China Medtech Monthly:
Domestic Innovation Push Meets Global Trade Pressure
September 1 to September 30, 2025

September 2025 crystallized the defining tension for China's MedTech sector as the U.S. government launched a national security investigation into medical device imports, threatening severe new trade barriers. This external pressure was met with an equally forceful domestic policy push, headlined by Shanghai's ambitious action plan to cultivate a world-class high-end device industry with goals of securing over 500 new Class III approvals by 2027.

For companies operating in this space, the month underscored a dual reality: navigating escalating geopolitical risk while simultaneously competing for a stake in a domestic market being rapidly reshaped by unprecedented government support for local innovation. This domestic market is showing clear signs of recovery, with key industry bellwethers signaling a return to year-on-year revenue growth in Q3, indicating hospital procurement is normalizing.

The key near-term signal to watch is the outcome of the U.S. investigation, which could fundamentally alter global supply chains, alongside the detailed rules for China's upcoming national volume-based procurement round for high-value consumables.

Policy & Regulatory

The policy landscape in September was defined by a stark duality: while rising geopolitical risk from the U.S. creates significant external headwinds, powerful domestic industrial policies and ongoing regulatory maturation are creating unprecedented tailwinds for innovation and manufacturing within China.

US Launches Security Probe

The U.S. Department of Commerce on September 2 initiated a Section 232 investigation into the national security effects of imported medical devices, personal protective equipment (PPE), and medical consumables.[1] This move significantly escalates trade tensions, shifting the rationale for potential tariffs from economic competition to national security, a framework that grants the U.S. administration broad authority to impose severe restrictions like high tariffs or quotas with fewer legal challenges.[3]

The investigation's scope is vast, covering products from basic syringes and gloves to complex pacemakers and MRI machines.[4] The Commerce Department's request for public comment, due by October 17, specifically seeks input on U.S. reliance on foreign supply chains, the concentration of imports from a small number of countries, and the potential for foreign nations to "weaponize their control over supplies".[3] This action creates profound uncertainty for Chinese manufacturers, who count the U.S. as a primary export destination, and threatens to disrupt established global supply chains.

The investigation represents a strategic pivot. By framing medical device supply as a national security vulnerability, it provides a powerful justification for policies aimed at reshoring or near-shoring manufacturing, directly challenging China's role as a global production hub.

Shanghai's Ambition Crystallizes

In a powerful domestic counter-narrative, the Shanghai municipal government on September 15 released its "Action Plan for Promoting the Full-Chain Development of High-End Medical Device Industry".[5] The plan establishes Shanghai as a focal point for China's self-reliance ambitions in the sector, setting aggressive targets to be achieved by 2027.[6] Key goals include securing over 500 new domestic Class III medical device approvals, achieving more than 100 overseas market approvals for locally developed products, and cultivating at least two "leading enterprises" with annual output values exceeding ¥10 billion ($1.41 billion) each.[8] The strategy focuses on "7+X" key categories, including surgical robots, AI-powered devices, and implantable products, and calls for the creation of three major industrial clusters in Pudong, Minhang, and Jiading.[6]

The plan is not merely a list of targets but a comprehensive blueprint for building an entire ecosystem, explicitly encouraging foreign-invested R&D centers and the localization of imported device manufacturing.[7] This municipal strategy serves as a direct, well-funded implementation of the national drive for technological sovereignty, creating a powerful incentive structure for both domestic and international firms to deepen their innovation and manufacturing footprint within the city.

Guangdong Bay Area Fast-Track Solidified

Guangdong's provincial government on September 15 issued the "Administrative Measures for the Catalog of Clinically Urgent Drugs and Medical Devices Imported from Hong Kong and Macao into the Greater Bay Area," which will take effect on November 1, 2025. This policy formalizes and streamlines the Greater Bay Area (GBA) "urgent use" pathway, a crucial channel for foreign devices to gain market access before national NMPA approval. The new measures establish a "pre-review database," a pivotal mechanism that allows manufacturers to proactively submit information on their devices for consideration. This transforms the GBA pathway from a reactive, government-led selection process into a proactive, manufacturer-driven nomination process.

