🇷🇴 Romania | 💊 Medical Raw Materials

Romania Medical Raw Materials Overseas Market Analysis Report

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Romania Medical Raw Materials Key Findings

Romania's medical raw materials market has an import dependency exceeding 80%. China is the largest supplier, accounting for approximately 30% of total API imports. In 2025, the Romanian pharmaceutical market totaled approximately €4.4 billion, with API imports valued at around €850 million. Stricter EU GMP regulations and global supply chain restructuring are driving import costs upward, but slow progress in local capacity expansion means the import landscape is unlikely to change in the short term.

- Total pharmaceutical market size: approx. **€4.4 billion** (2025)
- API import dependency: **>80%**
- China's share of Romanian API imports: approx. **30%**
- Annual API imports: approx. **€850 million** (2025)

Source: European Federation of Pharmaceutical Industries and Associations (EFPIA) 2025 Annual Report; Romania National Institute of Statistics (INS) 2025 trade data

Supply & Demand Fundamentals

Romania's annual demand for medical raw materials is approximately 18,000 tonnes, while local production capacity is only about 3,500 tonnes, leaving a supply-demand gap of roughly 14,500 tonnes to be filled by imports. Demand is primarily driven by generic drug manufacturing, with antibiotics and cardiovascular APIs accounting for the largest share. Local major producer Antibiotice Iași operates at approximately 75% capacity utilization, with expansion plans constrained by funding and technical barriers.

Indicator	Value	Notes
Local production	~3,500 tonnes/year	Mainly Antibiotice Iași
Import volume	~14,500 tonnes/year	Including APIs & intermediates
Total demand	~18,000 tonnes/year	Driven by generic drug production
Import dependency	80.6%	Remains at high level

Source: Romanian Association of Pharmaceutical Manufacturers (ARPIM) 2025 industry report; Antibiotice Iași 2025 annual report

China Market Overview

As the world's largest API producer, China's total API exports reached approximately $62 billion in 2025, with exports to the EU accounting for about 28%. Capacity utilization in major production regions—Zhejiang, Jiangsu, and Shandong—remains in the 75%-85% range. Tightening domestic environmental policies have forced some small and medium-sized capacities to exit, driving continued industry consolidation. RMB exchange rate fluctuations directly impact export pricing.

- China total API exports: approx. **$62 billion** (2025)
- Exports to EU: approx. **$17.4 billion**
- Industry average capacity utilization: **78%**
- Major production regions: Zhejiang (35%), Jiangsu (28%), Shandong (15%)

Source: General Administration of Customs of China 2025 import/export statistics; China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE) 2025 annual report

Romania Market Overview

Romania's medical raw materials market is dominated by generics, which account for approximately 75% of prescriptions by volume. Major API import source countries are China (30%), India (22%), Germany (12%), and Italy (10%). Local distributors apply markups of approximately 15%-25%. Due to EUR/USD exchange rate fluctuations, USD-denominated API procurement costs are volatile, and importers commonly adopt forward hedging strategies.

- Generic share (by prescription volume): **75%**
- API imports from China: approx. **€255 million**
- API imports from India: approx. **€187 million**
- Distributor markup: **15%-25%**

Source: Romania National Institute of Statistics (INS) 2025 import data; IQVIA Romania 2025 market report

Product Segment Structure

Among Romania's imported medical raw materials, antibiotic APIs hold the largest share (approx. 32%), followed by cardiovascular APIs (approx. 25%), CNS APIs (approx. 15%), anti-inflammatory and analgesic APIs (approx. 12%), and pharmaceutical excipients (approx. 16%). Within antibiotics, cephalosporins and amoxicillin-related APIs have the highest demand and are mainly imported from China.

Product Segment	Import Share	Main Source Countries
Antibiotic APIs	32%	China, India
Cardiovascular APIs	25%	China, India, Germany
CNS APIs	15%	China, Italy
Anti-inflammatory & Analgesic	12%	India, China
Pharmaceutical Excipients	16%	Germany, France

Source: Romania National Institute of Statistics (INS) 2025 classified trade data; European API Market Report 2025

Core Finished Product Supply & Demand

Taking amoxicillin API as an example, Romania's annual demand is approximately 800 tonnes, while local Antibiotice Iași production is about 120 tonnes, leaving a gap of roughly 680 tonnes to be met by imports. In 2025, the CIF price of Chinese amoxicillin API was approximately €28-32/kg, up about 8% from 2024. Romanian distributors typically maintain 45-60 days of safety stock to buffer against supply chain disruptions.

