risk of regulatory divergence becomes increasingly important.

The central challenge for global pharmaceutical development will be ensuring that the international growth of biomedical innovation is accompanied by equally effective mechanisms for generating, sharing, verifying and accepting clinical evidence across jurisdictions.

This is consistent with the underlying objectives of ICH E17 and international regulatory harmonization.

For U.S. multinational companies, the appropriate response is selective integration: capturing China's innovation opportunities while maintaining global regulatory acceptability, legal compliance, manufacturing flexibility and supply-chain resilience.

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