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Alert | Life Sciences & Medical Technology/ Export Controls & Economic Sanctions

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China's Proposed Biopharma and AI Technology Export Controls: Pre-Export Registration Already Applies

Go-To Guide:

- **Registration already applies.** Since Oct. 16, 2026, exports of the listed technologies, including licenses and unfinished transfers, require pre-export registration; the Catalogue additions remain open for comment until Nov. 15, 2026.
- **In biopharma, the rights transferred decide the treatment.** Transfers of ownership of covered cell and gene therapy (CGT) and small interfering RNA (siRNA) platforms would be prohibited, but licensing, contract research organization (CRO)/contract development and manufacturing organization (CDMO) services, and technology necessary for product research, development or manufacture in an outbound business development (BD) transaction would not. Novel-target discovery or validation technology for CGT or siRNA therapeutics would require a technology export license.
- **For AI, the proposed controls do not cover every form of model access.** The proposal would prohibit exports of specified high-risk technologies, including large models trained on China's "core data" and used to provide services. API, app/web, SaaS and lightweight on-device deployment to a restricted large model would fall outside the controls, but overseas local deployment and moving covered weights or other core technology abroad would require a license.

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- **Consider the whole life of the deal.** Stakeholders may wish to map initial and contingent deliveries, assign filing responsibility and the cost of undeliverable rights, and assess Chinese and U.S. rules separately.

What China Announced

On Oct. 16, 2026, China's Ministry of Commerce (MOFCOM) and Ministry of Science and Technology (MOST) issued Announcement No. 48 of 2026, which proposes adding 40 technologies to China's *Catalogue of Technologies Prohibited and Restricted from Export* (Catalogue): 23 in AI, five in biopharmaceuticals, and 12 in photovoltaics. Fourteen of the identified technologies would be prohibited from export, and the other 26 would be restricted. Comments are due Nov. 15, 2026, but interim pre-export registration of the listed technologies, including exports already under way, has applied since Oct. 16, 2026.

In both the AI and the biopharma sectors, the proposals separate certain underlying capabilities, such as reusable platforms and model weights, from the products and services built on them, paralleling the capability-control approach discussed in our September 2026 alert, 2 Tracks, 1 Enterprise Strategy. The central question for deal teams is which rights could lawfully be delivered under the proposed amendments, and when.

Biopharma: Platform Ownership Versus Product Rights

The biopharma entries target ownership of reusable platforms, rather than their use. The proposed amendments describe a CGT or siRNA "technology process platform" as reusable technology, developed through sustained research and development, that can support multiple pipelines.

Table 1: Proposed Treatment of Common Biopharma Deliverables

Deliverable	Proposed Treatment	Practical Note
Ownership of a proprietary CGT or siRNA "technology process platform"	**Prohibited**	Includes an outbound assignment, including contribution of the platform to a new company (NewCo) by way of an assignment.
Out-licensing of such a platform, or **CRO and CDMO services** using it, where ownership stays in China	Outside the platform prohibitions	Interim registration may still be required.
Technology needed for specific drug's research and development, testing, manufacturing, quality control, approval, and compliance	Outside the platform prohibitions	Interim registration may still be required.
Novel-target discovery: proprietary discovery and validation technology for "globally novel" CGT and siRNA targets	**Restricted**: export license would be required	Automatic approval proposed for out-licensing, public-health emergencies, humanitarian relief and joint R&D using offshore resources; approval still applies.
Pathogen technology: specified pathogen genetic modification and directed gain-of-function passages	**Prohibited**	The platform and product carve-outs do not apply.

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'Globally Novel' Targets

The proposal defines "globally novel" targets as targets not publicly disclosed anywhere through patents, academic literature, public databases, industry materials, conferences, or other public channels. Because the test would turn on public disclosure, the relevant point for a patent may be publication rather than filing, and dated evidence of prior disclosure would matter. Antibodies and antibody-drug conjugates (ADCs) are not named, although a deal involving them might still transfer technology within a listed entry, depending on how the antibodies or ADCs are being used.

