



ASSOLOMBARDA

# The importance of the Life Sciences value chain in Lombardia: a comparison between Italian and European regions

2020 Edition

REPORT

N. 09/2020

by

Centro Studi

Settore Organizzazione Sviluppo e Rapporti associativi

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# **The importance of the Life Sciences value chain in Lombardia: a comparison between Italian and European regions**

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# Introduction

## Preamble

Since 2017 the Report on the Life Sciences Value Chain in Lombardia has been a communication, policy and working tool for Assolombarda, its member companies, associations throughout Italy and policymakers working in this sector. The report offers a precise summary of the constant collaboration between Assolombarda and the Trade Associations operating in Life Sciences at a national level with the aim of promoting the development of optimal conditions for the sector's growth and its competitiveness, starting from an analysis of its performance. It is an in-depth study which goes beyond the fragmented data and information for the sector, to provide readers with an overview of this 'ecosystem'.

The importance of the Life Sciences sector in Lombardia has resulted in the need to have a study and constant monitoring of the value generated by this value chain through the use of an analytical tool that can provide a snapshot of this 'ecosystem', year after year. The Report, which is now in its third edition, represents a synergistic component of the 'Life Sciences Hub project'. The aim of this project is to improve the competitiveness and internationalisation of Lombardia's Life Sciences value chain and its Regional Health Service.

The Life Sciences Hub project, which is coordinated by the Deputy Chair of Assolombarda with delegated powers for Life Sciences, facilitates interaction and collaboration between the public and private sectors, with a focus on the following strategic actions:

- Promotion of the importance of the Life Sciences value chain and the Regional Healthcare System Healthcare Services in Italy and abroad through entrepreneurial events and missions;
- Definition of proposals and guidelines for the development of the sector, in collaboration with regional and national institutions;
- Improvement and analysis of the performance of the research and clinical trial sector, to increase its competitiveness;
- Creation of joint project initiatives between companies and the academic sector, to align demand for and supply of competencies;
- Facilitation of relations between companies and institutions in different regions and countries, to promote the development of collaborations and partnerships in Lombardia;
- Guidance of companies and institutions towards funding opportunities for research and development, at both a national and European level.

## Objectives

The objective of the report is to promote and analyse the entire Life Sciences value chain in economic terms, starting upstream with industry (production of pharmaceutical intermediates and active ingredients, pharmaceutical products, medical devices, gas for medical uses and biotech research services), and also including all commercial activities (from wholesale to the retail sale of pharmaceutical products, medical devices and sanitary goods), through to the supply of Healthcare Services.

The analysis of the Life Sciences value chain offers a comparison between Lombardia and Italy and certain national benchmark regions - i.e. Emilia-Romagna, Lazio, Piemonte, Toscana and Veneto - that have comparable socio-economic conditions. The comparison then extends to a European level and considers the benchmark regions of Baden-Württemberg, Cataluña and Île de France that have a similar economic structure, and represent significant sectors for the economies of their respective countries and, above all, along with Lombardia, these are the most developed European areas for the Life Sciences. The analysis at the European level is carried out in comparative terms for two main segments of the Life Sciences value chain, i.e. the pharmaceutical industry and the Healthcare Services, and also provides an in-depth look at scientific research. The project is the result of a working group involving Assolombarda, AIOP, Cluster lombardo scienze della vita, Confindustria Dispositivi Medici, Farmindustria and the Associations of Federchimica (Aispec, Aschimfarma, Assobiotech, Assogastecnici and Assosalute), with the scientific support of CERGAS-SDA Bocconi.

## Credits

The report was prepared by: Felice Lopane and Stefania Saini (Assolombarda). We would like to thank Michela Bobini, Francesco Petracca and Alberto Ricci (CERGAS-SDA Bocconi) for their scientific support. Furthermore, special thanks to the following contributors: Angelo Cassoni for AIOP, Sara Carbone for Confindustria Dispositivi Medici, Riccardo Pareschi and Carlo Riccini for Farmindustria, Juliette Vitaloni for Federchimica, Rita Fucci for Assobiotech, Vera Codazzi for Cluster lombardo scienze della vita, Cristian Ferraris and Valeria Negri for Assolombarda.

# Main results: the Life Sciences at a glance

Covid-19 affected Italy and particularly Lombardia in a very severe manner. In light of the health and economic emergency caused by the pandemic, assessing the data and potential of the Life Sciences becomes ever more important.

The Life Sciences are strategic to the resilience of a Country to key challenges. Such role extends beyond defining and providing access to treatment, and increasingly concerns healthcare sustainability in the face of demographic changes and unpredictable and sudden shocks like the recent pandemic. The value chain is also strategic to the competitiveness of an economic system, for the value added it generates, and for its pivotal role in research and innovation.

Today, the pandemic compels us to a careful and synergistic analysis of the Life Sciences' intrinsically dual strategic relevance both to healthcare and the economy. More than ever, Health has emerged in all its relevance for the individual and as enabling factor of the entire economic and social system. Under this perspective the value chain with all its players must be a strategic partner of the economic and social system: not just because it can satisfy the health demands of citizens, but also because of its enabling role across all economic and social activities, meaning that it represents an investment for the resilience and development of the entire country.

- In Italy the Life Sciences sum to 225 billion euro in turnover in 2018, 100 billion in value added and 1.8 million workers.
- Lombardia confirms itself the Italian region priding the most developed Life Sciences value chain in economic terms: with a turnover of 71 billion euro, a value added of over 25 billion and 355 thousand workers, the regional value chain accounts for 32%, 26% and 20% of the respective national totals, compared to population weighting 17% and GDP 22%. Moreover, in the last five years Lombardia has experienced fast growth rates, above the national average: +27.5% vs +13.2% the turnover between 2014 and 2018, +22.8% vs +7.2% the value added.
- The Life Sciences in Lombardia distinctively comprises a relevant industrial branch which generates more than 31 billion euro of turnover (44% of the supply chain) and almost 9 billion of value added (34.8% of the supply chain): both these figures represent more than half of the national Life Sciences industry. Also healthcare services are strategic and significant in economic terms, contributing to 57.8% of the regional value chain value added (35.9% in terms of turnover).

- Considering both the direct contribution and that of satellite industries, the Life Sciences in value added account for 10.0% of Italian GDP, while the weight in Lombardia is higher and equal to 12.8% of regional GDP, for an overall value of 50 billion euro (2.8% of national GDP), a testament to Lombardia's specialization in the Life Sciences.
- In Europe, Lombardia is one of the leading pharmaceutical regions, along with Cataluña, Baden-Württemberg and Île de France. In particular, the pharmaceutical industry generates more value added than the benchmarks - 539 euro per inhabitant - and has a robust international dimension, exporting over 8 billion euro in 2019, double the amount in 2008. With regard to healthcare services, care intensity is lower in Lombardia than the benchmark regions, mainly reflecting fewer non-medical healthcare professionals and hospital beds. Nevertheless, so-called 'inappropriate' hospitalisation rates (for chronic conditions like asthma, hypertension and diabetes) are distinctively low at 116 hospitalisations for every 100 thousand inhabitants.
- As to scientific density in the Life Sciences, the number of publications in Lombardia is lower than the benchmarks in terms of quantity: 659 articles per million inhabitants in 2018, compared with 723 in Baden-Württemberg, 894 in Cataluña and, especially, 1,516 in Île de France. But in qualitative terms, Lombardia is aligned with its European peers: 190 highly cited articles, i.e. 2.9% of the total, a share very similar to that of Baden-Württemberg (3.1%) which leads the way.



# Defining the Life Sciences value chain

The Life Sciences value chain is a diversified and interconnected ecosystem that includes public and private players who operate in industry (pharmaceutical intermediates and active ingredients, pharmaceutical products, medical devices and biotech research services, industrial gases for medical use), trade (wholesale and retail sale of pharmaceutical products, medical devices and sanitary goods) and healthcare services.

Table 1 provides a detailed breakdown of the Life Sciences value chain and the segments that make it up, along with their respective Nace codes. For additional information on the analysis please refer to the Appendix on methodology.