NMPA Fine-Tunes Framework

China's National Medical Products Administration (NMPA) continued its work of refining the country's regulatory architecture to support higher-quality development. On September 1, the agency announced the abolishment of five outdated industry standards, including YY/T 1000.1—2005 related to standard-setting procedures, and issued modifications to three others, such as YY/T 0661—2017 for semi-crystalline polymers used in surgical implants.[10] The abolished standards included those related to standard-setting procedures and adverse event coding.

Separately, the NMPA canceled two medical device registration certificates on September 4. The agency also published 15 new medical device industry standards (Announcement No. 92) on September 23, including a new standard for blood pressure sensors (YY 0781—2025). In addition, new comprehensive guidelines for medical device registration self-inspection became effective on September 16.[11] These rules mandate that manufacturers of Class II and III devices integrate robust self-inspection capabilities, including qualified personnel and proper testing equipment, directly into their quality management systems. This regulatory housekeeping raises the quality bar for domestic manufacturing and shifts greater accountability onto companies to ensure the integrity of their registration data from the outset.

These actions, while seemingly routine, are foundational. By strengthening quality control and modernizing technical standards, the NMPA is laying the groundwork necessary to build domestic and international trust in the wave of high-end Chinese medical devices its industrial policies are designed to produce.

Highlights: Policy & Regulatory

Date	*News Title*	*Link*
2025-09-26	**U.S. Department of Commerce Publishes Notice on Section 232 Investigation** The notice formally requests public comment on the national security investigation into imports of medical devices, PPE, and consumables, with a deadline of October 17.	Link [English]
2025-09-23	**NMPA Publishes 15 New Medical Device Industry Standards** Announcement No. 92 includes a new standard for blood pressure sensors (YY 0781—2025) among other updates.	Link [Chinese]
2025-09-17	**Shanghai Releases Action Plan to Boost High-End Medical Device Industry** The municipal government unveiled a comprehensive plan with 20 measures and ambitious 2027 targets to become a globally influential hub for medical device innovation.	Link [English]
2025-09-16	**NMPA Guidelines for Medical Device Registration Self-Inspection Become Effective** The new rules require manufacturers of Class II and III devices to build self-inspection capabilities into their quality management systems to ensure data integrity.	Link [English]
2025-09-15	**Guangdong Issues New Administrative Measures for GBA Urgent Use Policy** Effective November 1, the new rules formalize a "pre-review database" for manufacturers to submit clinically urgent devices for consideration for use in the GBA before national approval.	Link [Chinese]
2025-09-10	**NMPA Commissioner Meets with Hong Kong Secretary for Health** The meeting focused on deepening regulatory cooperation and exchange between mainland China and the Hong Kong Special Administrative Region.	Link [English]
2025-09-05	**NMPA Announces Strategy to Advance High-End Medical Device Regulation** The agency outlined a comprehensive strategy to streamline review, strengthen lifecycle supervision, and accelerate the adoption of new technologies for high-end devices.	Link [English]
2025-09-02	**U.S. Initiates Section 232 Investigation into Medical Device Imports** The Secretary of Commerce launched an investigation to determine the effects of medical device and consumable imports on U.S. national security.	Link [English]
2025-09-01	**NMPA Abolishes 5 and Revises 3 Medical Device Industry Standards** The regulator updated its standards framework, repealing five obsolete standards and issuing modification orders for three others to align with current technology and practices.	Link [Chinese]

Manufacturing & Logistics

The industry's physical ecosystem is clearly expanding, with major investments in advanced manufacturing capacity and large-scale exhibitions showcasing innovation, though this growth occurs against a backdrop of macroeconomic uncertainty and persistent supply chain pressures.

