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China Proposes Export Controls on CGT and siRNA Technologies: Key Points and How to React

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On October 16, 2026, the Ministry of Commerce ("MOFCOM") and the Ministry of Science and Technology ("MOST") issued Announcement No. 48 of 2026 ("Announcement 48"), opening a public consultation on amendments to China's Catalogue of Technologies Prohibited or Restricted from Export (the "Catalogue"). Announcement 48 also subjects the export of technologies proposed for inclusion to interim registration, effective from the date of its issuance.

The current Catalogue was promulgated in 2023 and partially adjusted in 2025. To date, its biopharmaceutical entries have centered on Chinese medicinal material resources, vaccine production strains, and tissue engineering and gene editing of human germ cells. The draft, for the first time, brings technology and process platforms and novel target discovery and validation technologies in cell and gene therapy ("CGT") and small interfering RNA ("siRNA") within the scope of control, reaching directly into the core of innovative drug R&D and cross-border collaboration. License-out, co-development and NewCo transactions have in recent years become key channels through which Chinese biopharmaceutical companies participate in international collaboration, and the proposed amendments have accordingly drawn close attention across the industry.

In brief

- **Scope.** In the biopharmaceutical field, the draft reaches only three areas: CGT, siRNA and pathogenic microorganisms. Small molecule targeted drugs, antibodies and other areas that have driven outbound deals in recent years are not included. Within CGT and siRNA, only two technologies are caught.
- **Drug technology and process platforms: prohibited.** Proprietary platforms may not be exported, but the prohibition is directed at one form of export, the outbound transfer of ownership. Arrangements that transfer no ownership, including license-out and the provision of outsourced R&D and manufacturing services using the technology, fall outside the scope of the prohibition

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itself. However, both an outbound transfer of ownership and a license-out of the technology to an overseas party must still be registered under the interim registration requirement described below.

- **Novel target discovery and validation technology: restricted.** Proprietary technology for discovering and validating novel targets ordinarily needs an export license, but license-out and co-development qualify for automatic export licensing. The control does not reach the later development or commercialization of a pipeline directed at such a target.
- **Already in force.** Interim registration applies from the date Announcement 48 was issued, and covers both an outbound transfer of ownership and a license-out to an overseas party. Transactions in progress need to be reviewed now rather than when the amendments are finalized.

What is being controlled

The draft adds three technologies to the prohibited list and two to the restricted list, across three fields: CGT, siRNA and pathogenic microorganisms. Controls on pathogenic microorganism technology reflect national security and biosafety considerations and are comparatively strict. In CGT and siRNA, the scope is narrowly drawn, reaching only platform technologies that are general in nature and reusable across products, together with target discovery and validation technology. At the conduct level, each entry comes with an exemption or facilitation measure for outbound licensing: licensing out platform technology is not subject to the prohibition, and licensing out target discovery and validation technology qualifies for automatic export licensing. Separately, and regardless of which of these categories a technology falls into, Announcement 48 requires interim registration of any outbound transfer of ownership or any outbound licensing of the technology to an overseas party.

Field	Technology	Control	Carve-out	Net effect on deals
CGT and siRNA	Proprietary **drug technology and process platforms**	Prohibited from export	Only an **outbound transfer of ownership** is prohibited; **License-out** and outsourced R&D or manufacturing services are **outside the scope of the prohibition**, though license-out still requires interim registration;	License-out and transfer transactions for specific **pipeline products** are unaffected. **License-out of the platform technology** is not prohibited; only outbound **transfer** of ownership is prohibited. Both license-out and transfer require interim registration.
	Proprietary **novel target discovery and**	Restricted (export license required)	**Automatic export licensing** for **license-out**, co-development, public	License-out and transfer transactions for specific **pipeline products** are unaffected.

Field	Technology	Control	Carve-out	Net effect on deals
	validation technology		health emergencies and humanitarian need;	License-out of **novel target discovery and validation technology** receives automatic export licensing; outbound **transfer** is generally subject to substantive export licensing.
Gain-of-function technologies for pathogenic microorganisms, whether by artificial genetic modification or by directed serial passage		Prohibited from export	None	Largely unrelated to ordinary pharmaceutical transactions

Platform technology: only an outright transfer is prohibited

The draft defines a technology and process platform as a reusable set of underlying, common technologies, built up through sustained R&D, capable of supporting the development of multiple drugs. Development technologies and processes used for a single drug product are expressly excluded. What the draft targets is the underlying platform supporting the development of multiple drugs, not the technology or process serving one particular drug.

Prohibition here does not mean that export is barred in every form. It bites on one form of export, the outbound transfer of ownership. The draft confirms that license-out, and the provision of outsourced R&D and manufacturing services using the relevant technologies and processes, transfer no ownership and fall outside the scope of the prohibition. It also confirms that technologies and processes necessary for the R&D, testing, manufacturing, quality control, marketing approval and compliance of a specific drug product, in the course of that product's cross-border collaboration or commercial transactions, are outside that scope.