Table 1 - The Life Sciences by segments

	Nace 2007
<b>INDUSTRY</b>	
<b>MANUFACTURE OF INDUSTRIAL GASES</b>	<b>20.11</b>
<b>MANUFACTURE OF BASIC PHARMACEUTICAL PRODUCTS AND PHARMACEUTICAL PREPARATIONS</b>	<b>21</b>
of which: Manufacture of basic pharmaceutical products	21.1
of which: Manufacture of pharmaceutical preparations	21.2
<b>MANUFACTURE OF IRRADIATION, ELECTROMEDICAL AND ELECTROTHERAPEUTIC EQUIPMENT</b>	<b>26.6</b>
of which: Manufacture of electromedical equipment (including parts and accessories)	26.60.02
of which: Manufacture of other equipment for irradiation and other electrotherapeutic equipment	26.60.09
<b>MANUFACTURE OF MEDICAL AND DENTAL INSTRUMENTS AND SUPPLIES</b>	<b>32.5</b>
of which: Manufacture of furniture for medical use, medical equipment, medical, surgical and veterinary material, appliances used in dental sciences	32.50.1
of which: Manufacture of dental prostheses (including repair)	32.50.2
of which: Manufacture of orthopaedic prostheses, other prostheses and aids (including repair)	32.50.3
of which: Manufacture of ophthalmic lenses	32.50.4
of which: Manufacture of all types of frames for glasses; in series frames for common spectacles	32.50.5
<b>REPAIR AND MAINTENANCE OF ELECTRONIC AND OPTICAL EQUIPMENT</b>	<b>33.13</b>
of which: Repair of electromedical equipment, medical, surgical and veterinary material, equipment and instruments for dental sciences	33.13.03
<b>RESEARCH AND DEVELOPMENT IN THE FIELD OF BIOTECHNOLOGIES</b>	<b>72.11</b>
<b>WHOLESALE AND RETAIL TRADE</b>	
<b>AGENTS SPECIALISED IN THE SALE OF OTHER PARTICULAR PRODUCTS</b>	<b>46.18</b>
of which: Agents specialised in the sale of pharmaceutical goods and cosmetics	46.18.3
<b>WHOLESALE OF PHARMACEUTICAL GOODS</b>	<b>46.46</b>
<b>DISPENSING CHEMIST IN SPECIALIZED STORES</b>	<b>47.73</b>
<b>RETAIL SALE OF MEDICAL AND ORTHOPAEDIC GOODS IN SPECIALISED STORES</b>	<b>47.74</b>
<b>HEALTHCARE SERVICES</b>	
<b>HUMAN HEALTH ACTIVITIES</b>	<b>86</b>
of which: Hospital activities	86.1
of which: Medical and dental practice activities	86.2
of which: Other human health activities	86.9
<b>RESIDENTIAL CARE ACTIVITIES</b>	<b>87</b>
of which: Residential nursing care activities	87.1
of which: Residential care activities for mental retardation, mental health and substance abuse	87.2
of which: Residential care activities for the elderly and the disabled	87.3
of which: Other residential care activities	87.9
<b>SERVICES OF PHYSICAL WELL-BEING ACTIVITIES</b>	<b>96.04</b>
of which: Thermal activities	96.04.2

# The value of the Life Sciences value chain: national benchmark

## The Life Sciences value chain

In Italy the Life Sciences overall sum to a turnover of approximately 225 billion euro in 2018, up by +13.2% on 2014<sup>1</sup>, over which the incidence of value added - which also increased to 100 billion euro (+7.2%) - remained fairly stable at 44%. The total workforce was 1.8 million in 2017, up by 60 thousand units from 2014.

Table 2 – The Life Sciences value chain: key economic indicators for Italy, Lombardia and national benchmark regions (2018)

	Resident population	Turnover (€ thousands)	Value added (€ thousands)	Workforce (2017)
Italy	60,359,546	224,480,179	99,772,747	1,789,173
<b>Lombardia</b>	<b>10,060,574</b>	<b>71,140,314</b>	<b>25,459,758</b>	<b>356,575</b>
Emilia-Romagna	4,459,477	17,628,443	8,566,443	153,383
Lazio	5,879,082	28,127,100	11,493,964	191,438
Piemonte	4,356,406	13,020,851	6,743,084	132,604
Toscana	3,729,641	15,645,373	6,734,312	117,461
Veneto	4,905,854	14,997,620	7,520,690	161,504

Source: based on Istat and AIDA data

In the national comparison with benchmark regions, Lombardia confirms its status as home of the economically largest Life Sciences value chain, with a turnover of 71 billion euro, more than 25 billion of value added and over 355 thousand workers.

The relevant contribution of Lombardia's Life Sciences to the national value chain is therefore confirmed: in Lombardia, where approximately one sixth of the national population resides (16.7%) and more than one fifth of Italy's GDP is generated (22.1%), one finds 19.9% of the Life Sciences's workforce, 25.5% of its value added and 31.7% of its turnover.

The other benchmark regions instead cover a share of the national economic

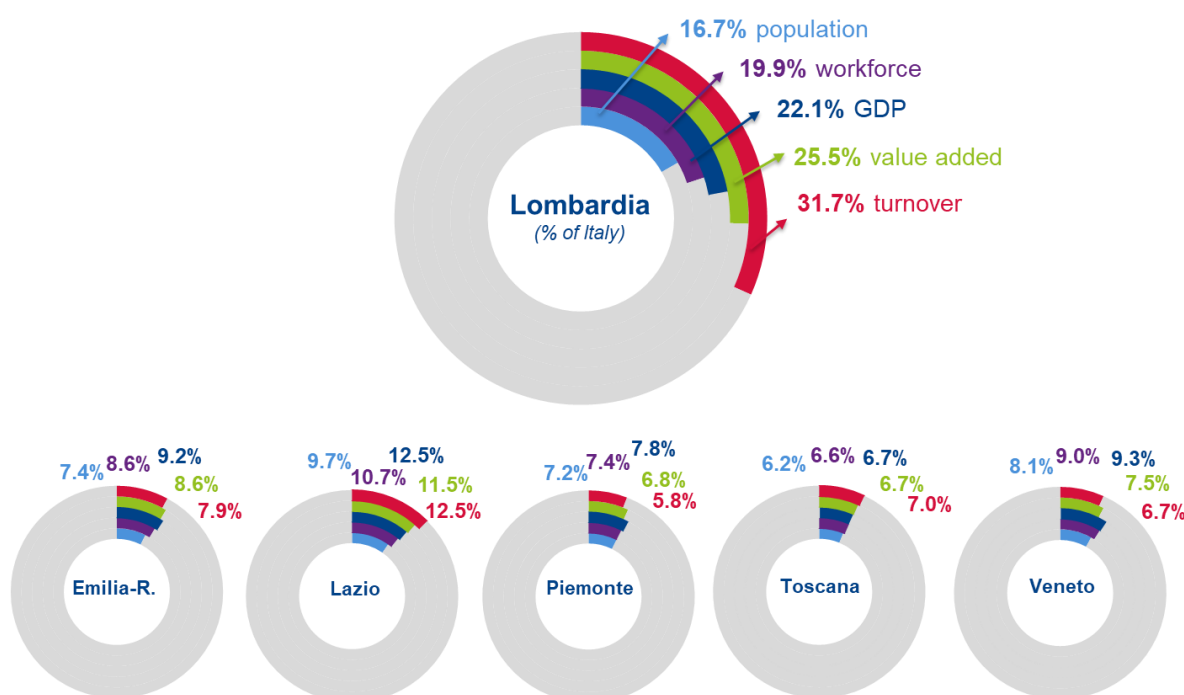
<sup>1</sup> Please refer to Assolombarda, *The importance of the Life Sciences value chain in Lombardia: a comparison between Italian and European regions*, 2017 edition.

figures above that broadly corresponds to their share of population and contribution to GDP.

Moreover, it should be noted that Lombardia's already significant contribution to the growth of the Life Sciences at a national level continues to rise. The region is experiencing high growth rates, above those observed at a national level: +27.5% vs +13.2% for turnover between 2014 and 2018, +22.8% vs +7.2% for value added.<sup>2</sup>

These results confirm Lombardia's specialisation in the Life Sciences and the sector's strategic role for the economic growth of the region and the country as a whole.

Figure 1 – The Life Sciences value chain: Lombardia's and national benchmark regions' shares of the Italian total (2018)



Source: based on Istat and AIDA data

Focusing on the main segments of the value chain, at a national level it is healthcare services that weight the most in terms of turnover (60.5%) and value added (79.1%). Industry follows, with a share of 25.8% of the turnover and 16.8% of value added. Finally, trade covers 13.7% and 4.1% respectively.

In Lombardia the contributions from industry and health services are more equally distributed. In terms of turnover, industry leads within the regional Life Sciences value chain, as it accounts for 44% of the total. Healthcare services account for the biggest contribution in terms of value added (57.8%). Trade has a marginal contribution (20.1% of turnover and 7.4% of value added).

<sup>2</sup> This positive gap with the national figure depends only to a minor extent from the addition of industrial gases for medical uses, a segment not included in the analyses on 2014 data. Over 90% of this sector, which is worth 2.4 billion in turnover and 800 million in value added, is concentrated in Lombardia.

Table 3 – The Life Sciences value chain by segments: Italy and Lombardia (2018)

	Italy				Lombardia			
	Turnover		Value added		Turnover		Value added	
	€ thousands	% of tot. value chain	€ thousands	% of tot. supply chain	€ thousands	% of tot. value chain	€ thousands	% of tot. supply chain
Industry	57,988,767	25.8%	16,808,427	16.8%	31,277,350	44.0%	8,850,676	34.8%
Trade	30,711,457	13.7%	4,091,464	4.1%	14,311,996	20.1%	1,890,923	7.4%
Healthcare services	135,779,955	60.5%	78,872,856	79.1%	25,550,968	35.9%	14,718,159	57.8%
<b>Total</b>	<b>224,480,179</b>	<b>100.0%</b>	<b>99,772,747</b>	<b>100.0%</b>	<b>71,140,314</b>	<b>100.0%</b>	<b>25,459,758</b>	<b>100.0%</b>

Source: based on Istat and AIDA data

## Industry

This edition of the report for the first time is able to capture the industrial branch. Firms were selected based on Nace codes and certain firm characteristics, such as the presence of own products on the market.

In Italy in 2018 the industrial segment of the Life Sciences industry registers a turnover of 58 billion euro and a value added of almost 17 billion euro. More than half of these figures are generated by industry in Lombardia, which demonstrates the specialisation and concentration of industrial activities in the region.

Indeed, the data for Lombardia reveal a highly consolidated segment, with a turnover of more than 31 billion euro and a value added of almost 9 billion, the equivalent of 28% of turnover.

