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ASCHIMFARMA

Associazione nazionale produttori principi attivi
e intermedi per l'industria farmaceutica

The role of Aschimfarma in Italian APIs manufacturing scenario

Gian Mario Baccalini – Presidente Aschimfarma

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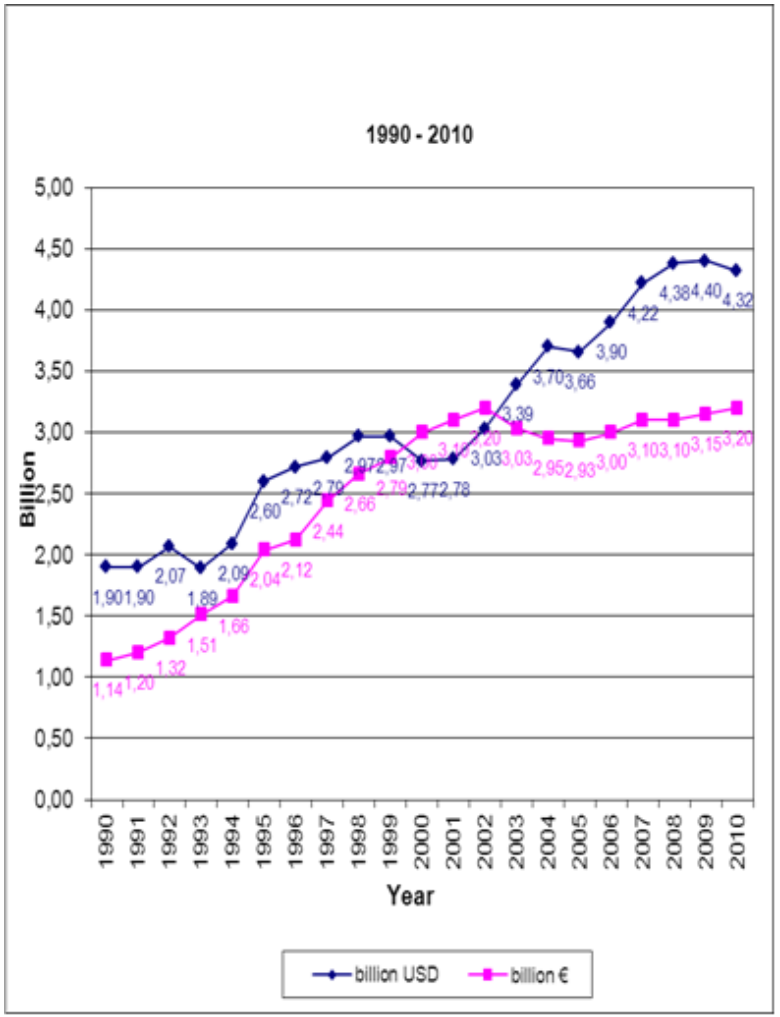
APIs sector in Italy

- 3,2 billion € total turnover, of which 83% Aschimfarma
- 88 manufacturers (mostly SME), of which 71% Aschimfarma
- 9.900 employees, of which 85% Aschimfarma
- 85-88% export for the companies Aschimfarma's members

Italian turnover development of active pharmaceutical ingredients and intermediates (current value)



