

# DOING BUSINESS WITH THE PHARMA INDUSTRY IN EUROPE LEVERAGE ON SKYMINDER SOLUTIONS

JANUARY 2023 SKYMINDER NEWSLETTER



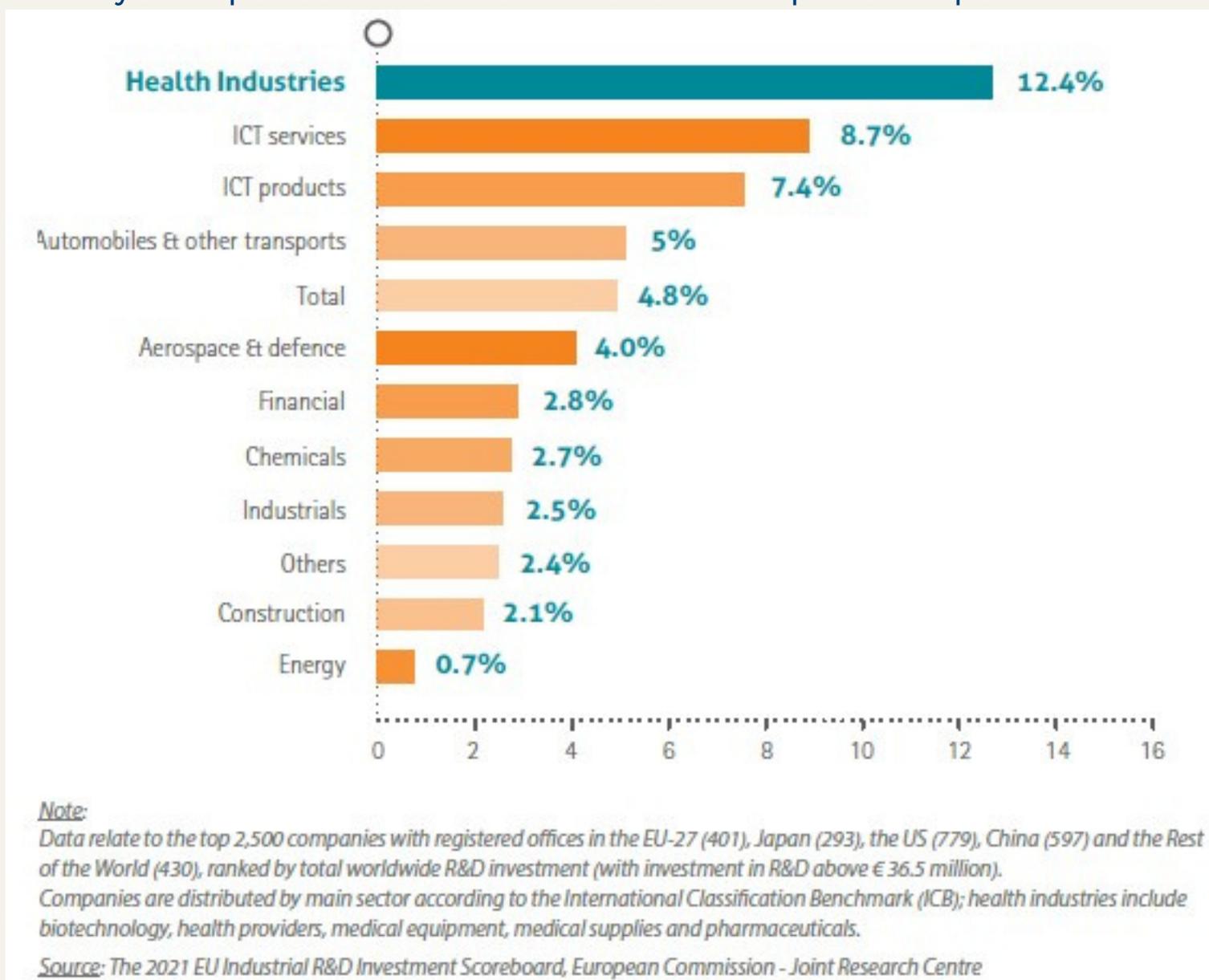
## Pharma Industry Overview

The pharmaceutical industry discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications to be administered to patients (or self-administered), with the aim to cure them, vaccinate them, or alleviate symptoms.

The pharmaceutical industry has a number of unusual characteristics, both in its structure and in the nature of its business operations, which are little known outside the industry but materially affect the process of bringing new pharmaceuticals to the patient. The development of a new pharmaceutical is very time-consuming, extremely costly and high risk, with very little chance of a successful outcome. The process of research and development is described, together with all its challenges, including environmental ones. The commercial realities and constraints of the business, together with its current problems, are discussed, followed by an exploration of some of the likely future commercial and technical developments in the business, including the development of a greener pharmacy.

