Facts & figures of the Pharmaceutical industry in Italy

July 2019
Key figures of the Pharma sector in Italy

- **200 companies**, members of Farmindustria, representing 90% of industrial value of the pharmaceutical sector in Italy

- **66,500 employees** (90% graduates), 42% women, and 79,100 in **upstream sectors**

- **6,600 R&D employees**, 52% women

- **€ 32 billion of manufacturing value**, 80% of which due to export (€26 billion)

- **€ 3 billion in investments**, €1.7 of which in R&D and €1.3 in hi-tech plants and machinery

Note: average of turnover, employees, investments in manufacturing and R&D, foreign sales, taxation

Source: elaboration of Istat, Eurostat, EfpiA, Farmindustria data
Pharmaceutical and upstream sectors by Regions

**Lombardy**
- 29,000 direct employees, 22,000 employees in upstream industries;
- Lombardia amongst top European pharmaceutical regions

**Piedmont and Liguria**
- 2,100 direct employees and 9,100 in upstream industries

**Tuscany**
- 7,000 direct employees, 5,400 employees in upstream industries;
- Tuscany is in the top-ten of hi-tech clusters in Italy

**Lazio**
- 16,300 direct employees;
- 42% of regional export (83% of hi-tech export);
- 7,400 employees in upstream industries

**Emilia Romagna**
- 3,800 direct employees and 8,500 in upstream suppliers;
- with excellence in upstream industries

**Veneto**
- More than 3,000 employees, 9,000 in upstream industries; 30% of regional hi-tech export

**Marche**
- 3,400 employees in pharma companies and upstream suppliers

**Abruzzo**
- 1,500 direct employees (100 in R&D) and 1,600 in allied industry

**Campania**
- More than 900 direct employees and 4,000 in upstream industries

**Sicily**
- About 1,000 direct employees and 3,000 in related industries

**Puglia**
- Centres of excellence of major international companies (3,500 employees in pharma companies and related industries)

**Fact & figures of the Pharmaceutical industry and upstream sectors in Italy**
- 146,000 employees
- 6.5 € bln of salaries (including social contributions)
- 3.5 € bln of R&D, plants and machinery investments

Source: elaboration of Istat, Efpia, Farmindustria data
Italy plays a role of leadership in EU for production, thanks to export, the engine of pharma companies

Pharma export: trend 2008-2018 for the big EU countries and EU28 average (% change)

With a production value of €32 bln in 2018, pharmaceutical companies in Italy have a role of leadership in the EU, also thanks to the quality of the supply and service chain.

From 2008 to 2018 pharma export in Italy has grown more than all big EU countries and more than big EU countries’ average.

Source: elaboration of Istat, Eurostat, Efpi data
Export and innovation as the engine of pharma manufacturing in Italy

The quality of Italy’s industrial pharmaceutical system has been a magnet for production activities previously carried out elsewhere in the world.

About one half of growth of production in the last 5 years (55%) is linked to investments in the country’s ongoing manufacturing activities, almost one third (29%) is the result of new product launches, reflecting the industry’s innovative capacity, while 16% derives from the relocation of activities previously conducted outside Italy.

In the last decade production has been growing in value and volume.

Composition of pharmaceutical growth in the last 5 years:

- Growth of existing productions: 55%
- Attraction of productions once made abroad: 16%
- New launches: 29%
Human Resources, the main competitive factor

Employment in the Pharma industry in Italy by educational level (% of total)

- The quality of Human Resources is the main competitive advantage for pharma companies and their investments in Italy.

In 2018 employment in pharma industry grew by 1.7%, mainly in production and R&D.

