



MENARINI
group

JPTA Seminar at CPHI Japan 2026

April 22nd 2026

Presentation n.1 Fabio Pirola Lusochimica SpA

Theme: Requirements for Stable Supply of Active Pharmaceutical Ingredients

Title: “Characteristics of the Japanese Market and Challenges for Stable Supply from an API Manufacturer’s Perspective”

Agenda

1. Introduction

importance of API supply stability

2. Characteristics of the Japanese market

quality expectations

regulatory aspects

3. Challenges for API manufacturers

cost pressure

regulatory complexity

supply chain risks

4. Global changes

covid

geopolitics

dependence on Asia

5. European response

reshoring

policy initiatives

6. Conclusion

EU–Japan collaboration opportunity

18 manufacturing plants

EUROPE is the Group's heart of production

In 2023 **609 million packs** were produced at these sites

Italy

Pisa (2 plants), Florence (2 plants)
Pomezia*, L'Aquila, Lomagna (Lecco),
Casaletto Lodigiano (Lodi)

Spain

Barcelona

Germany

Berlin (2 plants), Dresden

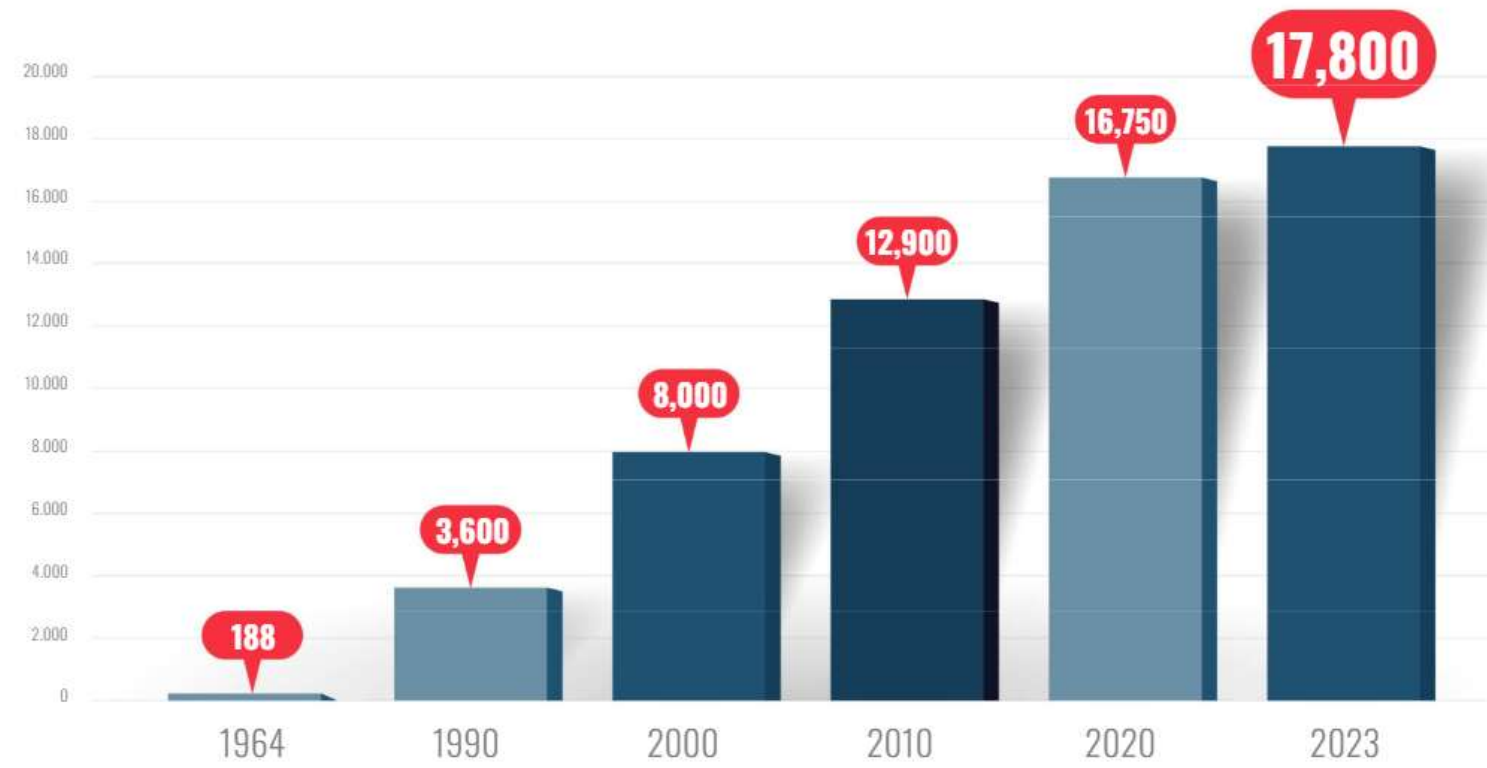
Plants dedicated to the **production for local markets** are located in Central America (Guatemala City), Ireland (Shannon), Turkey (Istanbul), Russia (Kaluga) and Indonesia (Jakarta).