Thanks to advances in science and technology, the research-based pharmaceutical industry is entering an exciting new era in medicines development. Research methods are evolving and we have many promising prospects on the horizon, with groundbreaking cell and gene therapies being increasingly available. The innovative pharmaceutical industry is driven by, and drives, medical progress. It aims to turn fundamental research into innovative treatments that are widely available and accessible to patients. Already, the industry has contributed to significant improvements in patient well-being. Today's European citizens can expect to live up to 30 years longer than they did a century ago. Some major steps in biopharmaceutical research, complimented by many smaller steps, have allowed for reductions in mortality.

Health industry, including also Pharma sector, is also considered the most innovative industry if compared investments in Research & development compared to net sales.



Source: Researchgate, EFPIA

# Facts and Figures

## THE PHARMACEUTICAL INDUSTRY: A KEY ASSET TO THE EUROPEAN ECONOMY

As well as driving medical progress by researching, developing and bringing new medicines that improve health and quality of life for patients around the world, the research-based pharmaceutical industry is a key asset of the European economy. It is one of Europe's top-performing high-technology sectors.



### INDUSTRY (EFPIA total)

2000

2010

2020

2021



Production

127,504

199,730

286,697

300,000 (e)



Exports (1) (2)

90,935

276,357

509,828

565,000 (e)



Imports

68,841

204,824

347,124

390,000 (e)



Trade balance

22,094

71,533

162,704

175,000 (e)



R&D expenditure

17,849

27,920

39,656

41,500 (e)



Employment (units)

556,506

701,059

835,590

840,000 (e)



R&D employment (units)

88,397

116,253

122,331

125,000 (e)

Values in € million unless otherwise stated

(1) Data relate to EU-27, Norway, Switzerland and United Kingdom since 2005 (EU-15 before 2005); Croatia and Serbia included since 2010; Turkey included since 2011; Russia included since 2013

(2) Data relating to total exports and total imports include EU-27 intra-trade (double counting in some cases)

Source: EFPIA member associations (official figures) - (e): EFPIA estimate; Eurostat (EU-27 trade data 2000-2021)

## PHARMACEUTICAL MARKET VALUE (AT EX-FACTORY PRICES)

EFPIA 2020	€ million		€ million
Austria	11,941	Latvia	456
Belgium	56,210	Lithuania	874
Bulgaria	1,054	Luxembourg	132
Croatia	1,052	Malta	367
Cyprus	381	Netherlands	45,000
Czech Republic	2,965	Norway	680
Denmark	18,529	Poland	4,377
Estonia	95	Portugal	1,378
Finland	833	Romania	895
France	34,065	Slovakia	541
Germany	87,203	Slovenia	7,062
Greece	2,883	Spain	12,709
Hungary	6,739	Sweden	10,897
Iceland	12	Switzerland	81,899
Ireland	62,092	Turkey	1,497
Italy	33,112	United Kingdom	21,898
<b>TOTAL</b>			<b>509,828</b>

**Note:**

All data based on SITC 54

**Source:** Eurostat (COMEXT database – May 2022)

Iceland: OECD; Norway: LMI; Switzerland: Swiss Federal Customs Administration; Turkey: Turkish Statistical Institute

## PHARMACEUTICAL EXPORTS

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Iceland: OECD; Norway: LMI; Switzerland: Swiss Federal Customs Administration; Turkey: Turkish Statistical Institute

## PHARMACEUTICAL IMPORTS

EFPIA 2020	€ million		€ million
Austria	9,561	Latvia	681
Belgium	46,261	Lithuania	1,292
Bulgaria	1,532	Luxembourg	500
Croatia	1,637	Malta	288
Cyprus	356	Netherlands	30,650
Czech Republic	5,314	Norway	2,112
Denmark	4,940	Poland	7,818
Estonia	565	Portugal	3,039
Finland	2,112	Romania	3,803
France	28,974	Slovakia	2,172
Germany	58,817	Slovenia	5,259
Greece	3,227	Spain	15,938
Hungary	5,875	Sweden	4,805
Iceland	163	Switzerland	34,624
Ireland	9,223	Turkey	4,626
Italy	28,051	United Kingdom	22,909
<b>TOTAL</b>			<b>347,124</b>