- Amoxicillin API annual demand: approx. **800 tonnes**
- Local production: approx. **120 tonnes** | Imports: approx. **680 tonnes**
- CIF price: **€28-32/kg** (2025 average) ↑8%
- Safety stock days: **45-60 days**

Source: Antibiotice Iași 2025 annual report; CCCMHPIE 2025 amoxicillin export data

Intermediates & Raw Material Values

Chinese pharmaceutical intermediate prices rose moderately in 2025, with 6-APA ex-factory prices at approximately $22-25/kg and 7-ACA at approximately $55-60/kg. Romanian importers' procurement prices, including freight and tariffs, are approximately 12%-18% higher. China-Europe sea freight costs remain affected by the Red Sea situation, with 40-foot container rates at approximately $3,500-$4,500.

Intermediate	China Ex-factory Price (USD/kg)	Romania CIF Price (USD/kg)
6-APA	22-25	26-30
7-ACA	55-60	64-72
p-Hydroxyphenylglycine	8-10	9.5-12

Source: SunSirs 2025 pharmaceutical intermediate price monitoring; Argus Media Chemicals Q4 2025

Trade & Macro Indicators

Romania's GDP growth rate in 2025 was approximately 2.8%, with the pharmaceutical industry accounting for about 2.1% of GDP. Bilateral pharmaceutical trade between China and Romania reached approximately €320 million, with a significant Chinese surplus. The Romanian Leu (RON) to Chinese Yuan (CNY) exchange rate was in the range of 1.55-1.60. The EU Recovery and Resilience Facility allocated approximately €2.9 billion to Romania's healthcare system, part of which is earmarked for pharmaceutical production capacity upgrades.

- Romania GDP growth: **2.8%** (2025)
- Pharmaceutical industry share of GDP: **2.1%**
- China-Romania pharma trade: approx. **€320 million**
- 1 RON ≈ **1.57 CNY** (2025 average)

Source: World Bank 2025 Romania Economic Report; Romania National Institute of Statistics; General Administration of Customs of China

⚠ Risks & Opportunity Windows

Regarding risks, continuously tightening EU GMP regulations may raise market entry barriers for Chinese APIs; Red Sea shipping disruptions increase supply chain uncertainty; and RON exchange rate volatility adds to import costs. On the opportunity side, Romania has introduced pharmaceutical investment incentive policies, and Antibiotice Iași plans to expand capacity to 5,000 tonnes/year, opening a window for Chinese API enterprises to pursue joint ventures or technical cooperation.

⚠ New EU GMP regulations (effective 2025) raise compliance costs for non-EU API suppliers
⚠ Geopolitical supply chain disruption risks | Exchange rate volatility ~8%
Opportunity: Romania pharmaceutical capacity expansion plan
Opportunity: China-Romania pharmaceutical cooperation MOU (signed 2025)

Source: European Medicines Agency (EMA) 2025 GMP guideline update; InvestRomania 2025 policy announcement

Data Source Summary (at least 5 independent sources)

- European Federation of Pharmaceutical Industries and Associations (EFPIA) — 2025 Annual Report
- Romania National Institute of Statistics (INS) — 2025 trade and import data
- General Administration of Customs of China — 2025 import/export statistics
- China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE) — 2025 annual report

- Romanian Association of Pharmaceutical Manufacturers (ARPIM) — 2025 industry report
- Antibiotice Iași — 2025 listed company annual report
- IQVIA Romania — 2025 market report
- World Bank — 2025 Romania Economic Report
- European Medicines Agency (EMA) — 2025 GMP guideline update
- SunSirs — 2025 pharmaceutical intermediate price monitoring
- Argus Media Chemicals — Q4 2025 report
- InvestRomania — 2025 policy announcement

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