Source: elaboration of Istat, Farmindustria data
Foreign-owned pharma companies in Italy: leaders for investments and export

Investments and export of foreign-owned companies in Italy, per industrial sector (% of overall manufacturing)

Among foreign-owned companies in Italy, pharma ranks top for investments and export overall value

And they are also leader for:
- share of export on production (90%)
- added value per employees

Source: elaboration of Istat data
Italian-owned pharma companies in Italy: performances beyond the manufacturing average

Among Italian-owned companies, pharmaceutical ones have added value and investments in production and R&D per employee higher than the average. This structural features allow companies to expand to foreign markets: in fact, more than 70% of total revenue is generated by foreign sales.

Foreign sales of Pharmaceutical Italian-owned companies (% of overall turnover)

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales</td>
<td>49%</td>
<td>71%</td>
</tr>
</tbody>
</table>

Source: elaboration of Istat, Famindustria data
Pharma CDMO: an Italian excellence

Pharma CDMO manufacturing value and employment in EU countries

<table>
<thead>
<tr>
<th></th>
<th>Manufacturing (euro mln)</th>
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<tbody>
<tr>
<td>EU total</td>
<td>8,159</td>
</tr>
<tr>
<td>Italy</td>
<td>2,057</td>
</tr>
<tr>
<td>Germany</td>
<td>1,818</td>
</tr>
<tr>
<td>France</td>
<td>1,568</td>
</tr>
<tr>
<td>UK</td>
<td>812</td>
</tr>
<tr>
<td>Spain</td>
<td>534</td>
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<tr>
<td>Other EU countries (*)</td>
<td>1,370</td>
</tr>
</tbody>
</table>

Pharma CDMO in Italy strengthens its leadership in EU: it ranks first for manufacturing value and it has been growing since 2010 in production (+53% especially in innovative products) and export (+98% especially towards advanced economies, i.e. US, EU15)

A result made possible also by constant investments on production lines and new technologies, aimed at endorse efficiency and products quality

(*) Austria, Belgium, Croatia, Greece, Ireland, Netherlands, Portugal, Czech Rep., Romania, Sweden

Source: Farmindustria-Prometeia survey, 2018
Double-digit growth for R&D investments in Italy in the last years

- €3 billion invested in R&D and Innovation
  - +35% for R&D in the last 5 years (more than European ave., +20%)
  - +95% for partnerships R&D in the last 10 years

- Worldwide excellence for biotech, vaccines, blood derivatives, orphan drugs, advanced therapies
  - About 300 biotech medicines in development
  - 3 advanced therapies out of 10 in Europe are developed in Italy

- Increasing role for clinical studies (€700+ million/year)
  - 18% of EU total
  - 37% of studies on biotech products, 26% of studies on orphan drugs
  - Scientific expertise and excellences in Industry, University and NHS

Source: elaboration of Istat, Aifa, Farmindustria data
The change in how to perform R&D: the “network innovation”

Innovation is the result of the network between companies and public-private partnership, non-profit, universities, biotech SMEs, start-up and no-profit companies.

Today, 80% of pharmaceutical innovation is the fruit of partnerships.

Source: European Commission, Pharmaprojects
Italy is among world’s «healthiest» countries, with lower expenditure

The NHS is one of the most important assets in the country. Many respected international sources (WHO and OECD to name but a few) place Italy among countries at the top of the list in terms of life expectancy in good health and quality of the health service.

Use of medicines and vaccines has made a major contribution to health in Italy and other countries, but in Italy the pharmaceutical spending is lower compared to other economies: over the last 10 years the expenditure/GDP ratio in Italy has been stable at 1%, compared to 1.2% average ratio in Europe.