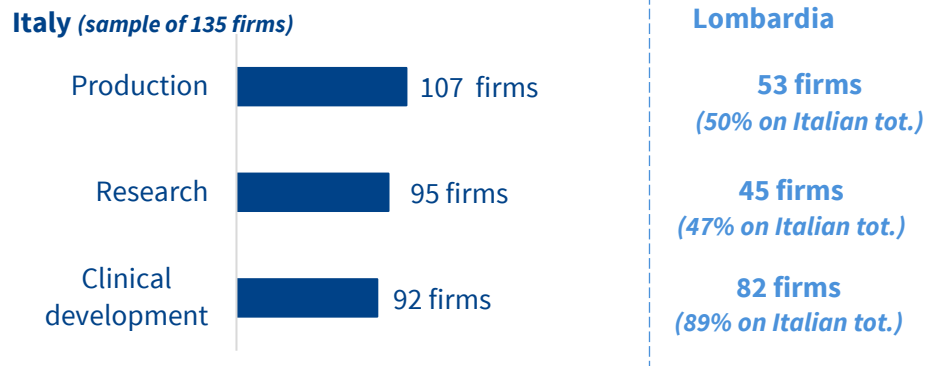
Table 4 - Focus on industry: key economic indicators for Italy, Lombardia and the national benchmark regions (2018)

	Turnover (€ thousands)	Value added (€ thousands)	% of Italian value added
Italy	57,988,767	16,808,427	100.0%
<b>Lombardia</b>	<b>31,277,350</b>	<b>8,850,676</b>	<b>52.7%</b>
Emilia-Romagna	3,977,687	1,520,116	9.0%
Lazio	10,673,247	2,669,317	15.9%
Piemonte	1,493,950	540,980	3.2%
Toscana	4,909,705	1,431,538	8.5%
Veneto	3,201,717	997,459	5.9%

Source: based on Istat and AIDA data

It is interesting to examine the type of activities these firms carry out. Analysing a sample of 135 of the Italian and foreign capital industrial firms most relevant in terms of turnover (together totalling over 40 billion euro in turnover), approximately 80% have one or more production sites in Italy, 70% conduct research activities and 65% clinical development activities. Approximately half the firms operating in Italy in Life Sciences production and research have at least one business site in Lombardia; this share is even higher considering clinical development activities which, in almost 90% of cases, are carried out in premises situated in the region.

Figure 2 - Focus on industry - type of activity: analysis on 135 of the biggest firms in terms of turnover



## Healthcare services

In Italy healthcare services<sup>3</sup> generates a turnover of 135 billion euro in 2017 and a value added of almost 78.9 billion euro. These two figures represent an increase of +10.1% and +4.5% respectively<sup>4</sup> compared to 2014 data published in the 2017 edition of the Report. The overall workforce now exceeds 1.4 million units, up by more than 48 thousand units (+3.6%) compared to 2014. This increase does not depend on the number of persons employed in the national healthcare system (SSN): 647 thousand in 2017, 1,000 fewer professionals compared to 2016.<sup>5</sup> Considering also that the main staff categories part of the SSN (general practitioners and family paediatricians) fell slightly in absolute terms (-605 units),<sup>6</sup> the increase might be attributed to private hospitals, employing around 120 thousand persons, and the segments of outpatient and laboratory activities, dental surgeries and residential and home services provided in the health and care sectors.

The distribution of healthcare services value added across regions reflects fairly accurately the demographic distribution of the population: Lombardia, where 16.7% of the Italian population resides, generates 18.7% of the overall value added for healthcare services. The significant public debt and the necessary extensiveness of health and care services indeed ensure a fair distribution of production and the resulting value added. Based on comparable data for 2014, in Lombardia value added increased by +8.9%, more than in Italy as a whole and, considering benchmark regions, lower only than the figure for Veneto (+9.7%).

Even with regard to the workforce, the regional distribution is broadly aligned with the demographic distribution. Compared with 2014, in Lombardia there was an increase of almost 11 thousand units, which was exceeded only by Lazio (approximately +13 thousand units).

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<sup>3</sup> Aside from public and private hospital services, specialist and outpatient services, health and care services with a prevailing health and care component, the calculation of health services turnover and value added also includes firms providing services (mainly medical gas and medical devices companies) to healthcare facilities. Overall, these companies generate a turnover of 1.4 billion euro and a value added of almost 546.5 billion euro.

<sup>4</sup> To guarantee comparability over time, percentage differences are computed without considering the contribution of firms providing services to healthcare facilities.

<sup>5</sup> Ministry of Economics and Finance - General State Accounting Office, 2017 Annual accounts.

<sup>6</sup> Please refer to the Statistical Yearbook of the SSN for 2016 and 2017 published by the Italian Ministry of Health.

Table 5 - Focus on healthcare services: key economic indicators for Italy, Lombardia and national benchmark regions (2017)

	Turnover (€ thousands)	Value added (€ thousands)	% of Italian value added	Workforce
Italy	135,779,955	78,872,856	100%	1,403,300
<b>Lombardia</b>	<b>25,550,968</b>	<b>14,718,159</b>	<b>18.7%</b>	<b>251,087</b>
Emilia-Romagna	11,559,585	6,742,919	8.5%	120,848
Lazio	14,487,771	8,393,399	10.6%	147,142
Piemonte	10,394,902	6,056,828	7.7%	110,302
Toscana	8,715,054	5,082,049	6.4%	90,221
Veneto	10,708,206	6,240,707	7.9%	115,286

Source: based on Istat and AIDA data

## The satellite industries of the Life Sciences value chain

The next step of the analysis is to appraise the value chain's satellite industries, to provide a measurement of the positive externalities and the indirect economic impact generated from the spill-over into other sectors of the economy. Methodological choices and assumptions are detailed in the Appendix.

The results of this exercise are presented in Table 6 which shows, next to the value added of the value chain illustrated above, the overall value added including satellite industries and the weight of the latter on regional and national GDP.

Table 6 - Life Sciences value chain: value added and value added including satellite industries for Italy, Lombardia and the national benchmark regions (2018)

	Value added value chain (€ thousands)	Value added satellite industries (€ thousands)	Value added value chain + satellite industries (€ thousands)	GDP (€ thousands)	% of value added (value chain + satellite industries) on regional GDP
Italy	99,772,747	77,714,942	177,487,689	1,766,168,200	10.0% <i>(of national GDP)</i>
<b>Lombardia</b>	25,459,758	24,628,746	50,088,504	390,461,000	<b>12.8%</b>
Emilia-Romagna	8,566,443	6,102,959	14,669,402	161,686,300	9.1%
Lazio	11,493,964	9,737,590	21,231,554	197,947,800	10.7%
Piemonte	6,743,084	4,507,813	11,250,897	137,471,000	8.2%
Toscana	6,734,312	5,416,421	12,150,733	117,917,700	10.3%
Veneto	7,520,690	5,192,170	12,712,860	163,682,800	7.8%

Source: based on Istat and AIDA data

In Italy satellite industries' value added is 77.7 billion euro in 2018. Considering both the direct value added (99.7 billion euro) and satellite industries' value added (77.7 billion euro), the Life Sciences value chain in Italy generates a total value added of more than 177 billion, which corresponds to 10.0% of national GDP. This value is unchanged compared to 2014, which demonstrates a similar growth trend for value added including the satellite industries and national gross domestic product in this period of time.

Conversely, in Lombardia the direct and indirect contribution of the Life Sciences to the regional economy altogether increased by more than 1 percentage point compared to 2014 and is equal to 12.8% of the regional GDP in 2018 (or 2.8% of the national GDP), with overall value added being 50 billion euro. The contribution generated in Lombardia by the Life Sciences industry is higher than the Italian average and than in the benchmark regions and further confirms the fundamental role played by the Life Sciences in the specialisation of the economy in Lombardia.



# The pharmaceutical industry, healthcare services and Life Sciences research: European benchmark

The analysis of the Life Sciences value chain was also conducted at an international level, by comparing Lombardia with Baden-Württemberg, Cataluña and Île de France which together are the main European regions for the Life Sciences. For the selection of the benchmark regions, given that the presence of workers involved in healthcare and social services is correlated with the catchment area at regional level, the attention was dedicated to the pharmaceutical industry identifying for each key country in this sector (France, Germany and Spain) the region with the largest share of the European total workforce.

The benchmark regions<sup>7</sup> have a population ranging from 7.4 million inhabitants in Cataluña to 12.2 in Île de France. The percentage of the population aged above 65 varies from 14.6% in Île de France to 22.2% in Lombardia, which reflects Italy's status as the most elderly country in Europe, with a demand for healthcare and especially social care that is significant and on the rise. Population density is particularly high compared to the European average (118 inhabitants/square kilometre): it ranges from 234 inhabitants/sq.km in Cataluña to 1,020 inhabitants/sq.km in Île de France, with Lombardia in a median position (435 inhabitants/sq.km).

In general, these are highly urbanised areas, where the supply of healthcare services is normally ample, but where the management of demand is particularly complex because of numerous factors: e.g. a plurality of stakeholders involved in promoting health and designing care programs, significant social inequalities and the presence of specific health risk factors.

The four regions being analysed are of significant economic importance in their respective nations, with shares of national value added ranging between 15% for Baden-Württemberg and approximately 31% for Île de France, which includes the capital Paris and therefore a significant concentration of economic activities for the proximity to institutional headquarters. Even in this case, Lombardia occupies an intermediate position (22.1%).

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<sup>7</sup> In terms of the Eurostat NUTS classification, Baden-Württemberg is code DE1, Cataluña code ES51, Île de France code FR10, Lombardia code ITC4.

