ITALIAN TRADE AGENCY

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NEWSLETTER

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China Seeks Input on Cell and Gene Therapy Pilot Program
China published draft working rules for the Sharp Plan supporting cell and gene therapy drug development. The framework offers early communication, pre-acceptance services and compressed review timelines for qualifying breakthrough candidates. Up to fifteen projects per year may enter the pilot with new targets or mechanisms. The initiative strengthens regulatory backing for frontier biopharmaceutical innovation**. (Xinhua)**

NMPA Issues Rules on Drug Market Exclusivity for Rare Diseases and Pediatrics
The National Medical Products Administration released draft implementation rules for drug market exclusivity to encourage research and development of treatments for rare diseases and pediatric use, supporting revised Drug Administration Law enforcement regulations. Stakeholders may submit feedback by November 18, 2026, to the designated NMPA email address as the regulator builds a system for clinical-trial data protection**. (NMPA)**

Guangxi's Qinzhou Port Opens as New Border Port for Traditional Chinese Medicine Imports
The National Medical Products Administration and the General Administration of Customs jointly announced the addition of Qinzhou Port in Guangxi as a new border port for importing traditional Chinese medicinal materials. The local market regulator will now handle registration and supervision, while the Guangxi Institute for Drug Control will conduct port inspections under the Imported Medicinal Materials Management Measures. **(NMPA)**

Global Tariff Wave Hits Chinese Chemical Exports
Over ten economies, including the EU and US, are imposing severe anti-dumping duties—some exceeding 400%—on Chinese chemical products. This widespread trade barrier disrupts a multi-billion-euro sector, forcing global logistics providers to rapidly restructure supply chains and navigate millions of euros in added compliance and rerouting costs. **(ChemNet)**

Red Sea Delays Spark Ethylene Glycol Shortage in China
Red Sea shipping detours and overseas maintenance have drastically slashed ethylene glycol arrivals at East China ports, depleting inventories to historic lows. This severe logistical bottleneck triggered a massive short squeeze, driving spot prices up to approximately €765 per ton as polyester manufacturers scramble to secure scarce raw materials. **(ChemNet)**