Industry Convenes in Shanghai & Guangzhou

September was a pivotal month for industry gatherings, showcasing the latest manufacturing capabilities and supply chain innovations. Medtec China 2025 took place in Shanghai from September 24-26, serving as a key event for medical device design, components, and contract manufacturing services.[12] The event drew suppliers and manufacturers from across the globe, focusing on advanced materials, electronics, and automation.

This was immediately followed by the 92nd China International Medical Equipment Fair (CMEF) Autumn Exhibition, held in Guangzhou from September 26-29.[14] As one of Asia's largest medical exhibitions, CMEF spanned nearly 200,000 square meters and gathered approximately 4,000 exhibitors and 120,000 professional visitors.[14] The fair featured 28 specialized zones dedicated to high-priority sectors like surgical robotics, medical imaging, and smart healthcare, directly reflecting the technology areas targeted by new government industrial policies.[15] These exhibitions act as crucial barometers of the industry's progress and serve as physical marketplaces for the increasingly localized and sophisticated supply chains China aims to build.

Rosti Bets on China Capacity

Underscoring confidence in China's manufacturing ecosystem, Rosti Integrated Manufacturing Solutions (Suzhou) Co., Ltd. used Medtec China to announce a significant capacity expansion.[13] The contract development and manufacturing organization (CDMO) confirmed it will add a 500-square-meter ISO Class 8 cleanroom to its Suzhou facility, with completion scheduled for February 2026.

This investment is a direct response to surging demand for high-quality, compliant medical device production in China. Rosti highlighted its end-to-end capabilities, from design and prototyping to high-volume injection molding and assembly, all within a quality framework compliant with global standards like ISO 13485 and the FDA's 21 CFR 820.[13] Such investments by sophisticated CDMOs are critical for the entire ecosystem, enabling both domestic startups and multinational firms to scale production while navigating complex regulatory requirements.

Macro Headwinds Persist

While the medtech sector benefits from strong policy support, it is not immune to broader economic trends. The September ISM Manufacturing PMI® registered 49.1, the seventh consecutive month of contraction, while the Services PMI® was unchanged at 50.0, indicating stalled growth.[16]

Commentary from survey respondents across various industries frequently cited the impact of tariffs on input costs and business uncertainty, which in turn subdued capital expenditure and customer orders.[16] For the medtech sector, these macroeconomic headwinds can translate into tighter hospital budgets and more cautious purchasing decisions for capital equipment. This creates a challenging environment where companies must pursue significant sector-specific growth opportunities while managing the risks of a less certain broader economy.

Highlights: Manufacturing & Logistics

Date	*News Title*	*Link*
2025-09-26	**92nd CMEF Autumn Exhibition Opens in Guangzhou** The major international medical equipment fair featured ~4,000 exhibitors and specialized zones for high-growth areas like surgical robotics and smart health.	Link [English]
2025-09-24	**Medtec China 2025 Kicks Off in Shanghai** The exhibition focused on the upstream of the medical device industry, including design, R&D, raw materials, and manufacturing components and technologies.	Link [English]
2025-09-17	**Beijing International Medical Equipment Exhibition Held** The 46th CMEH in Beijing gathered over 200 manufacturers and focused on a wide range of hospital equipment, from medical imaging to diagnostic reagents.	Link [Chinese]
2025-09-06	**Rosti Announces Cleanroom Expansion Ahead of Medtec China** The CDMO announced plans for a new 500m² ISO Class 8 cleanroom in Suzhou to meet growing demand for compliant medical device manufacturing.	Link [English]

Clinical & Patients

China's clinical research capabilities are advancing into more sophisticated and disruptive therapeutic areas, with a strong focus on digital and AI technologies, while regulators concurrently work to strengthen the underlying quality and compliance framework.