Table 7- The European benchmark regions: overview (2017)

	Baden-Württemberg	Cataluña	Île de France	Lombardia
Population (million)	11.0	7.4	12.2	<b>10.0</b>
% of population aged over 65	19.9%	18.8%	14.6%	<b>22.2%</b>
Population density (inhabitants/sq.km)	311	234	1,020	<b>435</b>
Value added (€ million)	440,576	200,723	631,948	<b>343,596</b>
% value added of national total	15.1%	19.1%	30.9%	<b>22.1%</b>

Source: Eurostat

The analysis of the international comparison focuses on two segments, the pharmaceutical industry and healthcare services, which contribute most significantly to employment and value added in the overall value of the Life Sciences value chain. These two segments also offer a complete set of data at a European level.

## Pharmaceutical industry

The European comparison show that the pharmaceutical industry in Lombardia generates more value added per capita than all the other benchmark regions: 539 euro per inhabitant, followed by Cataluña and Île de France with 511 and 465 euro respectively, and finally Baden-Württemberg with 375 euro.

The pharmaceutical industry in Lombardia emerges as an important sector for the local economy even when assessing the sectorial share of value added and turnover over the total generated by all regional firms registered in the ORBIS database. In Lombardia the pharmaceutical industry accounts for 1.8% of value added and 1.5% of turnover. These values put Lombardia behind Cataluña alone (which records a share of 3.5% for value added and 2.5% for turnover). In the comparison with the other benchmark regions, Île de France, which in absolute terms records the highest values after Lombardia, in percentage terms ranks at the bottom of the panel under consideration (1.1% and 1.0% of the total regional companies in terms of value added and turnover respectively), a testament to the fact that, while being extremely prosperous, the pharmaceutical industry in the Paris region exists alongside other equally developed industrial segments limiting its relative importance. Similarly, in Baden-Württemberg there are also other developed industrial (automotive, electronics, chemicals) and services sectors (banking and insurance) so the share of the pharmaceutical industry on the total regional economy is limited - 1.5% in terms of value added and 1.4% in terms of turnover.

Table 8- Indicators for the pharmaceutical industry in Lombardia and the European benchmark regions (2017)

	Baden- Württemberg	Cataluña	Île de France	Lombardia
value added for pharmaceutical industry, euro per inhabitant	375	511	465	<b>539</b>
% value added for pharmaceutical industry on total regional economy	1.5%	3.5%	1.1%	<b>1.8%</b>
% turnover for pharmaceutical industry on total regional economy	1.4%	2.5%	1.0%	<b>1.5%</b>
pharmaceutical industry workforce, per million inhabitants	3,015	2,920	5,047	<b>2,141</b>

Source: based on ORBIS, Eurostat data

These indicators confirm Lombardia's being a key player in the European pharmaceutical industry. Moreover, the pharmaceutical sector in Lombardia is significantly improving its competitiveness and international outlook. Indeed, in 2019 pharmaceutical companies in Lombardia exported goods for a total value of 8.4 billion (26% of total Italian exports for the sector), with an increase that was more than double 2008 levels (+140%) and higher than all European benchmarks. Lombardia's rising international stance has also been a driver for Italy in recent years, as the country has become one of the leading European pharmaceutical producers alongside Germany. In the comparison with the benchmarks, in terms of the absolute value of pharmaceutical exports, Lombardia is on par with Île de France (8.2 billion in 2019) and ahead of Cataluña (6.3 billion); Baden-Württemberg's exports are instead almost three times as high (23.9 billion).

Finally, the last comparative indicator between the European regions concerns the workforce of the pharmaceutical industry relatively to the resident population. Here, Lombardia (2,141 workers per million inhabitants) is behind the benchmarks, with Île de France leading with 5,047 workers per million residents, followed by Baden-Württemberg and Cataluña (with 3,015 and 2,910 respectively).

## Healthcare services

Table 9 shows the value added figures by the healthcare services segment (this includes hospital services, as well as specialist and outpatient services, health and care services with a prevailing health and care component) in the four regions being analysed and the respective share of regional value added. The total value added generated by the four regions amounts to 67.0 billion euro, including both public and private providers, with the region of Île de France (25.0 billion euro) at the top and Cataluña (8.8 billion) at the bottom. Lombardia ranks in the middle, with a value added of 14.5 billion. While there are significant differences in absolute terms, the percentage share of the total regional value added is similar across the benchmark regions, ranging between 4.0% in Cataluña and 4.3% in Baden-

Württemberg (4.2% in Lombardia). Compared to the data in the 2018 Report, which referred to the year 2016, we can see a stronger convergence between regions, with the gap between the maximum and minimum value having fallen from 0.9% to 0.4%.

Table 9- Healthcare services: regional overview (2017)

	Baden-Württemberg	Cataluña	Île de France	Lombardia
value added for healthcare services (€ billion)	18.8	8.8	25.0	<b>14.5</b>
% value added for healthcare services on total regional economy	4.3%	4.4%	4.0%	<b>4.2%</b>

Source: based on Eurostat data

Nevertheless, it should be noted that for healthcare services it is not possible to define in an objective and certain manner the trade value: the meaning of value added is therefore less clear and subject to interpretations that are not very robust. This remains the case even when healthcare fees are charged, because, even though these allow to compute turnover, they do not express the economic value of a service and are by their very nature different to pricing policies adopted in other sectors which tend to use genuine market prices.<sup>8</sup> As a result, measuring the value generated by goods and services production and distribution is insufficient to compare the selected regions' healthcare performance. A comparison of performances must consider qualitative and quantitative components which also express the system's contribution to the improvement of a population's level of health.

As a result, the indicators selected to assess and compare on an aggregate basis the performance of health services across the various regions refer to procedures and outcomes, with the aim of intercepting in a clear manner the ultimate institutional purpose of these activities, i.e. that of satisfying the healthcare requirements of citizens. The indicators are: healthcare workers per 1,000 inhabitants (including medical and nursing staff); hospital beds per 1,000 inhabitants; composite indicator of inappropriate hospitalisation; life expectancy at 65 years of age.

Table 10- Indicators of healthcare services for Lombardia and European benchmark regions (2017)

	Baden-Württemberg	Cataluña	Île de France	Lombardia
Healthcare workers per 1,000 inhabitants, of which:	17.4	9.5	13.3	<b>9.1</b>
<i>Medical staff per 1,000 inhabitants</i>	4.1	3.5	3.9	<b>3.7</b>
<i>Nursing staff per 1,000 inhabitants</i>	13.3	6.0	9.4	<b>5.4</b>
Hospital beds per 1,000 inhabitants	7.4	3.9	5.5	<b>3.5</b>
Life expectancy at 65 years of age	20.3	21.6	22.7	<b>21.4</b>
Composite indicator of 'inappropriate' hospitalisation for chronic conditions (asthma, hypertension and diabetes)	496.2	193.8	308.1	<b>116.7</b>

Source: based on Eurostat data, institutional websites

As highlighted in previous editions of the Report, the number of workers involved in

<sup>8</sup> Borgonovi E. (2017), *Il valore aggiunto delle pubbliche amministrazioni, Azienda pubblica*.

providing health services varies quite significantly, especially as a result of different healthcare system models. In Baden-Württemberg per capita workforce in the healthcare sector exceeds 17 units per 1,000 inhabitants in 2017 and 2016, a significantly larger number than in the other regions being analysed. In terms of services, the number of workers employed in the healthcare sector<sup>9</sup> in the German regions allows for an extensiveness of healthcare services that is larger than those of other regions, but this does not mean not better treatment outcomes and levels of health than the average for the main Eu countries. Île de France occupies an intermediate position, with 13.3 units, while Lombardia and Cataluña have less than 10 professionals per 1,000 inhabitants. These differences are attributable to the smaller number of nursing professionals: Baden ranks the highest with 13.3 nurses per 1,000 inhabitants, followed by Île de France with 9.4 nurses and last by Cataluña and Lombardia with 6.0 and 5.4 nurses per 1,000 inhabitants respectively. As in previous years, the figure for Lombardia is the lowest amongst the benchmark regions, which is also due to a lower number of beds per inhabitant.

The second indicator measures structural supply in terms of beds and therefore offers a proxy for hospital care capacity in the different regional systems. Baden-Württemberg has the highest number of beds per 1,000 inhabitants (7.4), significantly higher than the other regions being examined. Lombardia is the region with the lowest number of hospital beds, with 3.5 for every 1,000 inhabitants, while Île de France and Cataluña have values of 5.5 and 3.9 respectively. This result is certainly affected by specific healthcare policies that have been implemented (e.g. the DM/70 in Italy) to promote the merging of different health authorities or the closure of small peripheral units, as well as the introduction of medical technologies that allow certain conditions to be treated in an outpatient setting and/or in Day Hospitals and Day Surgeries, thereby reducing the need for hospital beds for ordinary hospitalisation.<sup>10</sup>

The third indicator measures the life expectancy at 65 years of age in the four regions and reveals differences that are not negligible: despite similar social demographic conditions, there is a difference of more than two years between the region with the highest life expectancy for people aged 65 (22.7 years in Île de France) and the region with the lowest life expectancy (20.3 years in Baden-Württemberg). Lombardia is in an intermediate position, with a figure of 21.4 years.

Finally, the fourth indicator measures the appropriateness of the hospital activities, by integrating in a single composite indicator the hospitalisation rates for three of the main chronic conditions (asthma, hypertension and diabetes), which should mainly be treated outside hospitals. Although the data are influenced by different hospitalisation models and a different supply size by the hospital network, they reveal what appears to be a virtuous performance for Lombardia and Cataluña, with composite hospitalisation rates below 200 for every 100 thousand inhabitants. Compared to 2016, in line with the other benchmark regions, one can see a further reduction in the composite hospitalisation rate for Lombardia, which fell to 117 from 129 in the previous year. The difference compared to the other benchmark regions is mainly attributable to diabetes (fewer

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<sup>9</sup>Healthcare workers include doctors and nurses.