Open Questions

- **License versus ownership transfer.** The Announcement and MOFCOM's Q&A distinguish ownership transfers from licensing but do not treat exclusivity or perpetual duration as converting one into the other. Broad exclusive licenses, purchase options, and assignments on breach or insolvency may warrant careful review.
- **Multi-modality platforms.** Lipid nanoparticles, viral vectors, and modality-agnostic discovery tools would require analysis against the specific entries. The siRNA entries would also sit under a broader "small nucleic-acid drug" heading while their control text names siRNA, leaving boundary questions for antisense oligonucleotides and other modalities that share delivery chemistry.
- **Actual control and minority investments.** Registration covers a change in the owner or "actual controller" (实际控制人) of covered technology to an offshore person. PRC company law uses that term for a person able to direct a company's conduct in practice, but the Announcement neither adopts that definition nor addresses variable interest entity (VIE) structures. A minority investment that changes neither ownership nor actual control would not, by itself, be a listed trigger, although accompanying rights may change the analysis.

Implications for Biopharma Transactions

- **Licensees** should consider mapping the rights they will need over the life of a deal, including manufacturing, technology transfer, improvements, and step-in rights, and should not assume a license avoids registration because platform ownership stays in China.
- **Chinese biotechs and their investors** may wish to assess the proposal's potential effect on exit routes, valuations, and NewCo contributions, and to keep records separating platform technology from candidate-specific deliverables.
- **CROs, CDMOs, and their customers** should consider separating customer-specific work product from platform technology and review assignment, background and foreground IP, and offshore vesting provisions before covered technology is delivered.
- **Acquirers of platform companies** may need to restructure transactions around product-level rights or co-development, with payment terms tied to the rights that can actually be delivered. Separately, the Foreign Investment Negative List (2024 edition) prohibits foreign investment in human stem cell and gene diagnosis and therapy technology, subject to a September 2024 pilot in the Beijing, Shanghai, and Guangdong pilot free trade zones and the Hainan Free Trade Port.

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AI: Technology Transfer Versus Model Access

The 23 AI entries generally follow a similar logic: core technology would be controlled, while certain service-access to restricted large model would not.

- **Prohibited technologies** would include specified AI-driven malicious-code generation and mutation technology; large models trained on China's "core data" and used to provide services; AI agents that meet the restricted-agent thresholds and are intended specifically or primarily for critical information infrastructure, defense or core government systems; and specified deep-synthesis detection systems and equipment-manufacturing technology, with accuracy and recall of at least 95%, used specifically or primarily for China's cross-border network-data security.
- **Restricted technologies** would include the weights, key checkpoints, source code and other core technology of large models meeting any one of three tests: compute of at least 10^{26} floating-point operations, at least two trillion parameters, or a global top 10 ranking on specified public evaluations at the time of export. China's restrictions would also cover, subject to thresholds and exclusions, models trained on "important data" and specified agent, computing-cluster, chip design, vulnerability-mining, detection, steganography, voiceprint, and translation technology.

Table 2 summarizes how MOFCOM's Q&A applies the restricted large-model entries.

Table 2: Proposed AI Treatment Under MOFCOM's Explanation

Arrangement	Proposed treatment
Overseas access through an API, app, web interface or SaaS, or lightweight local deployment on end-user devices	**Outside** large-model export management; "lightweight" is not defined
Other overseas local deployment of a restricted model, or transfer of its covered weights, source code or checkpoints	**Would require a technology-export license**. Deployment on the developer's own overseas cloud may qualify for automatic licensing where risks are considered controllable.
Open-sourcing; Chinese developer's own overseas computing centers; overseas chip tape-out; joint R&D using overseas resources; international standards work	**Proposed automatic licensing and other facilitation**; procedures and eligibility criteria remain to be defined
Technology already public through open-source release or academic publication	**Excluded** from the proposed AI entries
Prohibited technology, such as large models trained on core data	**No facilitation**; export would be prohibited

Implications for AI Developers and Users

- **A first release is not "already public."** The public-domain exclusion covers technology that is already public, so a first release of covered restricted technology would need to be assessed under the proposed facilitation route.
- **The service label does not decide the question.** Moving covered weights to an overseas environment would require separate analysis even if users receive only API access, so parties should consider documenting what actually moves and address portability if access ends.

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- **Contract structure matters.** For companies outside China using Chinese models, a hosted-service agreement may be easier to perform than a license requiring delivery of weights.