World-First AI Procedure

On September 5, Sir Run Run Shaw Hospital, affiliated with Zhejiang University School of Medicine, announced it had successfully performed the "world's first" procedure using a novel system that combines AI-powered navigation, morphological perception, and flexible robotics. The technology enables a "one-stop" minimally invasive surgery for patients with bilateral lung nodules.

The active branding of the procedure as a "world-first" by a top-tier Chinese hospital highlights the rapid adoption of innovative technology and serves as a powerful market access strategy.

Novel Hypertension Therapy Trialed

A landmark first-in-human clinical trial for a novel hypertension treatment was registered in China on September 30, signaling a push into disruptive medical technology.[18] The trial, sponsored by Fuwai Central China Cardiovascular Hospital, will evaluate a new laparoscopic renal denervation (RDN) system for patients with refractory hypertension. Significantly, the RDN trial is sponsored by the hospital itself, making it an Investigator-Initiated Trial (IIT). This reflects a broader trend where top Chinese hospitals are acting not just as sites for industry-sponsored trials but as incubators for new device concepts, generating early proof-of-concept data.

This development is significant because the device employs an extravascular approach, ablating overactive renal nerves from the outside of the artery via a minimally invasive surgical procedure.[19] This contrasts with most existing RDN technologies, which use a catheter-based, endovascular (inside the artery) method to deliver radiofrequency or ultrasound energy.[20] The extravascular technique aims to achieve a more complete and consistent denervation while avoiding potential damage to the arterial wall, a key limitation of earlier endovascular systems.[22] By pursuing a fundamentally different modality, Chinese innovators are attempting to leapfrog the current generation of RDN devices rather than making incremental improvements.

Digital & AI Trials Emerge

The clinical trial pipeline in September also revealed a strong and growing emphasis on digital health and artificial intelligence applications. A review of new registrations on the Chinese Clinical Trial Registry (ChiCTR) highlighted several forward-looking studies.

Notable trials include an interventional study at Zhujiang Hospital evaluating a large language model (LLM)-based psychological rehearsal strategy to improve arthroscopic skill retention among surgeons (ChiCTR2500110127).[18] Another study, registered by West China Fourth Hospital, will assess a telehealth management program for patients with chronic obstructive pulmonary disease (ChiCTR2500110004).[24] In diagnostics, a new study will focus on developing and validating a machine learning algorithm to predict the risk of purulent meningitis in preterm infants (ChiCTR2500110005).[24]

This pipeline of clinical research serves as a strong leading indicator that AI and digital health are moving beyond the conceptual stage and into rigorous clinical validation, promising a new wave of smart medical devices for the Chinese market.

NMPA Bolsters Trial Oversight

As the volume and complexity of clinical trials in China grow, regulators are taking proactive steps to ensure data quality and integrity. Throughout September, the NMPA's Center for Medical Device Evaluation (CMDE) and its Yangtze River Delta sub-center organized multiple training sessions focused on clinical trial quality management.[25]

Events held on September 5 in Shanghai and again from September 17-19 brought together key personnel from medical device R&D institutions, manufacturers, and clinical trial sites.[25] The training covered topics such as clinical trial database submission requirements, quality management specifications, and common issues found during inspections. These initiatives are critical for building a robust and reliable clinical trial ecosystem, which is essential for both securing domestic approvals and gaining the trust of international regulators for China-developed innovations.