<sup>10</sup>OASI 2019 Report.

than 100 hospitalisation rates per 100,000 inhabitants in Lombardia and Cataluña, compared to around 200 for Baden-Württemberg) and hypertension (where Lombardia has the lowest hospitalisation rate at 27.2). Île de France occupies an intermediate position, as a result of very limited hospitalisation for hypertension, average hospitalisation for diabetes and the highest hospitalisation rate amongst the benchmark regions for asthma (97.3 for every 100 thousand inhabitants).

## Life Sciences research in terms of scientific publications

Scientific research is measured in terms of both quantity, i.e. articles published, and in terms of quality, i.e. citations.

Between 2014 and 2018 Lombardia experienced a significant increase in scientific production (+11%) - more than all the benchmark regions. However, in terms of 'quantity', the number of Life Sciences publications in Lombardia remains below benchmark levels: 659 articles per million inhabitants, compared with 723 in Baden-Württemberg, 894 in Cataluña and, especially, 1,516 in Île de France, which doubles the other benchmarks. Nevertheless, it should be noted that compared to Germany and France, Italy has a lower level of investment in R&D in absolute terms.

In terms of the 'quality' of the research, there is a greater level of homogeneity across the European regions, with Lombardia accounting for 190 highly cited Life Sciences articles (2.9% of the total) just behind Baden-Württemberg (3.1%).

Table 11- Life Sciences scientific articles: total and % highly cited (2018)

	Baden-Württemberg	Cataluña	Île de France	Lombardia
Scientific articles on Life Sciences, per million inhabitants	723	894	1,516	<b>659</b>
% scientific articles on Life Sciences that are highly cited	3.1%	2.7%	2.2%	<b>2.9%</b>

Source: based on Incites Clarivate Analytics data

# Discussion

**The 2020 edition of this Report comes at an unprecedented moment in history. Covid 19 affected Italy and particularly Lombardia in a very severe manner, with 1.4 million and 371 thousand people managed respectively for infection from the SARS-CoV-2 virus (as at 22/11/20). Against this backdrop, the Life Sciences value chain reaffirmed its strategic importance, starting from healthcare and social care services that were put under an increasing level of pressure.** In the first half of April, Italian healthcare facilities registered a peak in hospitalisations, with more than 24 thousand COVID-19 patients (almost 4 thousand of whom were in intensive care). In the first phase of the pandemic, in Lombardia, public and private hospitals significantly increased the number of beds in intensive care units. In particular publicly contracted private hospitals increased the number of intensive care units beds by 79% (which shifted from 900 to 1755 during the first months of the virus spread), taking care of 30% of the overall COVID-19 patients. Furthermore, they increased by 90% COVID-19 inpatients beds, for a total of 12.300 beds. Even companies operating in the pharmaceutical, biotech research, gas for medical use and medical devices sectors contributed significantly to the management of the pandemic. Firstly, by ensuring operational continuity and guaranteeing the availability of treatments to citizens and operating in close synergy with the institutions to resolve all situations of insufficient supplies of products caused by the sudden spike in demand. Numerous clinical trials have been started by Italian and international companies to identify a cure for the SARS-CoV-2 virus and many companies have invested in R&D and developed medical devices that can intercept the virus and enable epidemiological prevention and monitoring activities. Moreover, many companies in the value chain reconverted or expanded production lines to manufacture products to prevent any shortcomings and gaps in health care, and also supported the creation of global value chains by making certain medical devices open-source and provided donations as well as ad hoc products and services to support the SSN and patients. All of this enabled the Life Sciences value chain to confirm, once again, its strategic importance in terms of the country's resilience in facing major challenges, not only in terms of determining and ensuring access to treatment, but also, and increasingly, in terms of the sustainability of the healthcare in light of demographic changes and potential economic and health shocks.

## **The role of industry in supporting the nation and the Lombardia region during the COVID-19 emergency**

Starting from the outbreak of the COVID-19 emergency, the Life Sciences value chain and its companies facilitated operations for the National and Regional Healthcare System in the following areas:

- ❖ **Investments in research, clinical development and innovation:** 80 companies responded to a national call from Confindustria to develop new Life Sciences technologies to fight the pandemic, for a total of 324 projects; of these, more than 80 projects are linked to the development of new diagnostics, vaccines, therapies, nutraceuticals. If we look to the situation internationally, in terms of vaccine projects alone, there are 226 candidate vaccines in the pipeline, of which more than 30 are already in a clinical trial phase involving humans;
- ❖ **Production of products for tackling the COVID-19 emergency:** By expanding production lines for pharmaceutical products, diagnostics, medical devices and lines of clinical research and development; by activating new production lines for the manufacturing of medical devices and essential personal protective equipment;
- ❖ **Technical support for the development of production chains:** by providing expertise and professionals to support companies in the national territory in launching local production;
- ❖ **Technical support to facilitate the country's access to reliable essential products:** by providing expertise and useful contacts for the creation of alternative channels for purchasing essential products;
- ❖ **Expansion of healthcare facilities:** with an increase in the number of beds in intensive care units and for COVID-19 patients, the creation of facilities for receiving patients with the virus, the increase of diagnostic activities for carrying out molecular and serological tests, the expansion of storage and distribution networks for oxygen, through to an increase in staff available for managing patients;
- ❖ **Increase in the number of professionals available for the SSN:** by providing the SSN and healthcare institutions with professionals trained in medical and scientific disciplines and operating in entrepreneurial environments of the Life Sciences sector;
- ❖ **Development of innovative services to support the SSN:** to allow for a reduction in waiting lists through the provision of specialist visits on digital platforms, but also through product delivery services (72% of pharmaceutical companies put in place these types of services);
- ❖ **Development of materials and projects for training and information:** for healthcare professionals and citizens, to reduce the risk of infection and promote compliance with the prevailing provisions during the pandemic;
- ❖ **Financial support to the SSN and the country:** through donations provided by companies and their employees;

On top of this there were numerous philanthropic activities with companies providing support through financial resources, the donation of products and specific projects for citizens in need, the SSN and the country.

The Life Sciences sector is strategic for its capacity to respond to health demands and for the competitiveness of the regional system, as a result of the economic



importance it has and its pivotal role in research and innovation. It is sufficient to note that at a global level, private investments in research and development for the pharmaceutical and biotech industries have been constantly growing for more than a decade and were above 140 billion in 2018<sup>11</sup>. Between 2020 and 2026 their combined international value will be 1,500 billion<sup>12</sup>. In 2019 more than 181 thousand patent applications were deposited with the European patent office, of which more than 28 thousand (16%) related to the categories "Medical technologies", "Pharmaceuticals" and "Biotechnologies".

Our analysis quantifies the value of the Life Sciences value chain to offer an overview of the Life Sciences ecosystem and constantly update Lombardia's international positioning. The report offers a snapshot for the year 2018 and focuses on Lombardia in comparison with Italy, the most significant and similar Italian regions from a socio-economic perspective (Emilia-Romagna, Lazio, Piemonte, Toscana, Veneto) and the European regions which, along with Lombardia, represent the most developed areas for Life Sciences (Baden-Württemberg, Cataluña and Île de France).

As the numbers presented in the Report have also confirmed, the Life Sciences ecosystem in Lombardia and the regional health service represent a virtuous model for Italy which, thanks to the strength of its interconnections and specific characteristics, generates social and economic value across the entire country, especially during this unprecedented moment in history. Indeed, despite the health emergency linked to Covid-19, the Life Sciences value chain and the health system represent a value added that is both a starting point and an area to focus on additionally for future progress and the economic, societal and health recovery.

In Lombardia the Life Sciences value chain is an extensive, diversified and interconnected ecosystem that includes public and private players, operating in the industry (pharmaceutical intermediates and active ingredients, pharmaceutical products, medical devices and biotech research services, industrial gases for medical use), trade (wholesale and retail sale of pharmaceutical products, medical devices and sanitary goods) and health and social care services. This ecosystem is completed by research centres, universities and non-profit bodies which, in synergy with companies, are a driver for the network's multidisciplinary research and innovation. Today 80% of research and innovation comes from this network which lies outside companies' laboratories: this represents a complete paradigm shift from the start of the century and it is thanks to this integrated value chain and the dissemination of technologies that innovation, state-of-the-art devices and treatments move from research directly to clinical phases and the patient.

**In Lombardia in 2018 the Life Sciences value chain sum to 71 billion euro in turnover and over 25 billion euro in value added. Considering also the satellite industries, the overall value added generated is more than 50 billion euro and represents 12.8% of the regional GDP, while at a national level this share is 10.0% (this value is stable compared to the results for the previous two year**

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<sup>11</sup> European Commission, The 2019 EU Industrial R&D investment scoreboard, December 2019.

<sup>12</sup> EvaluatePharma, 2020.

**period).** It is therefore a sector of specialisation which is particularly important for the economy in Lombardia and even more so for the national value chain, since Lombardia accounts for 25.5% of the value added and 31.7% of the turnover of the Italian Life Sciences sector, with a regional population of 16.7% and regional GDP of 22.1% of the respective national levels.