U.S.A. (Philadelphia - Huntingdon Valley): **diagnostic production**

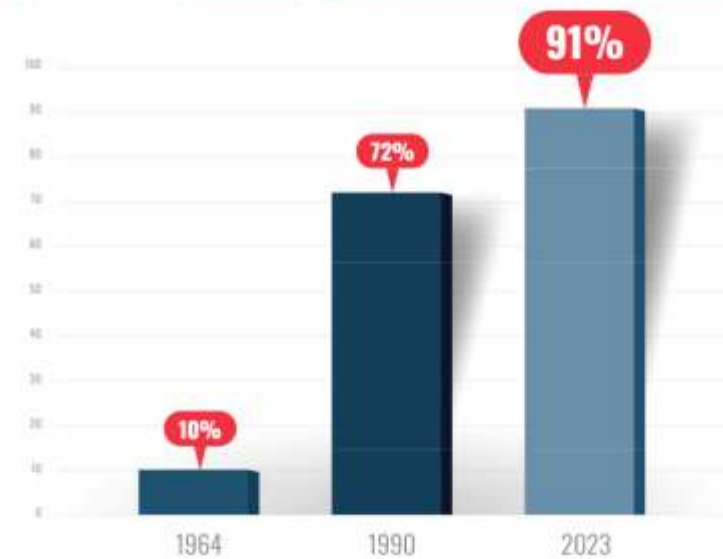


*Biotech manufacturing with development and production processes also for third parties.