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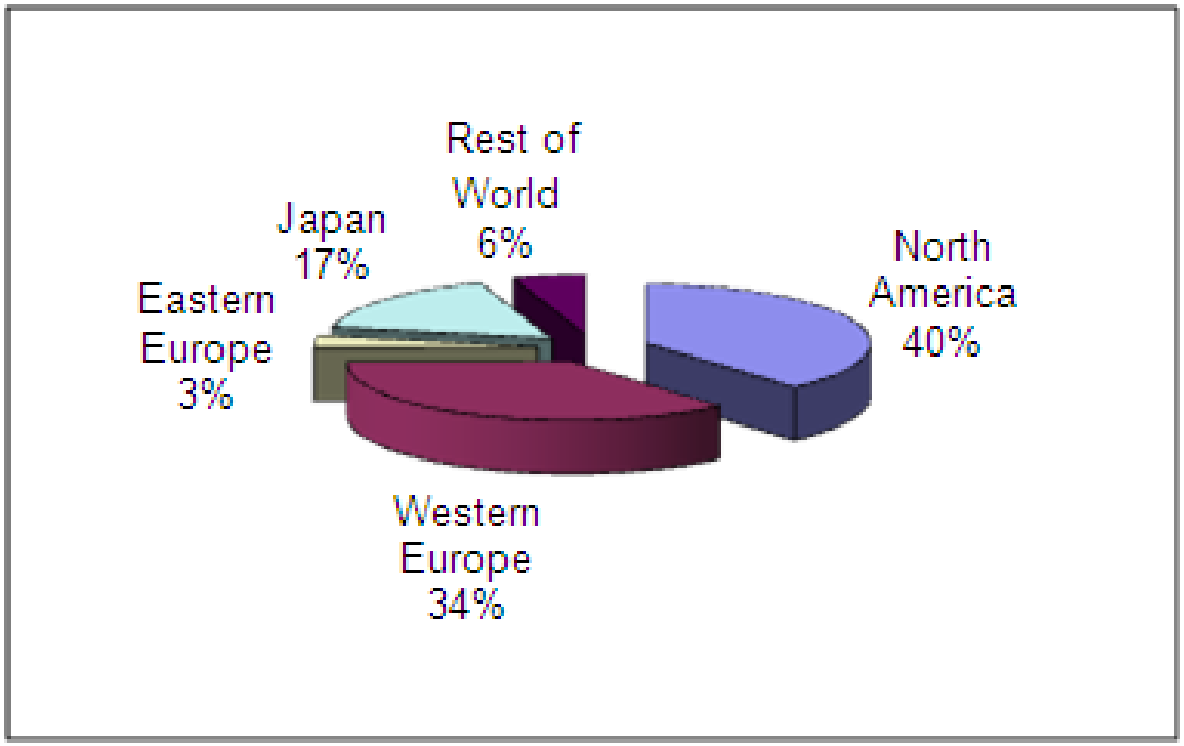
Italian export of active pharmaceutical ingredients and intermediates broken down by major geographical areas (%values, export=85% total turnover, 2010)



Italian manufacturers

- Production of intermediates and APIs for pharma sector, particularly generic drugs (65% of activity);
- Custom synthesis (15%);
- Custom manufacturing, mainly for big pharma industry (20%):
  - R&D
  - Technologies
- Strategic integration towards pharma

Features of the production

- High-level fine chemicals:
  - chemical synthesis, fermentation, purification and separation
  - development in new technologies (enzymatic reaction, chiral chemistry, green chemistry, flow chemistry)
  - many steps of reaction
  - flexible multipurpose plants and top level dedicated equipments
  - high technology plants with reference to process and engineering and quality system
- Production in compliance with GMP - Good Manufacturing Practices on the basis of inspections performed by Regulatory Authorities (FDA, AIFA)

Outline of API manufacturers

- Skills for early assessment of generics market opportunity
- Marketing
  - flexibility in following marketing demands
  - attention to niche products
  - great skill in dossier formulation
  - deep knowledge of topics in the field
- Qualified technical people
  - from laboratory to the development of original technologies for the industrial production
  - management of audits
  - expertise in QA and regulatory
- Skills in the patent issues

Critical success factors of Italian API manufacturers

- R&D with characteristics of originality and creativity (with wide cooperation with Universities);
- Availability of high-level plants in term of yield and quickly adaptable to the customer's changing needs;
- Acknowledged high quality production;
- Quality and safety system;
- Technical and professional preparation of the marketing and sales staff: an ever more important competitive factor is customer service.

Italian R&D and Production (1)

- 3% of total turnover addressed to R&D for process optimization;
- Applied research intended mainly for innovative process characterized by patentable multi-step synthesis;
- Creativity linked to high knowledge in the field of discontinuous process engineering;
- Multipurpose plants adaptable to a wide range of reactions, included those highly specialized;
- Great skills for production scaling-up with regard to efficiency, safety, quality, as well economics.

Italian R&D and Production (2)

- We have historical expertise in semisynthesis process. Many of our main producers are involved in important new families of semisynthetic products;
- In the future scenario of bioproducts we want have an important rank;
- Some of our top class companies are involved in R&D or new acquisitions in order to be inside the future market scenario of bioproducts;
- We are aware that we must be in and we think that we can have enough know how for learning and growing.

Present problems and technological future

- Too many SME, so we observe acquisitions/mergers with the establishment of bigger Groups;
- Development of biogenerics and biotechnological process;
- New technology on enzimatic catalysis;
- DNA recombinant technology;
- Engineering solutions for the respect of the environment and the quality.

Critical issues

- Lack of international regulatory harmonization; we are the unique country in which we are strictly inspected by AIFA, by FDA, by customers audit with the real GMP certificate;
- We are on the top of reliability of the quality system;
- Huge bureaucracy with admistrative/procedural rules in Italy not present in other countries, not only outside Europe, but Europe too;
- Energy cost;
- R&D not financed.

Conclusions

- We need a real common trust in developping pharma activities, because till now there are too many hurdles against our growth;
- We want to be again key important players in API market, but we need to simplify our regulatory system and to be supported by EMA, EDQM, European association, in order to enforce inspection in Asia;
- In the global market we must have a unique role, obviously the best and the safest for final users.