

The Pharmaceutical Industry in Italy: European excellence

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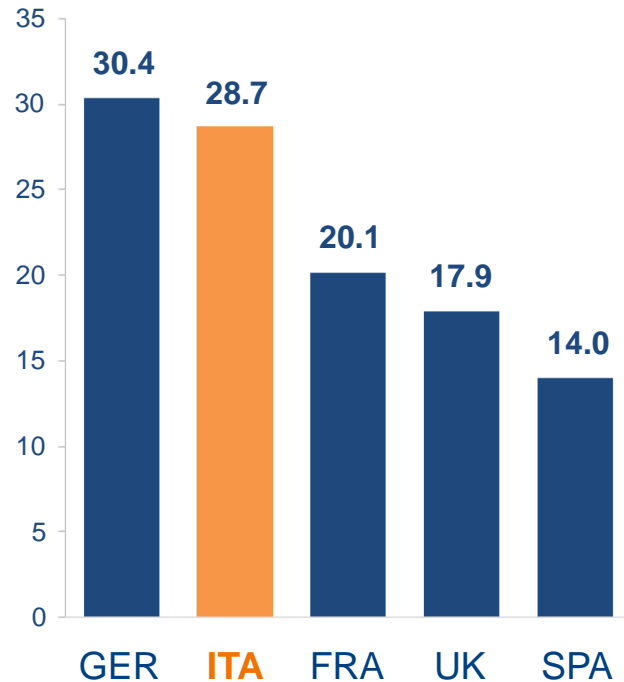
FARMINDUSTRIA

The pharmaceutical industry in Italy has a remarkable impact on Economy and Healthcare system



The pharmaceutical industry in Italy: an asset to the nation

Pharmaceutical production (€ billion, 2014)



About 200 companies producing medicines and vaccines and 100 more for active ingredients

63,000 direct employees and 65,000 more in upstream sectors

€ 29 billion of manufacturing value, of which 72% for export (€21 billion)

€ 2.5 billion invested each year, in R&D and hi-tech machinery

Worldwide excellence in upstream sectors, especially in machinery and packaging

40% from Italian-owned companies

60% from Foreign-owned companies



The pharmaceutical market in Italy ranks **3rd in Europe and 6th Worldwide**

Year 2014	MIn €	% on total
RETAIL SALES	17,649	66%
- Reimbursable	12,429	47%
- Not reimbursable and OTC	5,220	19%
HOSPITAL	8,994	34%
TOTAL	26,643	100%

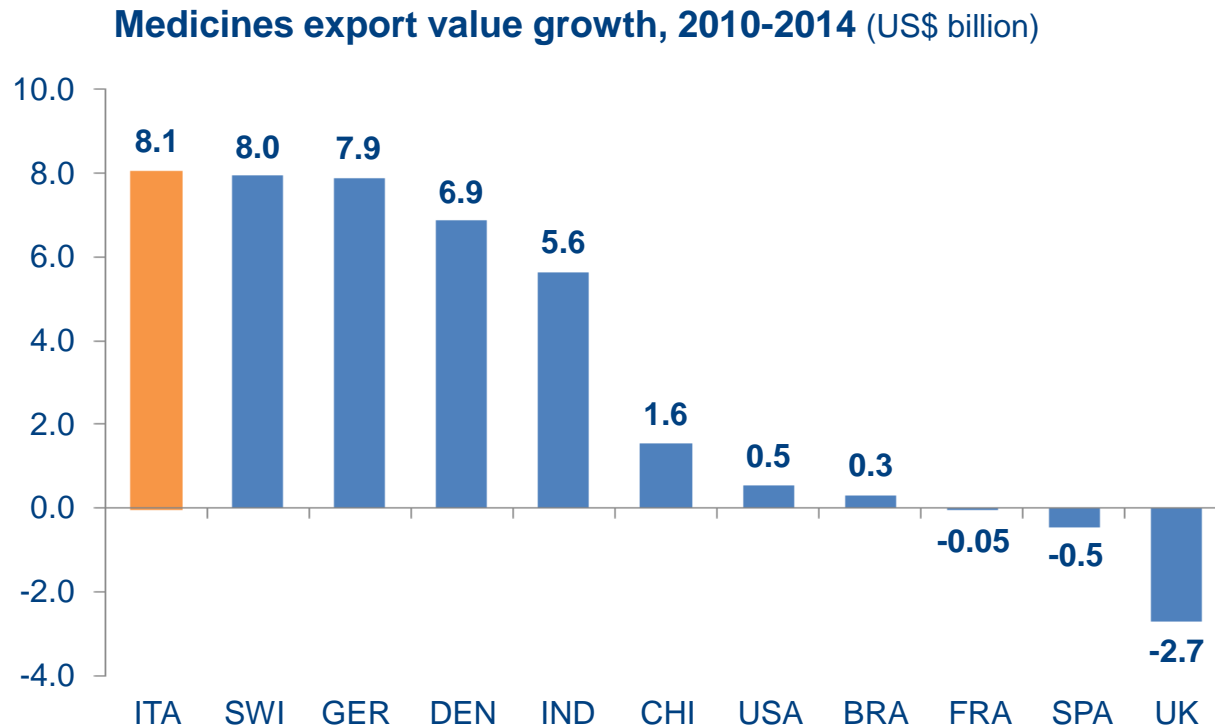
Pharmaceutical growth is mainly in Emerging Countries but Italy is still among the top 10 markets with increasing sales