*Note:*  
All data based on SITC 54

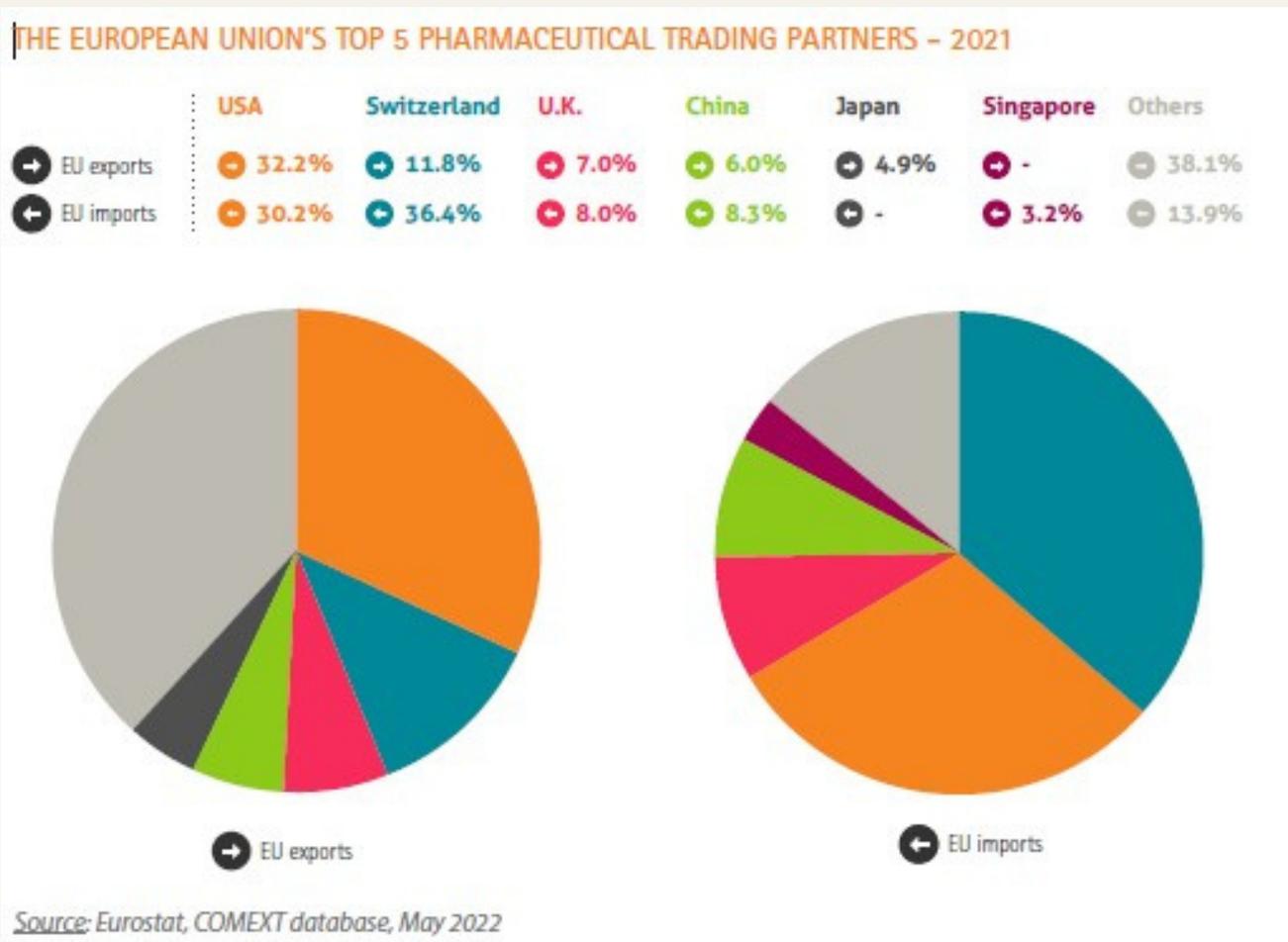
*Source:* Eurostat (COMEXT database – May 2022)  
Iceland: OECD; Norway: LMI; Switzerland: Swiss Federal Customs Administration; Turkey: Turkish Statistical Institute