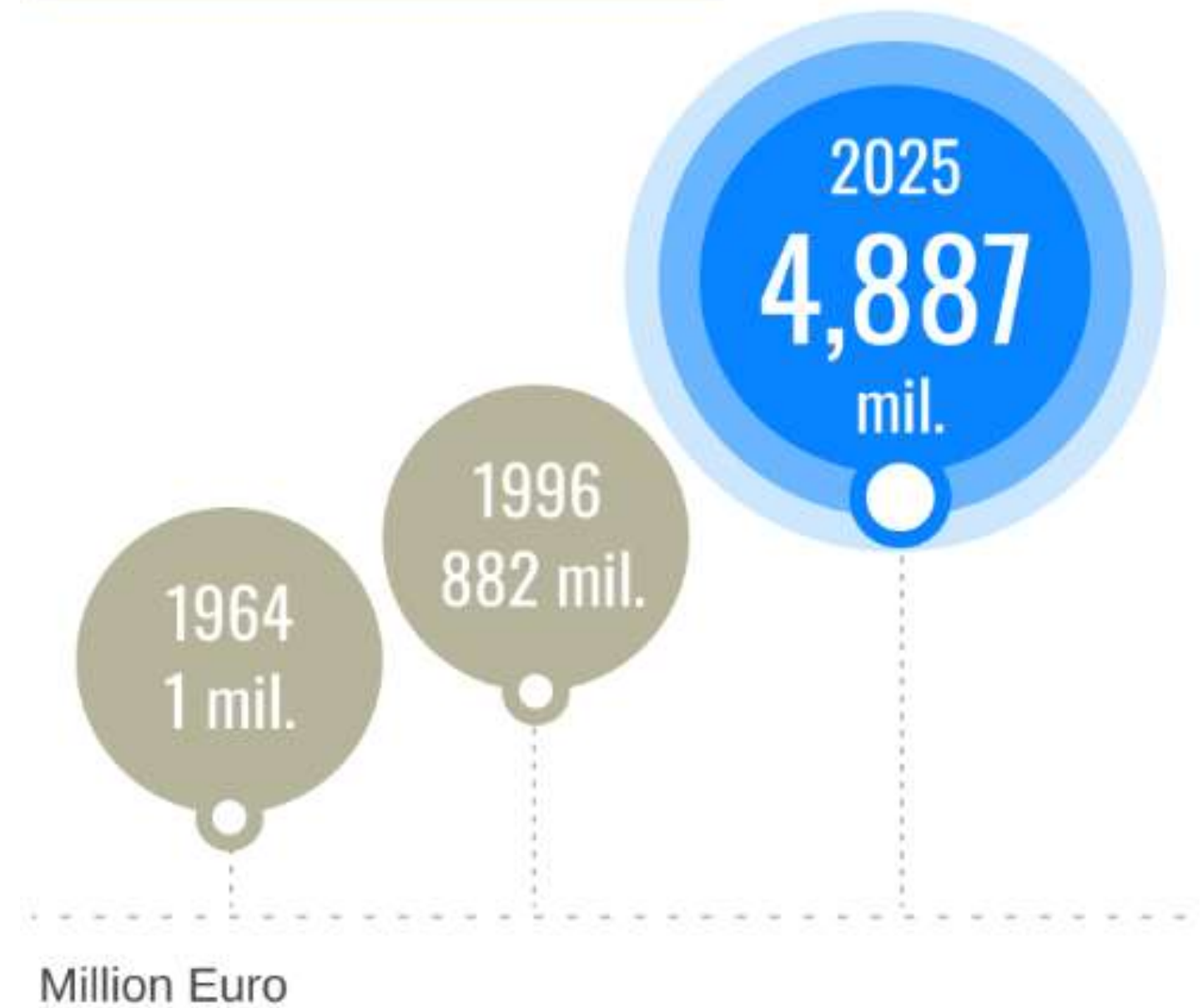
Number of employees



Employees % of graduates and technicians



Consolidated Turnover



Characteristics of the Japanese Market and Challenges for Stable Supply from an API Manufacturer's Perspective

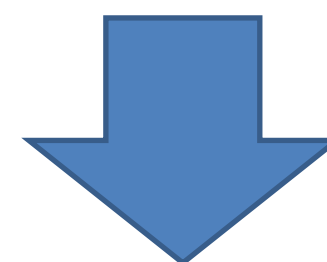
Characteristics of the Japanese market:

1. Highly demanding:

1. Multiple validated chemical steps (3 chemical steps) and strict control of starting materials (often >99.9% purity)
2. Very thorough GMP audits
3. Documentation requirements in Japanese (DMF in JP format, no CTD format)

 Implication: This goes beyond ICH baseline and reflects a “zero-risk mindset” and Need for local regulatory expertise

2. Price sensitive with an Increasing attention to cost efficiency: Strong competition from China, India and Local Manufacturers



 Strategic question: How to balance: **quality + compliance + cost efficiency?**

Characteristics of the Japanese Market and Challenges for Stable Supply from an API Manufacturer's Perspective

Stable Supply – requirements of the JP Market:

1. Strong control of the supply chain, including starting material suppliers
2. Robust change management systems and High regulatory sensitivity to manufacturing changes
3. Detailed and structured Quality Agreements

These requirements can be seen as drivers for stronger and more resilient partnerships and should be recongized as added values in a win-win optic

How Europe is Strengthening API Supply Stability

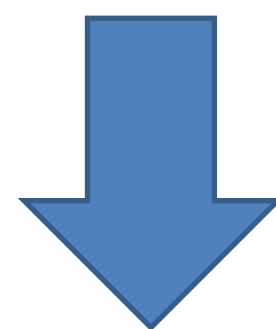
Recent global events have highlighted vulnerabilities in pharmaceutical supply chains:

1. COVID-19 pandemic
2. Geopolitical tensions
3. Concentration of API production in limited regions

How Europe is Strengthening API Supply Stability

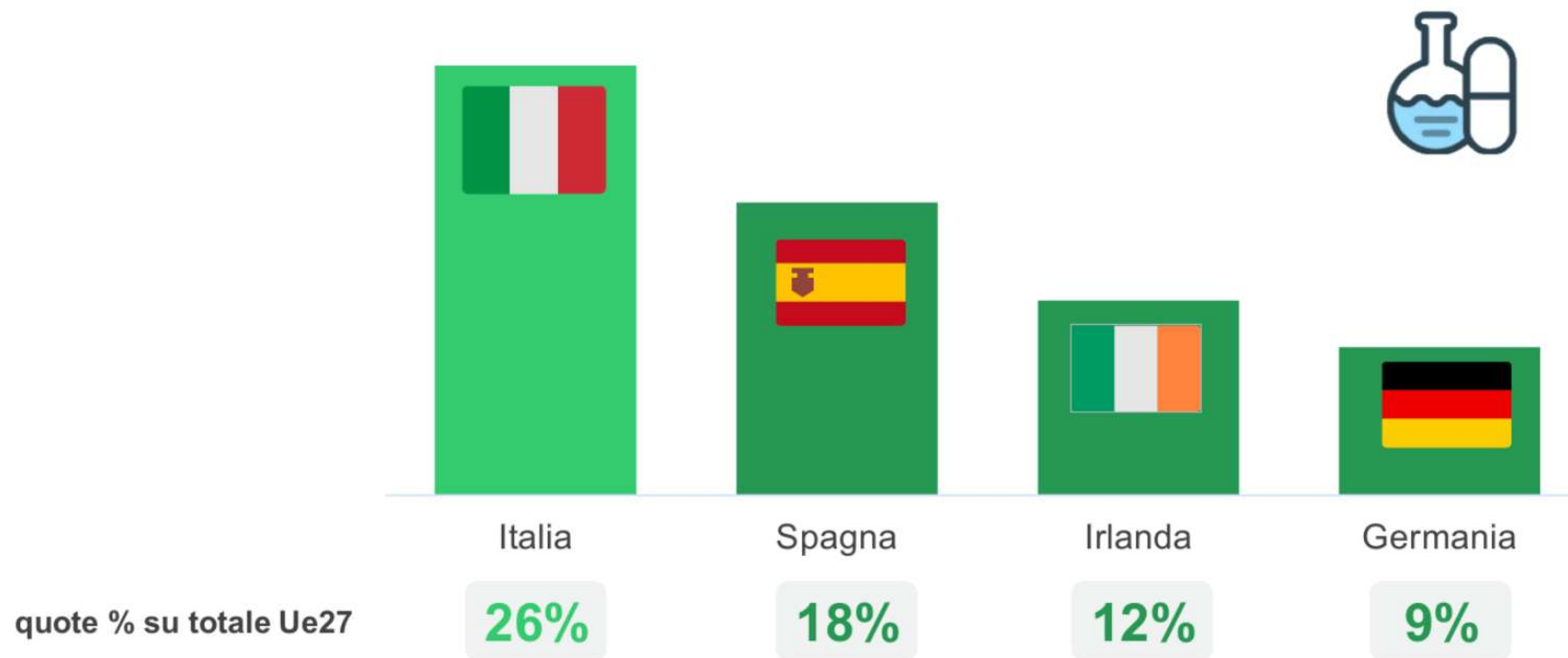
Europe is responding through:

1. Strategic initiatives such as the **Critical Medicines Act**
2. Policies encouraging **reshoring of API manufacturing**
3. Investment in **high-quality and reliable supply chains**



This creates opportunities for stronger collaboration between European API manufacturers and Japanese pharmaceutical companies