Interim Registration and Deal Terms

Until the revised Catalogue takes effect, exporters must register the listed technologies before export through the Technology Trade Management Information application on MOFCOM's unified business platform. Registration is currently triggered by (i) a transfer of technology ownership to an offshore entity or individual, (ii) licensing domestic technology for offshore use, (iii) a change in the owner or actual controller of domestic technology to an offshore entity or individual, and (iv) other situations MOFCOM specifies. MOFCOM expects exporters to determine for themselves whether a technology is covered.

How Registration Fits with Existing Procedures

- **Interim registration** is a filing made before export, not an approval, and does not replace any authorization otherwise required.
- **Licensing under TIER** applies to technology already classified as restricted under the Regulations on the Administration of Technology Import and Export (TIER): a letter of intent before substantive negotiation or signing, then an export license, with the contract effective only on issuance. A proposed entry does not, merely by being proposed, start that sequence.
- **Contract registration** under TIER applies to freely exportable technology, generally within 60 days after the contract takes effect, with a separate timetable for royalty-based contracts. That later deadline does not defer the pre-export filing.

Stakeholders should consider screening diligence disclosures at each stage; a non-disclosure agreement or closing condition does not substitute for a required authorization.

Deal Considerations

- **Contingent deliveries.** Default, step-in, escrow-release, and insolvency provisions may require platform ownership or model-weight transfers beyond the initial license or service. Parties should consider classifying those deliveries at signing and before performance, with lawful alternatives, price adjustments, or termination rights if a transfer would be prohibited or cannot be authorized.
- **Timing and conditions.** Parties should consider building registration and any required licensing into deal timetables, conditions precedent, long-stop dates, and change-in-law clauses, with clear allocation of filing responsibility and of the cost if an essential right cannot be delivered.
- **Definitions and payments.** Parties may benefit from agreements that distinguish product-specific know-how from platform technology; specify the permitted rights, delivery conditions, and treatment of improvements for each; and tie payments to rights that can be delivered separately.
- **Group structures and pending assignments.** Intra-group IP assignments, offshore holding structures, and shared R&D may merit review, because a trigger does not require a third-party sale. So do pending patent assignments: China National Intellectual Property Administration records assignments of Chinese invention or utility-model patents from mainland holders to offshore recipients only with technology-export documentation.
- **Other regimes.** Catalogue classification does not resolve data, human genetic resources, dual-use, investment-review, or outbound-investment obligations, including the State Council Provisions on

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Outbound Investment (Order No. 837), which would cover a Chinese parent's contributions to an offshore NewCo.

Policy Context and What to Watch

MOFCOM describes the revision as a routine adjustment addressing security, biosecurity, and international cooperation, and states that it is not directed at any particular country, region or entity.

- **Separate investment review in China.** On April 27, 2026, China's foreign investment security review office prohibited the foreign acquisition of Manus and required the transaction to be reversed. The brief notice gives no reasoning and should not be read as an origin-based rule under Announcement No. 48.
- **Parallel U.S. measures.** The United States has proposed similar outbound measures over the past several years. In January 2025, the United States issued the "AI Diffusion Rule," which established new export controls on AI technology, including certain model weights. However, in May 2025 the U.S. Department of Commerce announced a pause on enforcement of the AI Diffusion Rule, and has not announced any updates or revisions since that time. More recently, on Oct. 22, 2026, Treasury proposed COINS Act regulations that would, if finalized, extend outbound-investment prohibitions to specified biotechnology activities. Comments on the proposed rule are due Dec. 7, 2026. That proposed rule would apply the existing outbound investment security program framework to certain investments by U.S. persons in entities engaged in biotechnology activities in China. It would not cover exports or licensing transactions with no equity or investment component (though existing U.S. export controls may). The pending Biotech Investment National Security Act would expressly cover US-person licensing of a "prohibited technology" from a "covered foreign person."
- **What to watch.** Priority consultation questions include ownership versus licensing, actual control, platform versus product deliverables, AI threshold calculations, "lightweight" deployment and "own" cloud, automatic licensing (including whether counterparties on China's restricted lists will be excluded), and how interim registration fits with existing procedures. Companies with transactions in progress may wish to comment before Nov. 15, 2026. During the comment period, China's interim registration applies regardless, including for Japanese and European counterparties with no U.S. nexus.

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