The importance of the Life Sciences value chain in Lombardia is characterised by the presence of an industrial sector which exceeds the national average and generates more than 31 billion euro of turnover (44% of the value chain) and almost 9 billion of value added (34.8% of the value chain): both these figures account for more than half of the total value of the Italian Life Sciences industry.

In terms of industry it is interesting to analyse the types of activities carried out by companies in Lombardia and Italy as a whole, including for the purposes of identifying policy recommendations. From an analysis conducted on a sample of 135 of the biggest industrial companies in terms of turnover, approximately 80% of these have one or more production sites in Italy, 70% carry out research activities and 65% are involved in clinical development activities. These tend to be local companies or some of the large multinationals with production plants in Italy. Conversely, mid-size foreign companies tend to have a presence in the region through sales branches and are more inclined to invest in clinical development due to the presence of a specialised and competitive network of hospitals and IRCCs (university and research hospitals). Nevertheless, it should be noted that there is still a need to streamline bureaucratic processes and reduce the approval timeframes for clinical trials in order to remove factors that significantly penalise Italy and indirectly benefit other countries like Spain or countries in Eastern Europe. Although the number of companies with research hubs is significant, it is still not sufficient to make Italy one of the main European and global players in Life Sciences innovation, as confirmed by the comparative data for Italy, Germany and France on the number of patents registered every year in this field. To promote and strengthen the capacity of the value chain an industrial plan must therefore be developed, starting from research and the promotion of enterprise and the SSN, through a structural incentives plan and especially simpler and clearer rules for creating new productive and research hubs to attract professionals and increase the patent development capacity. This plan can only be productive within an environment that is attractive in terms of funding rules, respect for intellectual property and consideration for the industrial effects of healthcare policies, and also in terms of innovation development and access and more generally health expenditure governance policies. With regard to Lombardia, about half the companies considered and active in Life Sciences production and research at a national level have at least one business premises in the region. This figure becomes even more significant if we consider development activities which, in almost 90% of cases, are carried out in facilities situated within the region. These positive figures demonstrate the potential of the Life Sciences ecosystem in Lombardia (and Italy as a whole) to compete in a global market and attract significant investments in clinical development (more than 50% in the pharmaceutical sector alone) thanks especially to the presence of 19 IRCCS (of which 5 are public and 14 private) out of a total of 51 in Italy. The remaining percentage of companies that invest in production and research demonstrates the need to add to the agendas of national and regional governments specific policies

for promoting the development and growth of this segment which is an integral part of the SSN and represents one of the most important areas of national specialisation, in terms of its impact on the health system, the economy and society.

In Lombardia, along with industry, Healthcare Services are also strategic and significant in economic terms: the weight of the value added on the total for the regional value chain is 57.8% (35.9% in terms of turnover). It is useful at this point to provide certain supplementary indicators to offer a more precise snapshot of a sector that, even in Lombardia, represents a key driver for the entire value chain. This segment is largely funded by public health expenditure, but private parties also play an important role. A first figure shows that in Lombardia public health expenditure is the lowest in Italy in terms of the percentage of regional GDP: 5% compared to a national average of 6.8% in 2018<sup>13</sup>. This figure can be explained by the fact that GDP per capita in Lombardia is significantly higher than the national average, while the level of public health expenditure per capita is broadly in line with national levels (1,944 euro per capita compared to a national average of 1,958 euro, i.e. just 1% less)<sup>14</sup>. This paints the picture of a particularly modest regional health service compared to the wealth generated in the region and within the context of the country that is renowned for its poor and probably insufficient public health expenditure per capita. Nevertheless, it should be noted that the levels of private health expenditure in Lombardia are significantly higher than the national level (793 euro per capita compared to 604 Euro, a difference of 31%)<sup>15</sup>. This figure is characteristic of the situation in Lombardia, and, on the one hand, brings levels of health expenditure and the overall healthcare offer closer to the actual level of the wealth generated in the region, thereby confirming the importance of the healthcare sector within the value chain; on the other hand, it raises questions in terms of equity of access.

To complete the overview of the healthcare services sector, we report that in Lombardia the percentage of public expenditure allocated to the supply of services by accredited private parties is 28% of the total, compared to a national average of 20%<sup>16</sup>. On the other hand, pharmaceutical products sold under agreements with the state amount to 6.5%, which is in line with the national figure (6.4%). There is therefore a significant presence of private parties operating as providers or distributors in terms of the transformation of public expenditure into healthcare services.

Extending the analysis to Europe, Lombardia has a lower care intensity than all the

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<sup>13</sup> Armeni P., Bertolani A., Borsoi L., Costa F., La spesa sanitaria: composizione ed evoluzione, in 2019 OASI Report, CERGAS, Milan, Egea, 2019.

<sup>14</sup> *Ibidem*. Considering mobility (and thus expenditure for services provided to patients who are not residents) public expenditure per capita is 3% higher than the national average, 2020 euro.

<sup>15</sup> Del Vecchio M., Fenech L., Preti L., Rappini V., *I consumi privati in sanità*, in Rapporto OASI 2019, by CERGAS, Milano, Egea, 2019.

<sup>16</sup> Bobini M., Ricci A. *Gli erogatori privati accreditati: inquadramento e performance economiche dei grandi gruppi sanitari italiani*, in Rapporto OASI 2019, by CERGAS, Milano, Egea, 2019. This calculation includes the following items: accredited hospital care; accredited specialist outpatient care; accredited rehabilitative care; other accredited care, which mainly relates to health and care services. Unlike previous versions of the document, we have not considered certain items that are not comparable to accredited private healthcare, in particular general medicine.

benchmark regions, which is mainly linked to a smaller allocation of non-medical healthcare professionals and hospital beds. This difference is particularly evident compared to healthcare systems with an abundance of resources that are highly focused on hospitals, such as the German system. These lower parameters for resources do not appear to impact clinical outcomes for 2017: Lombardia has a life expectancy at 65 years of age that is slightly higher than Baden-Württemberg (21.4 years compared to 20.3) and slightly lower than Cataluña and Île de France (21.6 and 22.7). Moreover, Lombardia is characterised by particularly low rates of inappropriate hospitalisation - 116 hospitalisations for every 100 thousand inhabitants - less than a quarter of the rate in Germany and also less than the French and Spanish benchmarks. In normal times this type of system could therefore be defined as extremely frugal and cost-effective. There is no doubt, however, that figures for resources, process and clinical outcome will vary sharply in 2020 as a result of the Covid-19 epidemic. It is also equally probable that the system in Lombardia, which is borderline in terms of public underfunding and has very few backup resources in terms of beds and staff compared to international benchmarks, was more severely affected by the epidemic.

In the European comparison, Lombardia stands out in the pharmaceutical sector, thanks to a value added that exceeds the benchmarks (539 euro per inhabitant), with a share for the sector on the total regional economy that is second only to Cataluña (1.8% in terms of value added) and a robust international outlook (with exports of more than 8 billion, which more than doubled between 2008 and 2019 and higher than the benchmark regions).

To summarise all of the above, in Lombardia we have a Life Sciences value chain which, starting from modest levels of public funding compared to GDP - which are comparable in absolute terms to the rest of Italy - has developed significantly in both the segment of pharmaceutical products, medical devices and biotech research services, as well as in the segment for the supply of accredited and private services. This vital production system, which involves positive partnerships with the public sector, represents the key area of specialisation for the economy in Lombardia and was able to develop thanks to the traditional strengths of the local socio-economic ecosystem: an advantageous geographical position, a solid infrastructure network, availability of income and capital for companies and households, a manufacturing tradition, a lively and professional services sector and cutting-edge research and innovation hubs like universities and IRCCS.

The qualitative and quantitative overview of the value chain represents a preliminary step for reflecting on the future of the sector and its development opportunities. To complete the analysis it may be useful to present certain characteristics that define the Life Sciences value chain: some apply across the board to the entire value chain and explain some existing interconnections between the segments that make it up, while others represent specific characteristics for each segment. Collectively they make Life Sciences a sector that should be protected and developed at both a regional and national level, by public and private players.

**The health value chain is driven by the segment of services to people which, in**

**Lombardia and Italy as a whole, is funded mainly by public expenditure. Given the progressive reduction of funding for health expenditure a process of greater attention towards intermediated and out-of-pocket private expenditure is currently ongoing.** Unlike many other crucial sectors (education, universities, justice, central government authorities) public expenditure in health is only allocated in small part to the direct payment of salaries and wages, with the main share allocated to the purchase of goods and services from the private market (which partly merge with the value chain and partly with the satellite industries). The percentage of public expenditure allocated to purchases is 64.0% at a national level and 69.4% at the regional level. As such, health is one of the few areas of public expenditure (along with defence and transport) where we can make assessments in terms of industrial policy and not just on its impact on individual consumption. The significant presence of centres of excellence which can attract demand from all across Italy (from both the public and private sector, with the latter accounting for more than 50% of this mobility) makes the segment of personal services in Lombardia one that can position itself - at a European and global level - as an attractor for patients and an exporter of a modern and efficient organisational model (it is sufficient to think of outcome indicators in relation to the actual resources that are used), in a process that could represent a form of 'internationalisation' with a positive spillover effect for the entire value chain and the health of citizens, since it would promote major investments in technologies and innovation.