Developed Markets CAGR 2014-2018		Pharmerging Markets CAGR 2014-18	
US	5-8%	Tier 1 (China)	9-12%
Japan	1-4%	Tier 2	9-12%
Germany	2-5%	Brazil	9-12%
France	(-2)-1%	Russia	7-10%
Italy	2-5%	India	9-12%
Canada	3-6%	Tier 3	5-8%
Spain	(-1)-2%	Pharmerging	8-11%
UK	4-7%		
Developed	3-6%		



2010-2014: Italy accounted the **highest increase in world export of medicines** produced in the Country

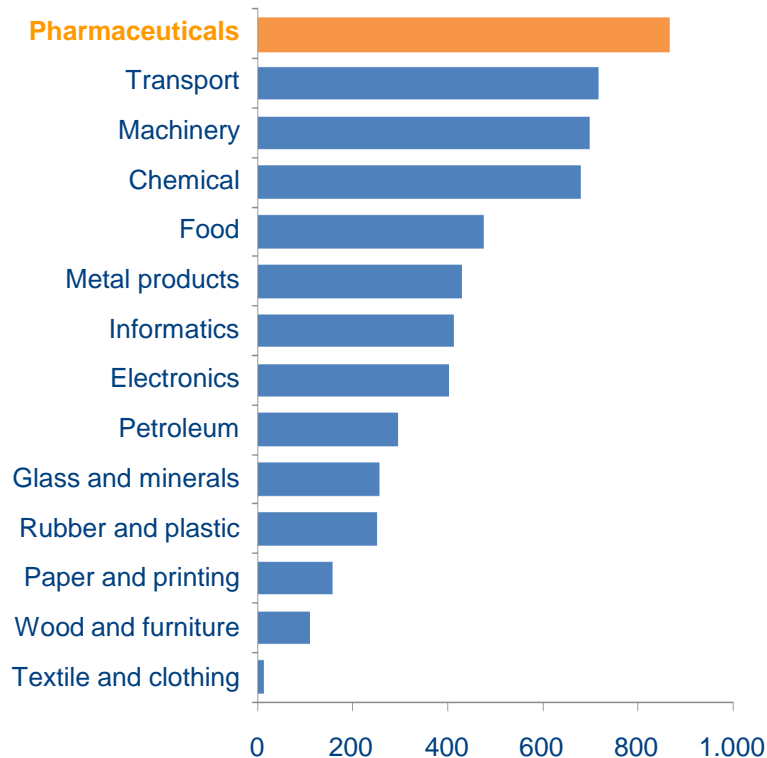


Italy can be the
European pharmaceutical hub and attract investments and opportunities

Pharmaceutical companies' leadership in R&D and internationalization

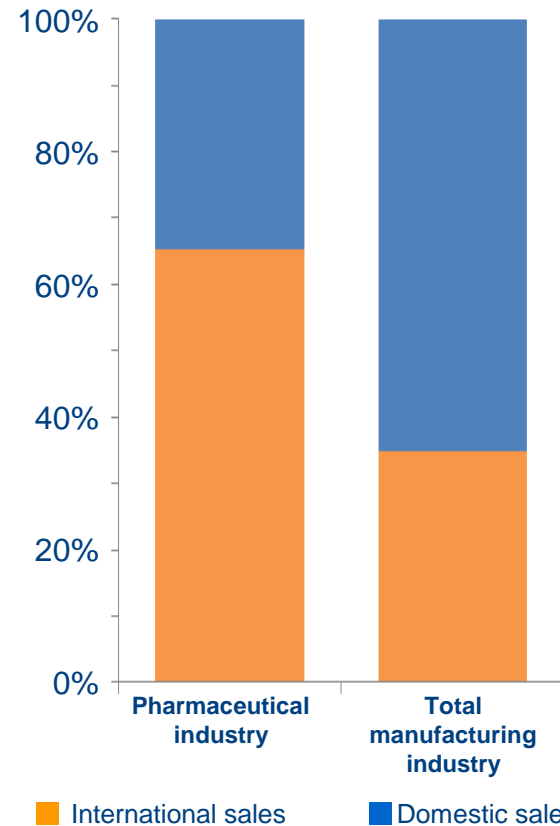
Foreign-owned companies' R&D and manufacturing investments in Italy