In our view, a license-out of platform technology and a conventional co-development project will therefore not be caught by the prohibition, provided no transfer of ownership is involved, though the license-out itself will still need to be registered under the interim arrangement. Exporting technology tied to a single pipeline or product is unaffected either way, whether structured as a license or as an assignment.

Novel target discovery and validation: restricted, but with automatic export licensing for license-out transactions

The draft defines novel target discovery and validation technology as technology used to screen, discover and confirm novel targets and to identify drug action sites with druggable potential. It does not reach the other technologies used in the subsequent development and commercialization of pipelines directed at those targets. A novel target means one that has not been publicly disclosed anywhere in the world through patents, academic literature, public databases, industry technical materials, academic conferences or similar channels, so technology for screening and validating known targets stays outside the Catalogue.

Restricted technology ordinarily requires an export license and may not be exported without approval. Here the draft makes automatic export licensing available for exports in connection with public health emergencies, humanitarian relief, joint R&D drawing on overseas resources (co-development), license-out and similar situations. Under the Foreign Trade Law as it stands, automatic export licensing describes an arrangement under which the regulator shall grant the license applied for in respect of the technology concerned and issue the corresponding certificate. In our view, automatic export licensing gives co-development and license-out transactions involving this technology a predictable path, and significantly reduces the uncertainty that approval of restricted-export technology would otherwise introduce into deal effectiveness and timetables. An outbound transfer of ownership, by contrast, would generally remain subject to substantive export licensing.

Interim registration

Although the draft itself has not taken effect, an interim pre-export registration requirement introduced alongside it has already been in force since October 16, 2026. Until the revision formally takes effect, a technology exporter must register before exporting any technology listed in the draft. Registration is made through MOFCOM's online platform (https://ecomp.mofcom.gov.cn). Exports that have already begun but are not yet complete are also subject to interim registration.

Interim registration is required for the following exports of such technologies: (i) an outbound transfer of technology ownership; (ii) a license-out of the technology for use overseas; (iii) a transaction that results in the owner or actual controller of the relevant domestic technology becoming an overseas entity; and (iv) any other circumstance MOFCOM separately designates.

What to do now

Taken as a whole, the scope of control here is restrained. On the face of the draft, it reaches essentially only CGT and siRNA, and small molecule targeted drugs, antibodies and many other areas that have driven outbound deals in recent years are not included. Even within CGT and siRNA, control extends only to two categories of underlying technology, namely platforms and novel target discovery and validation, and exceptions or facilitation measures are provided for common pharmaceutical transaction models. Ordinary license-out of a specific product is unaffected.

On that basis, we suggest companies react as follows:

I. Day-to-day operations: inventory, segregate and classify controlled technologies

We suggest running an internal inventory of technology assets, splitting CGT and siRNA technologies into three categories: underlying general platform technology, target discovery and validation technology, and development processes dedicated to a single pipeline. Keep a technology list, ownership documentation and R&D records for each. When a transaction later arises, the company can state clearly which category the technology proposed for export falls into, and in particular demonstrate that what the transaction involves is only the technologies and processes for a "single drug product".

II. Pharmaceutical transactions: interim registration, deal structure and contract terms

1. **Complete the interim registration.** As mentioned above, any transaction that might involve an export of technologies listed in the draft during the interim period has to be registered. This also applies to exports that have already commenced but are not yet complete. In particular, a company that has recently signed a patent assignment, license or co-development agreement should review those projects carefully, checking whether there is any ongoing or pending technology transfer obligation and whether any formalities for change of patent ownership need to be fulfilled, and decide whether registration is required accordingly.

2. **Carefully design the transaction structure to comply with export control rules.** Both the offshore buyer or licensee and the onshore seller or licensor should factor these measures into the deal, run proper due diligence, and establish whether it touches the technology types and fields above. The structure should then take into consideration: which technology is controlled, and which export activity is controlled. Where CGT platform technology is involved, for example, only a licensing model rather than a transfer of ownership meets technology export administration requirements.

3. **Adapt the transaction terms.** The draft will affect a number of contract terms in China's pharmaceutical deals. One example is the definition of know-how: its scope may need to be capped at what export controls allow. Both parties should review the provisions in their transaction documents that bear on the Catalogue, raise the implications with their legal teams early, and revise the wording where that is needed to protect each side under the contract. If the subject technology falls within scope, they should also prepare in good time for the administrative procedures and filings that may apply once the amendments formally take effect.

Concluding remarks

Overall, the scope of control proposed for the biopharmaceutical field is restrained. The focus is the outbound transfer of platform technologies and novel target discovery and validation technologies in CGT and siRNA, while exceptions or facilitation measures are provided for common transaction models such as license-out, outsourced R&D and manufacturing, and co-development. This approach reflects a policy orientation that weighs guarding against technology risk alongside protecting normal international collaboration.

It should be noted that the interim registration requirement has applied since Announcement 48 was issued. We suggest that companies review their ongoing and planned cross-border transactions as soon as possible to determine whether registration is required, and that they use the consultation period to assess their compliance boundaries against their own business and submit comments in time.

We will continue to follow the progress of the amendments to the Catalogue, work with others across the industry to understand and keep pace with the latest requirements on technology export regulation, and share our observations as matters develop.

Important Announcement

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