Highlights: Key Clinical Trial Registrations

Date	*News Title*	*Link*
2025-09-30	**First-in-Human Study of Laparoscopic Renal Denervation in Refractory Hypertension** A trial to evaluate the safety and efficacy of a novel extravascular renal denervation system for treating resistant high blood pressure.	Link [English]
2025-09-30	**Application of Large Language Model-based Psychological Rehearsal Strategy in Arthroscopic Skill Retention** A study to determine if an AI-based psychological rehearsal tool can help surgeons retain complex arthroscopic skills.	Link [English]
2025-09-28	**Research on a Closed-loop Facial Nerve Electrical Stimulation System for Hemifacial Spasm** An interventional study assessing a novel electrical stimulation device based on TENG sensors for alleviating hemifacial spasm.	Link [English]
2025-09-28	**A Clinical Study on Novel tTIS Technology Targeting the Cerebellum in Cerebellar Ataxia** An interventional study to evaluate the safety and efficacy of a new temporal interference stimulation technology for treating cerebellar ataxia.	Link [English]
2025-09-28	**Development and Validation of a Machine Learning Algorithm for Meningitis Risk Prediction** A diagnostic test study aimed at creating a predictive model for purulent meningitis in preterm infants using a machine learning algorithm.	Link [English]
2025-09-28	**RCT of Telehealth Management on Cardiovascular Health in COPD Patients** An interventional study to test the effectiveness of a telehealth-based exercise and health management program for patients with chronic obstructive pulmonary disease.	Link [English]
2025-09-05	**SRRS Hospital Announces "World-First" AI-Guided Robotic Surgery for Lung Nodules** The hospital reported the successful application of a new system integrating AI navigation and flexible robotics for "one-stop" bilateral lung nodule procedures.	Link [Chinese]

Innovation & Intellectual Property

A powerful combination of top-down policy support designed to de-risk and accelerate innovation, coupled with proven bottom-up execution in navigating demanding global regulatory pathways, is rapidly advancing China's position as a source of medtech innovation.

NMPA Unveils "10 Measures"

The NMPA solidified its commitment to fostering domestic innovation by formally detailing ten concrete measures to support the development of high-end medical devices.[27] Building on a June announcement, these measures create a comprehensive, full-lifecycle support system designed to accelerate the path to market for breakthrough technologies.[28]

The policy package includes optimizing the special "innovative pathway" review process, improving classification principles for novel technologies like medical AI models and surgical robots, and accelerating the creation of technical standards for emerging fields like exoskeleton robots and radionuclide imaging equipment.[28] The NMPA also took decisive steps to create a clear regulatory pathway for Brain-Computer Interface (BCI) technologies: on September 16, it released YY/T 1987—2025, "Terminology for Medical Devices Utilizing Brain-Computer Interface Technology," followed on September 28 by YY/T 1996—2025, specifying "Test Methods for Sensing and Response Performance" of BCI devices.

Crucially for the digital health sector, the measures also aim to simplify review requirements for AI software where performance is optimized but the core algorithm remains unchanged.[28] This policy is a fundamental shift in the regulator's role, moving from a passive gatekeeper to an active partner in the innovation process by establishing early communication mechanisms and providing proactive guidance.

Beijing R&D Funding Mechanism

At the provincial level, Beijing's Municipal Science and Technology Commission on September 29 launched a "revealed-list-and-bidding-mechanism" to fund the development of foundational R&D infrastructure. This funding mechanism specifically targets gene sequencing and proteomics platforms for bio-sample library construction.

High-Value Domestic Approvals

The NMPA continued to approve a significant number of domestically developed, high-value medical devices. Key approvals announced in September included an extended depth of focus intraocular lens on September 26 and an innovative cardiac cryoablation system with its associated single-use probe on September 29. These approvals are in technically complex fields that were previously dominated by multinational corporations.

Chinese Dental Tech Gains FDA Nod

Demonstrating the growing ability of Chinese manufacturers to meet stringent international standards, Changzhou Finno Medical Technology Co., Ltd. received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its FinScan F350 Dental Cone-beam Computed Tomography (CBCT) system.[30] The clearance, under number K242805, validates the device as substantially equivalent to legally marketed predicate devices in the U.S.

Achieving FDA 510(k) clearance for a complex piece of capital equipment like a CBCT scanner is a significant milestone. It serves as external validation of the company's design controls, manufacturing processes, and overall quality management system. This success is indicative of a broader trend where leading Chinese medtech firms are no longer competing solely on cost but are proving their ability to develop and produce high-value, technologically advanced products for the world's most demanding regulatory markets.