(€ million)



Data on pharmaceuticals are referred only to R&D intra-muros, net to clinical research

Italian-owned companies' international sales as a % on turnover



Pharma companies in Italy are upscaling quality, investing in new plants and therapies

Industrial production % change 2010-2015 (top 3 sectors)

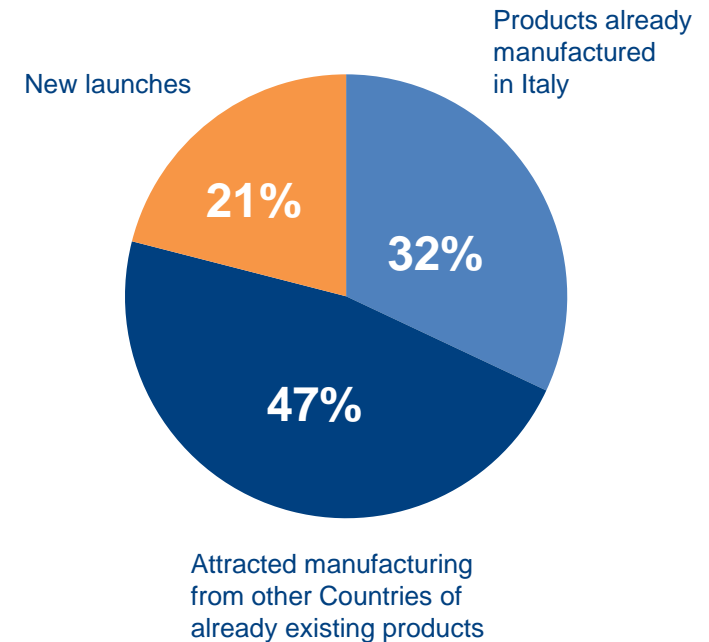
Overall Manufacturing -7.1%

Pharmaceuticals +10.6%

Means of transportation +4.7%

Mechanic industry +0.1%

Composition of production growth in the last 5 years (% on total)

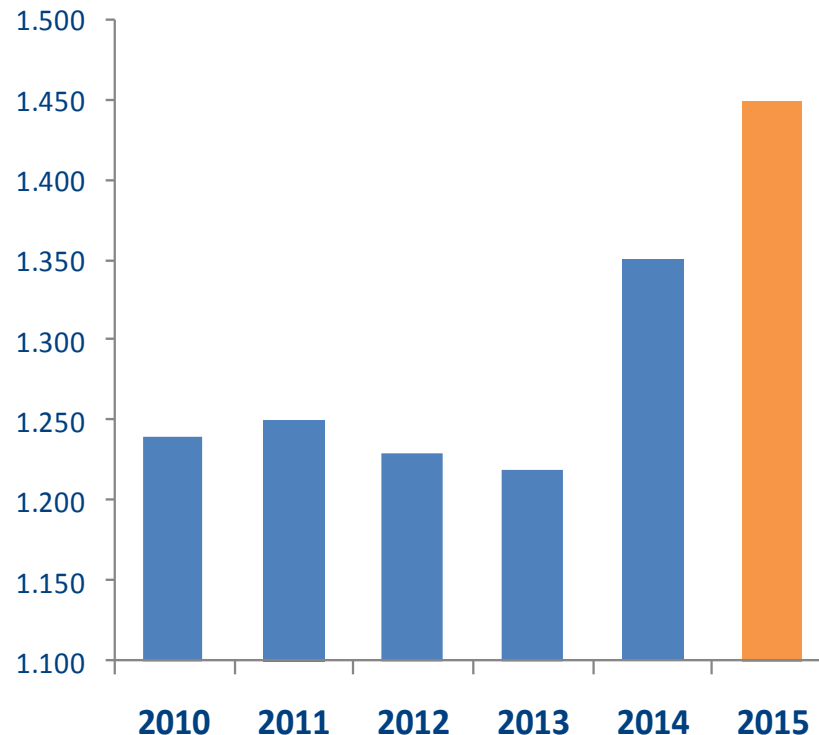


The highest contribution to overall industry, thanks to new investments



Double digit growth for R&D investments in Italy in the last years

Pharmaceutical R&D investments in Italy
(€ million)