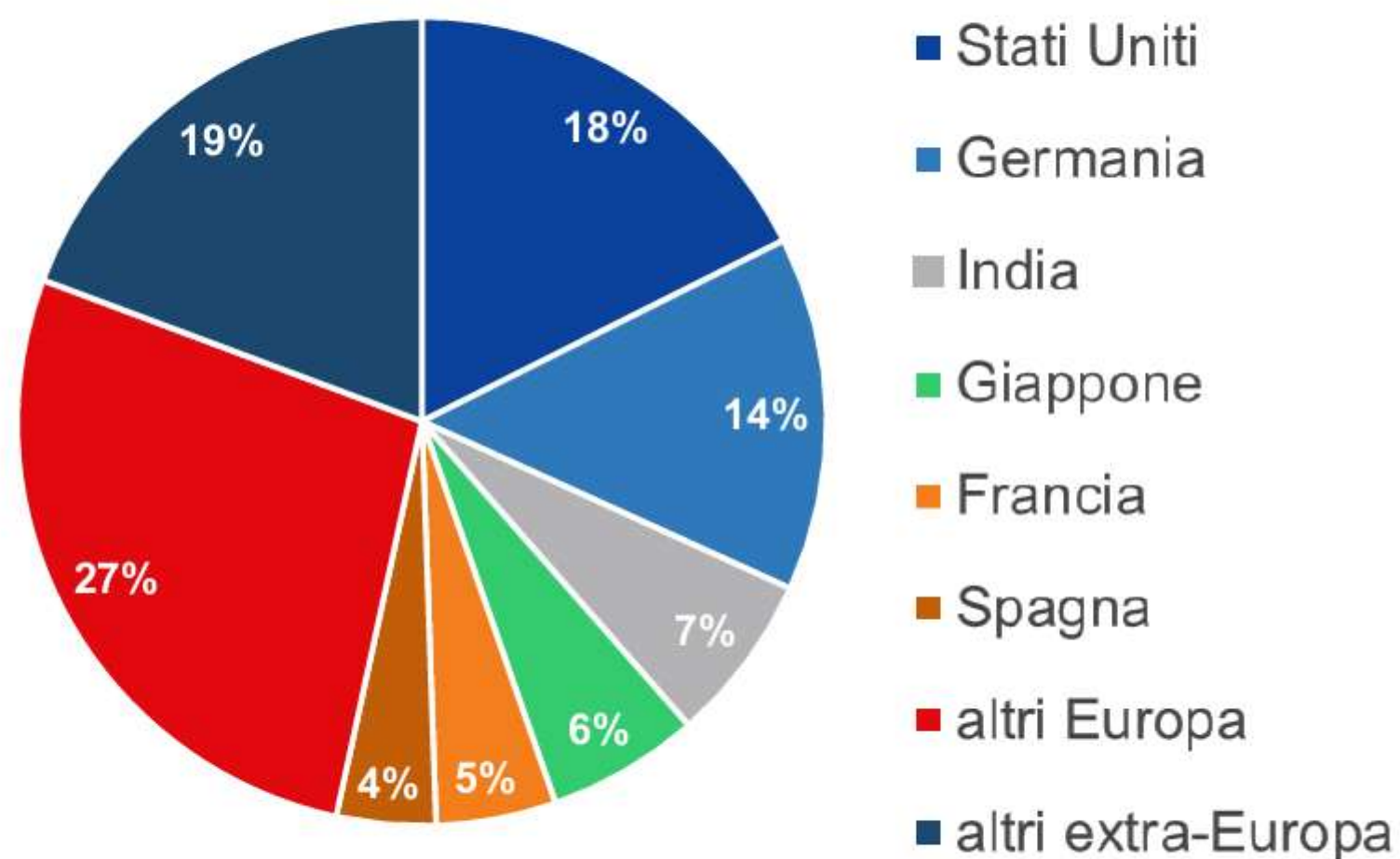
Basic Pharma Turnover: an EU comparison



Fonte: Prometeia Analisi dei Microsettori 2025 (elaborazioni su dati Eurostat-SBS e Moody's BvD)

Today Japan represents the 6% of the export TO

Mercati esteri serviti
quote % in valore, media 2022-2024



Fonte: Indagine Aschimfarma-Prometeia 2025

Conclusion

“Long-term partnerships are the key to ensuring stable and high-quality API supply.”

Japan can see Italy as a strategic partner and together we can increase our cooperation

ご清聴ありがとうございました。