<table>
<thead>
<tr>
<th>Healthcare expenditure, % on GDP</th>
<th>Total</th>
<th>Public</th>
<th>Out-of-pocket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eu-15 (ave.)</td>
<td>10.0</td>
<td>7.9</td>
<td>2.1</td>
</tr>
<tr>
<td>Italy</td>
<td>8.8</td>
<td>6.5</td>
<td>2.3</td>
</tr>
<tr>
<td>USA</td>
<td>17.1</td>
<td>8.3</td>
<td>8.7</td>
</tr>
<tr>
<td>Japan</td>
<td>10.9</td>
<td>9.2</td>
<td>1.7</td>
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</tbody>
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Source: elaboration of Oecd, Istat data
Italy is playing a leading role in outcome-based assessment schemes

Italy is the world leading country for the number of innovative contracts between companies and the NHS (36% of the world’s total)

Although still at an early stage in development, Italy decided to introduce MEAs, or Management Entry Agreements, following them up with monitoring registers managed by AIFA in order to guarantee their appropriateness and applicability. As a result of these agreements, pharmaceutical companies, between 2013 and 2018, returned € 3.8 billion to the NHS

% of MEAs of world total*

Italy: 36%  USA: 20%  Australia: 15%  Canada: 10%  UK: 5%  Spain: 5%  France: 5%  Germany: 5%  Sweden: 5%  Denmark: 5%  Portugal: 5%  China: 5%

*since 1994
Italy’s pharmaceutical expenditure is lower than big European countries

2018 per capita pharma public expenditure (territorial+hospital, index Other big European c.*=100)

- In Italy pharmaceutical public expenditure is more than 25% lower than big European country’s average.
- Italy has also a lower share of pharma public spending on GDP compared to big European’s average: 1% vs 1.2%
- Italy has a lower pharmaceutical spending compared to big European countries (-15%), considering also the private expenditure

(*) Germany, France, UK, Spain, Ireland, Belgium, Denmark, Switzerland (with 10 bln of production at least, according to Efpi data)

Source: elaboration of Oecd, Eurostat, Efpi data
Share of off-patent market in Italy is aligned with other European countries

In and off-patent share in pharmacy market (% of total packages, 2017)

<table>
<thead>
<tr>
<th>European countries total</th>
<th>Off-patent</th>
<th>In-patent</th>
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<tbody>
<tr>
<td>FRA</td>
<td></td>
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<td>ITA</td>
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<td>GER</td>
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<td>UK</td>
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<td>IRE</td>
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<td>AUS</td>
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<td>SPA</td>
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<td>GRE</td>
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Italy is in line with other European countries in terms of diffusion of generics (90% of pharmacy consumption)

Source: elaboration of IQVIA data
Italy is leader in EU for biosimilar consumption and market share on total

Biosimilar consumption in 2018
(% on total for Top7 EU countries, standard units)

According to 2018 data on biosimilar sales in top 7 EU countries (Italy, Germany, France, Spain, UK, Belgium, Sweden) Italy:

- ranks 1st for consumption (36% of total)
- has a volume market share on total (originator + biosimilar) higher than that of many countries and the average

Volume market share on total EU Top7
(% of originator + biosimilar, standard units)

Source: elaboration of IQVIA data
The Pharmaceutical industry and upstream sectors in Italy

Direct and indirect economic contribution of the Pharma industry, compared to public expenditure for reimbursed medicines - 2018 (€ billion, ex-factory prices)

- Investments, Production and R&D
- Wages and social security contributions (*)
- Direct tax, other taxes (**)
- VAT
- Effective contribution of pharmaceutical and related upstream sectors
- Public expenditure for medicines and vaccines (territorial+hospital excl. payback)
- Contribution of pharmaceutical industry with a solely commercial presence

(*) excluding R&D employees, included in «R&D investments»
(**) fares, duties and non-deductible calculated on expenditure in promotional events and conventions

Source: elaboration and estimates of Ista, Aifa, Farmindustria data
Why to invest in Pharma in Italy? Companies say …

Competitive advantages in Italy for investments in Pharma Industry

- Quality of **Human Resources**, excellent and highly productive, entrepreneurs and managers
- Excellence of **upstream sectors** (1st ranking in machinery and packaging)
- **Market size** (3rd market in EU) and no. of companies (2nd in EU; >300)
- Quality of **clinical structures**/access to expertise and skills
- Quality of **life/environment**