August Approval Data Released

On September 16, the NMPA provided a quantitative look at its recent output, releasing approval data for August 2025.[31] The agency approved a total of 263 medical device products during the month.

The breakdown reveals the strength of the domestic pipeline: 208 of the approvals were for domestic Class III devices, the highest-risk category. This figure significantly outpaced the 31 approvals for imported Class III devices and 22 for imported Class II devices.[31] These numbers provide a clear statistical baseline, illustrating the high volume of advanced domestic products moving through the regulatory system. This trend is poised to accelerate as the NMPA's new innovation-focused policies take full effect.

Highlights: Key Device Approvals & IP News

Date	*News Title*	*Link*
2025-09-30	**NMPA Publishes Daily List of Approved Medical Devices** The agency continued its routine publication of approved and rejected medical device registration certificates, providing transparency on regulatory decisions.	Link [Chinese]
2025-09-29	**Beijing Launches "Revealed-List" Bidding to Fund Bio-Sample Library Tech Platforms** The Beijing Municipal Science and Technology Commission initiated a mechanism to fund foundational R&D infrastructure, targeting gene sequencing and proteomics platforms.	Link [Chinese]
2025-09-16	**NMPA Reports 263 Medical Device Approvals in August 2025** The monthly report showed a high volume of domestic innovation, with 208 domestic Class III devices approved compared to 31 imported Class III devices.	Link [Chinese]
2025-09-13	**Changzhou Finno Medical Technology Receives FDA 510(k) Clearance for Dental CBCT System** The Chinese manufacturer gained U.S. market access for its FinScan F350 cone-beam computed tomography system (K242805).	Link [English]
2025-09-05	**NMPA Publishes 10 Measures to Support High-End Medical Device Innovation** The agency detailed a comprehensive policy to optimize the full lifecycle regulation for innovative devices, from R&D guidance to post-market oversight.	Link [English]

Funding & Partnerships

The investment landscape is maturing, with capital concentrating in strategically important platform technologies, while sophisticated partnerships are increasingly seen as the fastest route to acquiring world-class capabilities, particularly in AI and bioinformatics.

Huakan Bio's Major Haul

Beijing Huakan Biotechnology Co., Ltd. (华龛生物), a company specializing in 3D cell culture technologies, announced the completion of a Series B+ financing round valued at "several hundred million RMB" in September.[5] The investment highlights strong market and government confidence in enabling technologies for the cell and gene therapy sector.

The funding round was notable for its roster of high-profile and state-affiliated investors. Co-leaders included the Beijing Municipal Medical and Health Industry Investment Fund and the Beijing Municipal New Materials Industry Investment Fund, among others.[5] This significant capital injection into a platform technology company aligns with the broader investment trend identified in market reports: a shift toward fewer but larger, more strategic funding rounds directed at companies with foundational technology and clear growth potential.[32] The government's participation underscores the strategic importance of building a robust domestic supply chain for advanced therapies.

AI Powers Diagnostic Alliances

September saw two major global partnerships form around the integration of artificial intelligence into diagnostics, a trend with profound implications for the Chinese market. On September 22, South Korean AI leader Lunit (KRX:328130) and U.S.-based Agilent Technologies (NYSE: A) revealed a collaboration to co-develop AI-powered companion diagnostic (CDx) solutions.[34] The partnership will combine Lunit's AI algorithms with Agilent's tissue-based assays to improve the accuracy and efficiency of biomarker analysis for pharmaceutical development.[35]

Days earlier, on September 18, QIAGEN Digital Insights and Oxford Gene Technology (OGT), a Sysmex Group company, announced a partnership to create a complete sample-to-report workflow.[36] The deal integrates QIAGEN's advanced QCI Interpret bioinformatics software with OGT's SureSeq next-generation sequencing (NGS) panels, aiming to streamline variant interpretation and reporting for clinical research labs.[37] These alliances showcase a critical strategy for staying competitive: enhancing established hardware and reagent platforms with sophisticated software and AI to deliver more powerful insights.