**In this context the issue of Digital Health has become increasingly important for the value chain.** Digital Health comprises technologies, platforms and systems that can be used to purchase, store, process or transmit health data and/or support Life Sciences and clinical activities involving individuals and their lifestyles, in their everyday well-being and for chronic or acute health-related purposes. For example, with the outbreak of the Covid-19 health emergency we have seen an acceleration in remote patient consultations (telehealth) and the telemonitoring of patients by doctors. According to the new 2020 research by the Digital Innovation Observatory for Healthcare at the Politecnico in Milano, in recent months:

- 51% of general practitioners (GPs) that were interviewed worked remotely;
- 63% of GPs were able to respond to urgent requests and shared information;
- 40% of GPs believe that digital technology will still be useful when the emergency is over;
- 75% of specialised doctors believe that telehealth was crucial for the sudden spike in workload during the acute phase of the spread of the Coronavirus;
- 39% of health authorities introduced or expanded communication and collaboration platforms;
- 33% of citizens is interested in testing teleHealthcare Services and applications.

The pandemic has clearly accelerated our ability to use digital technologies for healthcare purposes. Tools and technologies (mobile devices, 5G networks, big data, artificial intelligence, blockchain) that will reshape healthcare are quickly becoming available in hospitals and homes throughout Europe: specialised doctors can offer consultations to patients from remote positions, "intelligent" inhalers help monitor the use of drugs by asthma patients, big data on outcomes

are grouped together to extract RWE about how interventions add value, hospitals share patients' medical records securely to improve individual treatments, radiologists use artificial intelligence (AI) to improve diagnoses, etc.

We are witnessing a transition towards a healthcare that is more "person-centred", that will enable citizens to have a new and different ability to manage their health. These changes concern the empowerment of patients, self-management, decision-making processes shared with one's doctor and also the orientation of Healthcare Services towards the fulfilment of individuals' health objectives.

This transformation that is centred around the patient is also quickly changing the way products and services are developed and provided by Life Sciences companies, thereby reshaping relations between the key players in the value chain.

For the health sector, as well as the demand-side effects, this digital transformation is of great value on the supply side, particularly for an innovative and high-tech area like Lombardia.

New technology players are also joining the health value chain: large, medium and small enterprises as well as start-ups. By working together, companies in the Life Sciences sector and technology companies - which have the highest Italian concentration in Lombardia - can help to improve results on health, personalised treatments and enable the coordination of healthcare and shift services towards home care: this requires a greater trust in digital solutions and increased investments in digital infrastructure and services. In terms of shared infrastructure, the Life Sciences value chain can play a key role by contributing to the creation of HUB models through public-private partnerships, local centres for shared services for researchers, start-ups, public companies and facilities that would not, for example, be able to independently access telehealth or computing platforms for analysing big data through state-of-the-art AI tools.

In terms of the structural characteristics of the Life Sciences value chain that could be exploited, the main one is without doubt the high research intensity.

**The largest contribution in quantitative terms to research comes from pharmaceutical companies which invested 1.6 billion in R&D in 2019<sup>17</sup> (7% of total national research expenditure, up +20% in the last three years), with 6,650 people employed in this field.** The pharmaceutical industry in Lombardia contributed approximately one third of the national R&D expenditure and features outstanding players in both basic research and clinical research. Moreover, it accounts for approximately 50% of the national total for the sector in terms of employment and production, for which we also report the importance of the activities of CDMOs (Contract Development and Manufacturing Organizations).

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<sup>17</sup> Farmindustria, *Indicatori farmaceutici*, July 2020.

At the Italian level - with an important contribution from Lombardia - we can see the emergence of a growing specialisation in areas of significant innovative potential such as medicines for gene and cell therapy, orphan medicines, biotech diagnostics, vaccines, nanobiotechnologies, gender medicine as well as genomics and Big Data management. Thanks also to research conducted in collaboration with research institutes in Lombardia, Italy was also a European leader in advanced therapies and initially placed the largest number of products on the European market.

Aside from an ability to attract capital from abroad, research by companies in Lombardia has already demonstrated its excellence by providing innovative therapies for previously incurable illnesses. The clinical phase plays a key role in attracting investments, which amounts to 1 billion euro per year at a national level, of which almost 700 million are allocated to medicines<sup>18</sup>. In recent years Italy has increased its share of the total number of clinical trials carried out in Europe (20% compared to 18% in 2012), with a growing number of trials on biotech pharmaceutical products. Nowadays in Italy 42% of pharmaceutical products in a clinical trial phase are biotechnological and advanced therapies, in particular recombinant proteins, vaccines, monoclonal antibodies, advanced therapies that include products for cell/gene therapies and regenerative medicine<sup>19</sup>. This activity is of great value for the entire country, and almost half is conducted in collaboration with centres of excellence in Lombardia.

Investing in clinical trials means providing innovative therapies for patients, offering professional development opportunities for doctors and researchers and ensuring important resources and less costs for the SSN since companies cover all the respective costs, such as hospitalisation, medicines and diagnostic tests. For example, it has been calculated that for every euro invested in oncology clinical trials - an area of specialisation for research in Lombardia - the system saves 2.2 euro<sup>20</sup>.

**Within the health value chain even the most mature sectors can contribute to the economic sustainability of the national and regional health systems and the promotion of human health.** This is the case for the segment of medicines not requiring a prescription -i.e. for self-medication - which currently sees more than 46% of companies producing and/or commercialising over-the-counter medicines in Italy operating in Lombardia. The segment of self-medication products can contribute to pharmaceutical research and innovation because it enables resources and investments to be reallocated from medicines that have reached maturity (and for which research costs have been amortised) to innovative medicines and, by enabling citizens to manage minor health issues in a conscious and responsible manner, it limits the impact on public health expenditure. In 2018 a study produced by Assosalute in collaboration with Cergas Bocconi was published which quantified the savings for the national health service as more than 800 million per annum if medicines that are available over-the-counter in the main EU countries no longer required a prescription in Italy and thus no longer had to be

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<sup>18</sup> Ibidem.

<sup>19</sup> AIFA, *La Sperimentazione Clinica dei Medicinali in Italia. 18° rapporto nazionale*, 2019.

<sup>20</sup> Altems Università Cattolica.

paid for by the national Healthcare Services.

Moreover, Italian industry is renowned globally in the production of pharmaceutical active ingredients, with a market share of 9% and more than 85% of its production exported. More than half the companies in the sector are based in Lombardia, with productions focusing on generic medicines and custom synthesis and custom manufacturing in partnership with client pharmaceutical companies. The sector invests 3% of its turnover in applied research, ensuring the optimisation of processes and high quality standards that have also enabled Italian manufacturers to get a foothold in the most strictly controlled markets (America, Europe, Japan). In 2019 and until the outbreak of the Covid-19 epidemic, the positive growth trend continued for the sector of pharmaceutical raw materials. The full and official acknowledgement - in accordance with prevailing regulations - that the sector of pharmaceutical active ingredients represents "an essential public service for the protection of health", in close collaboration with the pharmaceutical production chain, made it possible for the sector to continue production activities during the lockdown after adopting all the required measures to contain the spread of the virus.

In terms of research and innovation, Lombardia is now the most developed Italian region in terms of the presence, commitment and results in biotech, thereby maintaining its leading role for the Italian biotech sector, with 28% of companies (195 companies in total), 30% of internal investments in R&D and 45% of national biotech turnover<sup>21</sup>. This is a segment dedicated to research and innovation which has shown all its value and potential in the early months of 2020 in its response to the health emergency caused by the spread of the SARS-CoV-2 virus. Companies in Lombardia developed molecular and serological diagnostic devices, phylogenetic analyses for viral sequences to study the epidemiology and establish in advance which patients will have the worst outcomes, and were involved in research for new antiviral biomedicines. This required a major effort in the transfer of the results from industrial research, which in close collaboration with the leading public research and academic centres in the area, made it possible to use these results for innovation and generated positive spillover effects for the society.

A particular area of the value chain involves medical gases, which are recognised as pharmaceutical products (in accordance with legislative decree 178/91) and governed by specific provisions surrounding their production and commercialisation, and by home care service providers for patients with chronic conditions and which can ensure precise qualitative standards for services, as also certified by the patients' primary clinicians. Obviously in 2020 medical oxygen experienced an unprecedented peak in demand since it was the main pharmaceutical product for treating Covid-19. Given the expected increase in the number of people aged over 65 (from 22.3% to 26.9% of the total population between 2017 and 2030<sup>22</sup>), home care will represent a strategic instrument for the sustainability of the health and welfare system.

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<sup>21</sup> Assobiotec-ENEA, *Le imprese di biotecnologie in Italia 2020 - Facts & Figures*.

<sup>22</sup> Ministry of Economics and Finance - General State Accounting Office accounts.



**Within the scope of medical technologies for health, the medical devices sectors represents an area of significant development at an Italian and global level. Indeed, medical technologies contributed in an important way to protecting the health of citizens, by providing state-of-the-art tools for prevention, treatment and rehabilitation. In Italy the sector accounts for 7.4% of total health expenditure (11.4 billion on a total of 152.4 billion) and has 3957 companies** that employ approximately 76,400 highly qualified workers, 43% of whom are graduates. In terms of the internal market, the estimated value is 11.4 billion, of which 66.1% is the public and the remaining 33.9% is the private market. The concentration is highest in Lombardia, with more than 1,200 companies and more than 24,000 workers, almost a third of the national total<sup>23</sup>.

The economic crisis generated by the Covid-19 health emergency significantly affected the segment. Indeed, excluding the few companies operating in therapeutic areas that grew in a manner that was strictly correlated to their direct or indirect Covid 19 response, from a survey conducted by Confindustria *Dispositivi Medici* it emerged that the majority of companies experienced an average reduction in turnover of 5.5% between January 2020 and April 2020, with the most pronounced effects felt by smaller companies. Moreover, 79.2% of companies stated that their 2020 turnover will fall (on average the difference between the budget that was set at the end of 2019 and the turnover forecast in May for 2020 as a whole is 24.8%); while 11.9% do not expect any variations and 8.9% expect to see an increase. It is therefore essential to return to investing in medical technologies: this is a sector with a high concentration and intensity of innovation, which contributes significantly to the improvement of the health system and has a small impact on the overall health expenditure.