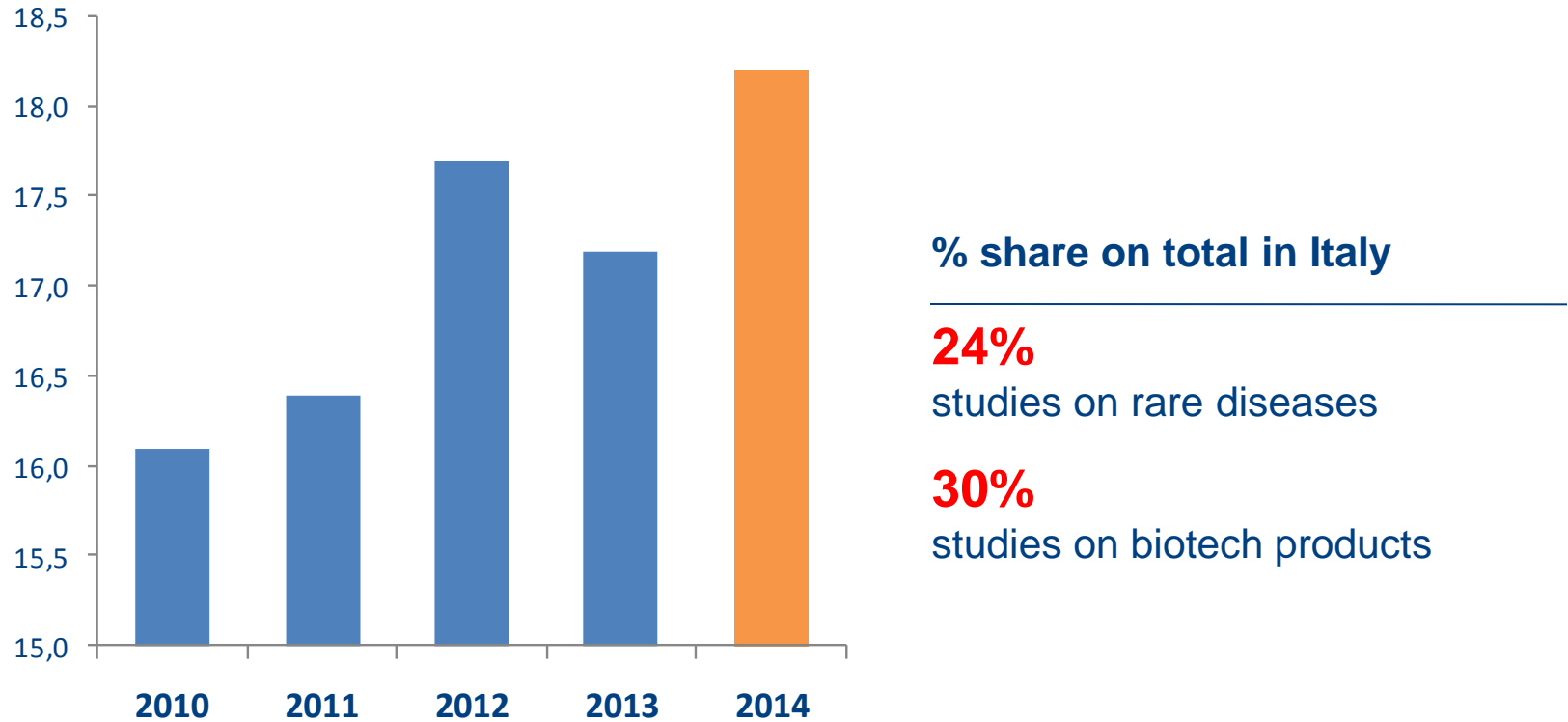
Specialization for biotech, vaccines, blood derivatives

- R&D investments: +20% in 2 years
- more than 300 biotech products under development
- excellence in advanced therapies and rare diseases
- utmost scientific quality also in NHS and public-private partnerships



A growing share on Eu clinical studies, that has to be fostered with actions for competitiveness

Clinical studies in Italy as a % share on EU total



Italy's R&D system has the capability to become a **European hub for clinical studies**, with a more efficient authorizing process and an innovation-oriented governance