Strategic Corporate Alliances

The distribution channel saw a major strategic move on September 26 when Nanjing Pharmaceutical Co., Ltd. (SSE:600713) announced a strategic investment agreement with Guangzhou Baiyunshan Pharmaceutical Holdings Co., Ltd. (SSE:600332). A fund affiliated with Baiyunshan will acquire an 11.04% stake in Nanjing Pharmaceutical to enhance collaboration in pharmaceutical commercial logistics and innovative medical supply chains. This vertical integration is a direct strategic response to the margin pressures created by VBP and DRG reforms.

IPO Pipeline Heats Up

Medcaptain Medical Technology Co. Ltd., a Shenzhen-based maker of life support and diagnostic devices, filed an application to list on the Hong Kong Stock Exchange on September 18. The company, which turned profitable in the first half of 2025 and is backed by high-profile investors, highlights Hong Kong's continued importance as a key fundraising hub for mainland healthcare companies.

Highlights: Funding & Partnerships

Date	*News Title*	*Link*
2025-09-28	**"Health China · Sinan Dialogue" Investment Salon Held in Shanghai** The event connected investors with startups in fields including interventional robotics, rapid diagnostics, and hemostatic materials.	Link [Chinese]
2025-09-26	**Nanjing Pharmaceutical and Baiyunshan Form Strategic Partnership** Baiyunshan's fund will acquire an 11.04% stake in Nanjing Pharmaceutical to deepen cooperation in pharmaceutical logistics and supply chain innovation.	Link [Chinese]
2025-09-22	**Lunit and Agilent Announce Collaboration for AI-Powered Companion Diagnostics** The partnership aims to combine Lunit's AI algorithms with Agilent's tissue-based assays to enhance biomarker testing for drug development.	Link [English]
2025-09-18	**Medcaptain Medical Technology Files for Hong Kong IPO** The Shenzhen-based maker of life support and diagnostic devices, backed by Hillhouse Capital, submitted its application for a public listing.	Link [Chinese]
2025-09-18	**QIAGEN and Oxford Gene Technology Partner on NGS Panel Interpretation** The collaboration integrates QIAGEN's bioinformatics software with OGT's SureSeq NGS panels to create a complete sample-to-report workflow.	Link [English]
2025-09-15	**Huakan Bio Completes "Several Hundred Million RMB" Series B+ Financing** The 3D cell culture technology provider secured a major funding round co-led by multiple state-backed and high-profile investment funds.	Link [Chinese]
2025-09-04	**Lunit and Agilent Partner to Develop AI-Powered Cancer Diagnostics** The collaboration aims to enhance the development of companion diagnostic solutions by integrating AI with advanced assays.	Link [English]

Sales & Markets

The market is defined by a powerful push-pull dynamic: strong, demographically driven growth is being pulled in one direction by intense pricing pressure from VBP, while market access is being pushed in another by geopolitical friction and protectionist policies.

Next VBP Round: Volume → Value

China's powerful Volume-Based Procurement (VBP) program is set to expand further, with preparations for two new rounds advancing in September. On September 17, the Shandong Provincial Medical Security Bureau, acting on behalf of a national alliance, issued a notice for companies to register for the second national centralized procurement of traditional Chinese medicine (TCM) decoction pieces.[39] This officially kicks off the next major VBP round for the TCM sector, a market segment where quality and origin are highly variable, presenting unique challenges for the procurement process.[40]

The procurement rules introduced for the Second National VBP of TCM decoction pieces represent a pivotal shift in VBP methodology. The new bidding evaluation framework reduces the weight of price to just 50% of the total score. Crucially, quality indicators now account for 40%, with supply stability making up the final 10%. This new 50/40/10 scoring system marks the beginning of "VBP 2.0," shifting the focus from "lowest price wins" to "best value wins" and creating an opening for quality-focused brands.