**An additional important aspect of the Life Sciences value chain that should be noted is the qualified human capital.** In Italy the SSN employs 256,067 graduates, which represents 39.4% of its workforce, and 20.6% of the total number of graduates working in the Italian public sector, just behind the educational sector (which employs 577,779 graduates)<sup>24</sup>. Managers, the category that includes the vast majority of medical staff, represent 20% of the total workforce of the SSN<sup>25</sup>. In the pharmaceutical industry, the share of managers and assistant managers is 23%, compared to 4% for all companies<sup>26</sup>. This share rises to 27% in Lombardia, where managers and assistant managers represent 6% of the total workforce<sup>27</sup>.

**Finally, the value chain represents a traditional area of employment for females in a country where female participation in the labour market is low.** In the SSN female employment is 65.4%, compared to a level of 56.7% for the public sector as a whole<sup>28</sup>. Moving to the private sector, at the national level in pharmaceutical companies the percentage of female employment is 43%, which is in line with the total for companies across all sectors, while in private companies providing healthcare the percentage is 77%. In Lombardia the figures are 47.8% for pharmaceutical companies and 79% for companies providing Healthcare Services,

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<sup>23</sup> Centro Studi Confindustria Dispositivi Medici.

<sup>24</sup> Ministry of Economics and Finance - General State Accounting Office, 2016 Annual accounts.

<sup>25</sup> Ibidem.

<sup>26</sup> Calculations using INPS data, statistical databases on dependent employees in 2016.

<sup>27</sup> Ibidem.

<sup>28</sup> Ministry of Economics and Finance - General State Accounting Office, 2016 Annual accounts.

compared to the total for all companies where the share is 43%<sup>29</sup>. It should be noted that, in Life Sciences, high levels of female employment can also be found in the most qualified and managerial roles: amongst the doctors in the SSN the figure is 40%, with levels in excess of 60% for the under-40 workforce, while for managers in the SSN who are not doctors the figure rises to 66%; amongst managers of pharmaceutical companies at a national level, women account for 31% of the total, compared to 18% across all companies; in Lombardia these figures are 35% and 20% respectively <sup>30</sup>.

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<sup>29</sup> Calculations using INPS data, statistical databases on dependent employees in 2018.

<sup>30</sup> Ibidem.

# Appendix on methodology

The assessment of the Life Sciences value chain extends until 2018, the latest year available with a sufficient coverage of necessary data. 2017 is instead the most recent year for workforce and health services data.

The analysis builds on a mix of sources. With regard to the national comparison, the analysis was carried out on the data from the ISTAT National Accounts (to quantify the health services sector - turnover, value added, workforce - and for key macroeconomic data), the business register ASIA-ISTAT (for quantifying the workforce in the industrial and trade sectors), the AIDA-Bureau van Dijk database (for the analysis of the economic dimensions of industrial and trade enterprises). The list of firms for each segment was selected based on Nace business activity codes and in certain cases was provided by trade associations. Specifically, for a sample of large companies/multinationals were considered as industrial firms those with their own products on the market, and as trade firms those that do not put own products on the market but rather sell third parties' products. With regard to the European comparisons, the analysis was conducted on data from Eurostat national and regional accounts (for the appraisal of the economic dimensions of health services and the workforce employed in the health sector and in the pharmaceutical industry) and the ORBIS-Bureau van Dijk database (for the analysis of the economic indicators of the pharmaceutical industry).

The detailed methodology is provided below.

## **Methodology for measuring the Life Sciences value chain at national level**

### **National accounts - ISTAT**

ISTAT National Accounts regional and economic aggregates provide only the value added for each macro sector of activity within a region, without providing turnover. Moreover, there is only the gross figure summing health services to social care and assistance. In order to quantify value added and turnover of health services at the local level the following assumptions and estimates were necessary:

- To calculate the value added of health services alone, starting from the available figure for the value added of health and social care services, the percentage of value added for health services compared to the national total for health and social care, i.e. 84.6% for 2017, was applied to all regions. It was therefore assumed that in all regions analysed health and social services weighted the same on value added. Once computed the value added for health services at a regional level, turnover was estimated by assuming that the local weight of value added on production was constant across all regions and equal to the national average (58.3% in 2017).
- A similar assumption was used for computing health services workforce size; ISTAT National Accounts provide overall employment data for the health and social care services segment at a regional level. To compute the regional workforce in the health sector alone the weight of health sector workers on the total (i.e. health plus social care) at the national level for the year 2017, i.e. 72.2%, was applied across all reference regions.

### **ASIA - ISTAT**

ISTAT ASIA statistics on the workforce of active companies sometimes do not make it possible to identify precisely the segments of the Life Sciences value chain as identified in this report as there is no data unbundling to five-six digits. As a result, in

these cases a broader representation than the Life Sciences value chain here identified was necessary.

These are the specific cases where we had to use a broader representation:

- Nace 20.11 also includes the production of industrial gases that are not destined for medical use;
- Nace 26.6 includes sub-segments 26.60.02 (*Manufacture of electromedical equipment including parts and accessories*) and 26.60.09 (*Manufacture of other equipment for irradiation and other electrotherapeutic equipment*) which belong to the Life Sciences value chain, but also sub-segment 26.60.01 (*Manufacture of irradiation equipment for foodstuffs and milk*) which is not part of this value chain.
- Nace 72.11 also includes research in green and white, besides red, biotechnologies, which are not part of the Life Sciences value chain;
- Nace 33.13 includes sub-segment 33.13.03 (*Repair and maintenance of electromedical equipment, medical, surgical and veterinary material, equipment and instruments for dental sciences*) which belong to the Life Sciences value chain, but also sub-segments 33.13.01 (*Repair and maintenance of optical, photographic and cinematographic equipment excluding video cameras*), 33.13.04 (*Repair and maintenance of distillation equipment for laboratories, centrifuges for laboratories and machinery for the ultrasonic cleaning of laboratories*) and 33.13.09 (*Repair and maintenance of other electronic equipment, including those for telecommunications and computers*) that are not part of the value chain;
- Nace 46.18 includes sub-segment 46.18.3 (*Agents specialised in the sale of pharmaceutical goods and cosmetics*) which belongs to the Life Sciences value chain, but also sub-segments 46.18.1 (*Agents specialised in the sale of paper and stationery products and books*), 46.18.2 (*Agents specialised in the sale of audio and video consumer electronics, electrical material for domestic use, electrical appliances*) and 46.18.9 (*Agents specialised in the sale of sports equipment, bicycles and other products not classified elsewhere*) which are not part of the value chain.

### **AIDA - Bureau van Dijk**

The AIDA database was queried using the following criteria:

- inclusion of only active firms
- exclusion of firms with a consolidated financial statement
- exclusion of firms with a negative value added
- regionalization of firms based on their registered offices

### **Methodology for quantifying the satellite industries of the Life Sciences value chain**

With regard to the internal-origin-input demand coefficients, estimates by Confindustria's Technical Committee on the Health Sector (2011) were used:

- |                            |       |
|----------------------------|-------|
| • pharmaceutical industry  | 1.654 |
| • medical devices industry | 2.020 |
| • wholesale                | 1.899 |
| • retail                   | 1.802 |
| • health services          | 1.709 |

The weighted average coefficient for the turnover s of individual segments was therefore found to be 1.734.

For the calculation of the value added of the satellite industries we used the average ratio between value added and turnover in the Italian economy in 2018, i.e. 47.2%. This is a conservative assumption as it implies value added to be constant across all segments of the economy.

## **Methodology for computing the main economic aggregates for health services and the pharmaceutical industry at a European level**

### **European System of National and Regional Accounts (Eurostat)**

The accounts and territorial economic aggregates from the Eurostat National and Regional Accounts provide only the value added for each macro sector of activity within a region. The data for health services is therefore included in the macro sector relating to government administration, which includes: defence, compulsory social insurance, education, health and social assistance. In order to establish the value added of health services at the local level we had to use the following assumptions and estimates:

- For Baden-Württemberg, Cataluña and Île-de-France the value added of regional healthcare was calculated on the basis of the healthcare share of the value added of the public sector at the national level;
- However, for Lombardia there is only a gross figure for health care and social assistance, to which the national coefficient of health services value added on the health and social assistance national total, which was 85.4% for the year 2015, was applied.

For estimating the size of the workforce in health services, we started from healthcare workforce data by Eurostat, which refers to “practising professionals”. Nurses and midwives for the German Lander are instead calculated on the basis of the ratio of doctors to nurses at the German national level. For quantifying the workforce of the pharmaceutical industry Eurostat regional employment data were.

### **ORBIS - Bureau van Dijk**

To estimate economic aggregates for the pharmaceutical industry, ORBIS was queried using the following criteria:

- inclusion of only active companies
- exclusion of companies with a consolidated financial statement
- exclusion of companies with a negative value added
- regionalization of firms based on their registered offices
- for the appraisal of the value added, in the event of the 2017 figure being missing:
  - if only the 2016 figure was available, the 2016 figure was used;
  - if only the 2018 figure was available, the 2018 figure was used;
  - if the 2016 and 2018 figures were both available, the average between these two values was computed.



List of published reports:

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