China's exclusivity framework is arriving one pillar at a time

Patent term compensation, regulatory data protection, and market exclusivity are all in Chinese law — but not at the same stage of readiness. The 2026 Measures supply the procedures regulatory data protection had been missing.

Part one: patent term extension and adjustment in China

01 Not one reform but three

They are usually discussed together. They did not arrive together, and they are not equally usable today.

2002

Implementing regulations introduce six years of protection for undisclosed data submitted for marketing authorization. The provision exists; no procedure exists to invoke it.

2020–24

The amended Patent Law creates patent term compensation for new drugs, in force from 2021. Implementing rules and examination guidelines follow, giving it working procedure.

2026

Revised implementing regulations take effect on May 15 and supply the procedures regulatory data protection was missing. Market exclusivity stays at the level of statutory text.

02 Three pillars, three different jobs

They are often discussed together, but they protect different things, and they are not established in the same way.

PILLAR 01

Patent term compensation

Restores patent life lost to regulatory review. Tied to the patent, not the approval.

Up to 5
years
Effective term after approval capped at 14 years.

In force, procedures set

PILLAR 02

Regulatory data protection

Stops a competing application relying on the originator's undisclosed data — nonclinical and CMC as well as clinical. Independent of patent status.

Up to 6
years
For eligible undisclosed data, on the terms in the regulations.

Procedures set in 2026

PILLAR 03

Market exclusivity

Blocks approval of a competing product for a set period. China has no orphan or pediatric designation to apply for — eligibility follows from the product itself, unlike the US and EU.

Up to 7
years, rare disease
Seven years rare disease; two years pediatric.

No procedure published

03 How it compares

China now has the same three instruments as the established markets. The periods are shorter, the procedures are newer, and eligibility is reached by a different route.

INSTRUMENT	UNITED STATES	EUROPEAN UNION	CHINA
Regulatory data protection	5 years for new chemical entities; 12 years for biologics	8 years data protection plus 2 years market protection	Up to 6 years for eligible undisclosed data
Rare disease market exclusivity	7 years	10 years	Up to 7 years, no designation procedure
Pediatric incentive	6 months added exclusivity	2 years added orphan exclusivity, with an agreed pediatric plan	Up to 2 years, no designation procedure
Patent term restoration	Up to 5 years, 14-year effective cap	Supplementary protection up to 5 years, plus 6 months pediatric	Up to 5 years, 14-year effective cap
Where the framework stands	Long established, with settled practice	Under reform — agreed, not yet in force	Data protection operational; exclusivity procedure pending

China operates no orphan drug or pediatric designation procedure: eligibility follows from the product and its indication under Chinese criteria, so a US orphan-drug designation or EU orphan status has no counterpart to carry over. European figures reflect the current framework; the agreed pharmaceutical package would revise baseline protection periods once in force. Periods shown are maxima and depend on product type and eligibility.

04 What it means for sponsors

The three pillars sit at three stages of readiness. That is what should drive planning.

Match the pillar to the product, and decide it during development

Patent term compensation turns on patent timing. Data protection turns on what the dossier contains. Rare disease and pediatric exclusivity turn on whether the product qualifies under Chinese criteria — there is no designation to secure, and US or EU orphan status brings nothing across.

Two pillars can be planned on today; the third cannot

Patent term compensation has had working procedure for years, and the 2026 Measures supply what data protection was missing. Rare disease and pediatric market exclusivity remain high-level statutory text with no published procedure — track it rather than build a position on it.

THE FULL ANALYSIS

What each pillar covers, how eligibility is decided, and where the gaps remain

Read the article

A specialist life sciences product development partner supporting regulatory strategy, clinical research, evidence generation, vigilance, market access, and medical, scientific, and commercial communications.

Reflects developments as of August 2026. The implementation procedure for rare disease and pediatric market exclusivity has not been published. Not legal advice.