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Guan Yue, 18 February 2026, first published by IAM

On 27 January 2026, China's State Council promulgated the amended Implementation Regulations of the Drug Administration Law, which will come into force on 15 May 2026. This is the fourth amendment but the first overhaul since its enactment in 2002, with more than 90% of the articles amended, covering the entire lifecycle of pharmaceuticals, from R&D and registration to manufacturing, distribution and supervision.

The amended regulations address key issues, including market exclusivity, protection of pharmaceutical trial data and the acquisition, re-registration and assignment of drug registration certificates.

Clinical-oriented innovation

Article 3 outlines the objectives and priorities of the drug watchdog – the National Medical Products Administration (NMPA) – including improving the drug innovation regime, supporting clinical-oriented drug development and innovation, encouraging R&D, clinical promotion and administration of new drugs, and facilitating the R&D and innovation of generic drugs to enhance their quality and efficacy. It explicitly underlines the overarching role of "clinical value" in driving drug development and innovation.

Market exclusivity period

Article 21 marks that the NMPA is incentivising R&D and innovation of paediatric drugs and drugs for the treatment of rare diseases by offering them market exclusivity period.

For new varieties of paediatric drugs or those in new dosage forms, of new specifications or with expanded paediatric indications, a market exclusivity period of no more than two years may be granted.

For pharmaceuticals used to treat rare diseases (ie, orphan drugs), and for which the marketing authorisation holder commits to ensuring supply, a market exclusivity period of no more than seven years may be granted. The market exclusivity period will be terminated if the holder fails to fulfill the supply commitment.

This newly introduced market exclusivity period represents a new policy initiative, which offers an alternative route in parallel to the patent protection regime that grants exclusive rights over technical solutions. While competitors could utilise a circumvention strategy via design-around of an existing patent, market exclusivity grants an ironclad monopoly to the rights holder, erecting an administrative barrier to block the market entry of a functionally similar design-around product developed by a competitor until the granted exclusivity period expires.

Innovators can leverage this practice to create a robust dual-moat strategy: patenting technical solutions during the R&D process and reinforcing it by securing regulatory exclusivity where possible. This bifurcated approach would significantly enhance the predictability of ROI for drug development in underserved areas like paediatrics and rare diseases.

Undisclosed trial data

Article 22 offers protection for undisclosed trial data and data concerning drugs that contain new chemical components or other eligible drugs. This protection can be obtained and submitted by a marketing authorisation holder on its own. It also bans unfair commercial exploitation of this data by any individual or organisation.

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The regulations set a six-year protection period for this data from the date of drug registration. During this time, any registration application filed by other applicants using the protected data without the marketing authorisation holder's consent will be dismissed, except where such data is obtained by the applicants on their own.

The regulations also enjoin the NMPA from disclosing the protected data, unless such disclosure is necessitated by public interest or measures have been taken to ensure that such data will not be commercially exploited in an unfair manner.

Undisclosed and compliant trial data is a valuable asset in which pharmaceutical companies invest heavily to acquire during R&D. The data exclusivity regime thus serves as a potent weaponry the legitimate holder could wield against free riders. Similar to trade secrets, holders must take reasonable efforts to document the generation of such data, testify its legitimate ownership and maintain its confidentiality.

Holders are therefore strongly advised to exercise strict control over public access to the data assets, explicitly labelling those disclosable in papers, conferences or roadshows and those categorised as "undisclosed data for registration". It is also essential for holders to introduce safeguards and acquaint employees with data ownership, confidentiality obligations, usage and liability for breach of contract.

Drug registration certificates

Article 16 provides that the NMPA shall review and approve the drug along with the chemical active ingredients, and issue drug registration and chemical active ingredient approval certificates. The application for assigning these certificates will be subject to NMPA approval, and its decision will be made within 20 working days from the date of accepting the application. Article 17 sets a five-year validity period for these certificates and holders are obligated to file for re-registration upon expiration.

The articles further establish the legal basis for the acquisition, re-registration and assignment of these certificates, making them an integral part of M&A transactions in the pharmaceutical field.

Key takeaways

It is a very welcome development that the newly amended regulations have overhauled the whole drug administration regime by adopting seismic changes, like market exclusivity for players in the underserved fields, safeguards for data assets and registration certificates as tradable assets. It is also worth noting that the NMPA's prioritisation of clinical value may have a far-reaching impact on its practice. Industry observers will be keeping a close eye on how these developments evolve in practice.