Important results coming from a positive dialogue with the Government

- excellent dialogue with the Government.
The pharmaceutical industry is perceived as an asset for Italy and a reliable partner for growth

- stability to the pharmaceutical system after years of budget cuts from the previous Governments which underfunded it compared to actual needs

- increased resources on healthcare and pharmaceuticals

2014: +2,900 € mln for National Healthcare Fund (NHF) that is **+425 € mln for pharma caps**

2015: **+500 € mln for the pharma system**, due the Innovation Fund

2016: +1,000 € mln for NHF that is **+150 € mln for pharma caps +500 € mln for the pharma system**, due the Innovation Fund

- sharp reduction of DSO (2015 vs 2013: about -30%)
- active role of the high Level Steering Committee for the pharmaceutical sector set up by the Ministry of Industry, involving Ministries of Health, Economy, Research, the Regions, AIFA, Trade Unions, Farindustria and other stakeholders in order to shape appropriate measures for competitiveness



**Gaps to overcome as soon as possible
to keep Italy attractive for investments**



A positive dialogue with the Government but a **heavy legacy from the past and rising costs**

1 Hospital pharmaceutical expenditure (cap: 3.5% of NHF)



High burden on inpatient products: clawback about 25-30% of their turnover

2 Territorial pharmaceutical expenditure (cap: 11.35% of NHF)

In 2015 a manouvre with more than **300 € million cost**

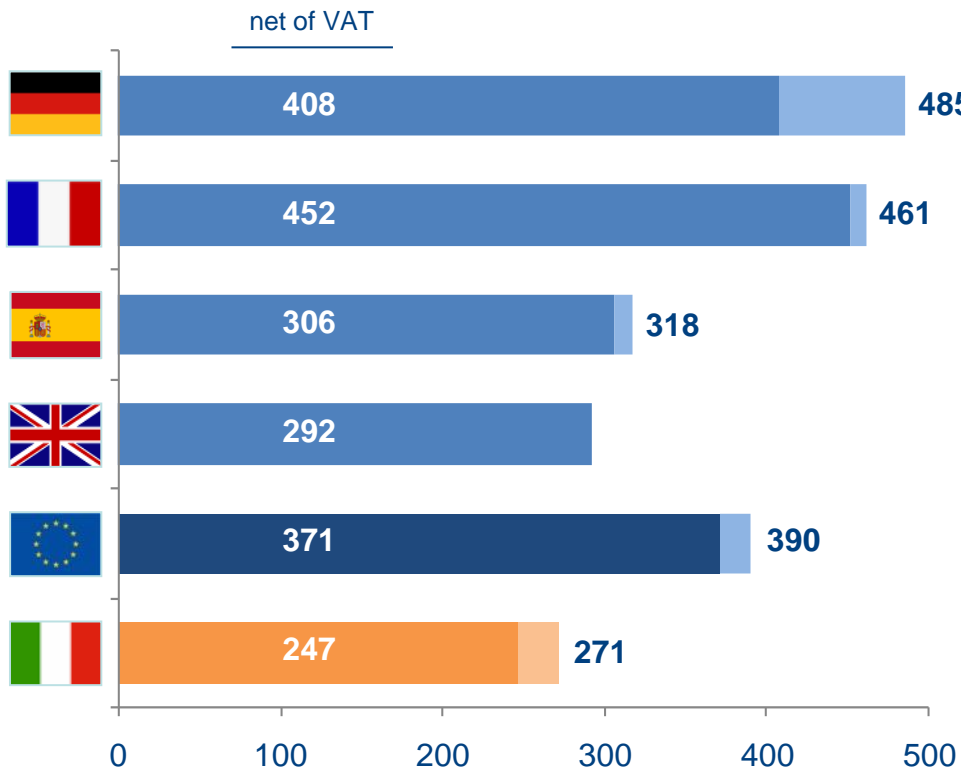
Expenditure for innovative drugs overpassing the Innovation Fund (500 € million/year in 2015 and 2016) included in territorial expenditure

The system is already underfunded and by 2020 innovative products will bring € billions of further spending. **Additional resources are needed or the system will be not sustainable and not attractive for investments**



The system in Italy is already underfunded and expenditure is decreasing

Public pharma expenditure per capita in Italy and other big EU countries
(territorial+hospital, €, public prices and net of VAT)



Lower prices compared to EU
for in-patient and off-patient,
both retail and hospital

-2%
public pharmaceutical expenditure
in Italy in 2006-2014



Innovation: access to new products must be improved

About 2 years

the overall time for access to new medicines

Even after market access **several restrictions to actual use especially due to regional and local constraints**