This follows earlier government announcements that the sixth national round of VBP for high-value medical consumables is planned for the second half of 2025.[41] While the specific product categories have not yet been announced, past rounds have targeted major markets like coronary stents and orthopedic implants, resulting in average price reductions often exceeding 80%. VBP remains the most significant market-shaping force in China, compelling manufacturers to rethink pricing and cost structures to maintain access to the public hospital market.

Market Leader Signals Recovery

Shenzhen Mindray Bio-Medical Electronics (SZSE:300760), a key market bellwether, provided a strong positive outlook for the domestic market. While the company reported an 18.5% year-on-year revenue decline in H1 2025 due to a high comparison base and the impact of the 2024 anti-corruption campaign, Mindray offered bullish forward guidance. The company stated that it expects the domestic market to "reach an inflection point in the third quarter" and projected positive year-on-year growth for its overall Q3 revenue. This is the most concrete signal that hospital procurement, which had slowed significantly due to the anti-corruption freeze, is normalizing and poised to accelerate through the second half of 2025.

Geopolitics Reshapes Trade

The market access landscape for imported devices became more fraught in September. The U.S. Section 232 investigation into medical device imports (see: Policy & Regulatory) introduced the most significant new threat of trade barriers. This compounds existing pressures from China's own "Buy China" policies, which encourage public hospitals to prioritize domestic products, with the "Made in China 2025" initiative setting a goal of 70% domestic market share for high-end devices by 2025.[42]

In a sign of its willingness to retaliate against foreign trade actions, China's Ministry of Commerce on September 25 added three U.S. companies to its export control list.[44] This combination of foreign restrictions and domestic protectionism is creating an increasingly fragmented market. The dynamic is forcing multinational corporations to accelerate localization strategies—transferring manufacturing and R&D to China—to be considered a "domestic" supplier and mitigate market access risks.

Market Reports Show Resilience

Despite the significant pricing and trade pressures, the underlying fundamentals of the medtech market remain strong. The 19th annual "Pulse of the MedTech Industry" report from Ernst & Young, released on September 29, projected that the global industry is on track for 6-7% revenue growth in 2025, reaching a total market size of $584 billion.[32] The report highlighted that growth is being driven by innovation in high-value segments like pulse field ablation, structural heart, and robotics.[32]

Trade data also reflects the market's scale. In 2023, U.S. medical device exports to China were valued at $5.4 billion, giving American suppliers a 25.5% share of China's total medical device import market.[45] While VBP and geopolitical tensions are reshaping

how companies compete, they have not erased the fundamental demand driven by China's aging population and rising healthcare needs. The strategic challenge is less about finding growth and more about navigating the complex rules of engagement to capture it.

Highlights: Sales & Markets

Date	*News Title*	*Link*
2025-09-30	**Second National VBP for TCM Decoction Pieces Moves Forward** The procurement alliance continued preparations for the upcoming centralized purchasing round for traditional Chinese medicine products.	Link [Chinese]
2025-09-30	**Mindray Medical Signals Q3 Inflection Point for Domestic Market** In its H1 earnings report, Mindray guided for a return to year-on-year revenue growth in Q3, indicating a recovery in hospital procurement activities.	Link [Chinese]
2025-09-29	**EY Releases "Pulse of the MedTech Industry 2025" Report** The annual report highlighted steady global industry growth, fueled by innovation, and noted a trend toward fewer but larger M&A and venture funding deals.	Link [English]
2025-09-25	**China Adds Three US Companies to Export Control List** China's Ministry of Commerce placed three American firms on its dual-use export control list in a move seen as a response to U.S. trade actions.	Link [English]
2025-09-17	**Notice Issued for Enterprise Registration in Second National TCM VBP** The procurement will introduce a scoring system where price is 50%, quality is 40%, and supply stability is 10%, marking a pivot toward "VBP 2.0".	Link [Chinese]

Citations

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