# PHARMACEUTICAL TRADE BALANCE

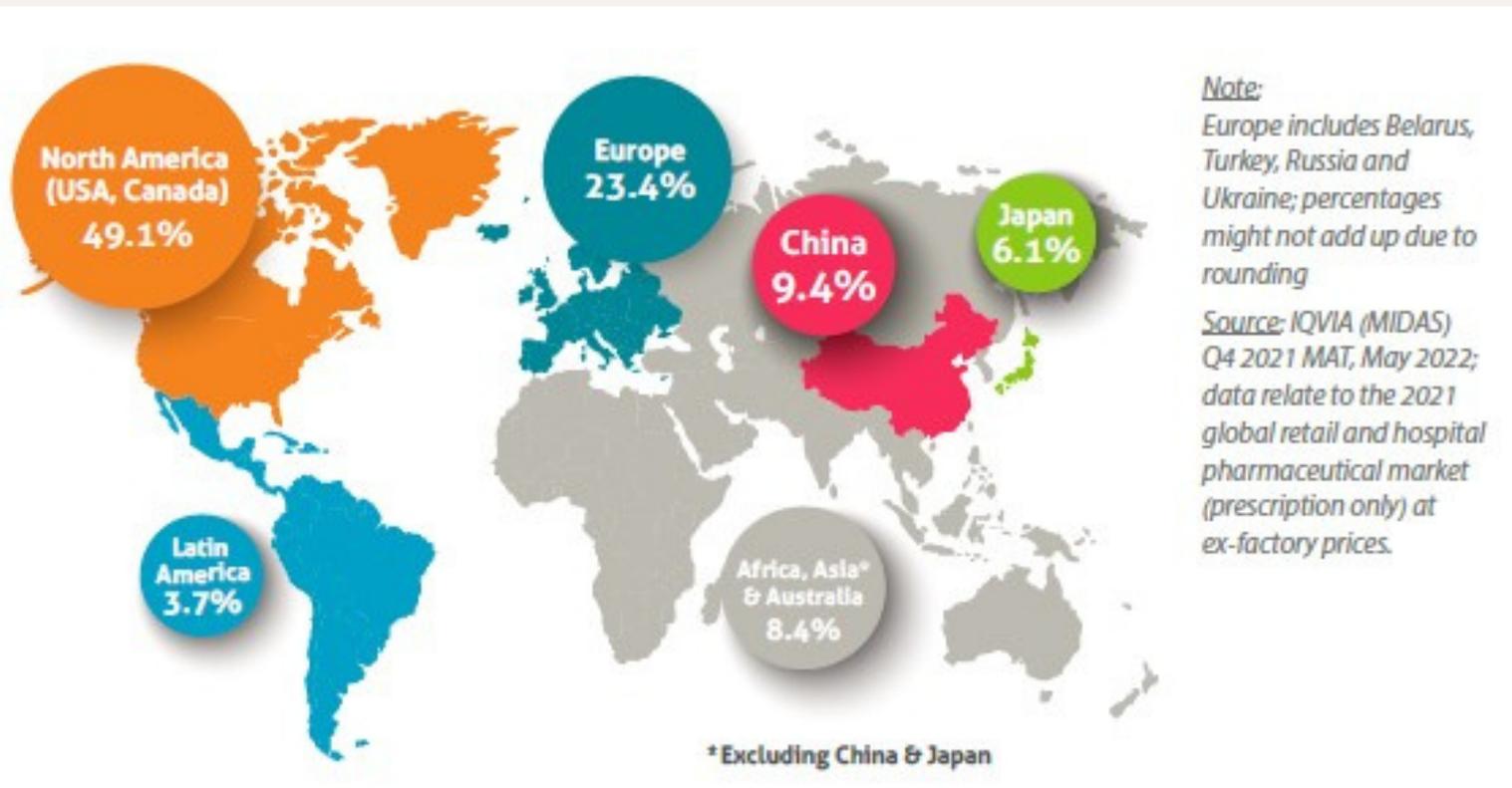
EFPIA 2020	€ million	€ million	
Austria	2,380	Latvia	-225
Belgium	9,949	Lithuania	-418
Bulgaria	-478	Luxembourg	-368
Croatia	-585	Malta	79
Cyprus	25	Netherlands	14,350
Czech Republic	-2,349	Norway	-1,432
Denmark	13,589	Poland	-3,441
Estonia	-470	Portugal	-1,661
Finland	-1,279	Romania	-2,908
France	5,091	Slovakia	-1,631
Germany	28,386	Slovenia	1,803
Greece	-344	Spain	-3,229
Hungary	864	Sweden	6,092
Iceland	-151	Switzerland	47,275
Ireland	52,869	Turkey	-3,129
Italy	5,061	United Kingdom	-1,011
<b>TOTAL</b>		<b>162,704</b>	

*Note:*  
 All data based on SITC 54  
 Source: Eurostat (COMEXT database – May 2022)  
 Norway: LMI; Russia: Clifor Import/Export, 2019; Switzerland: Swiss Federal Customs Administration; Turkey: Turkish Statistical Institute

## THE EUROPEAN UNION'S TOP PHARMACEUTICAL TRADING PARTNERS 2021



The world pharmaceutical (prescription) market was worth an estimated € 1,062,707 million (\$ 1,256,863 million) at ex-factory prices in 2021. The North American market (USA & Canada) remained the world's largest market with a 49.1% share, well ahead of Europe, China and Japan.



## PRICE STRUCTURE



Source: EFPIA



# INNOVATION AND RESEARCH AND DEVELOPMENT

The research-based pharmaceutical industry can play a critical role in restoring Europe to growth and ensuring future competitiveness in an advancing global economy. In 2021 it invested an estimated € 41,500 million in R&D in Europe. It directly employs some 840,000 people and generates about three times more employment indirectly – upstream and downstream – than it does directly (PwC, Economic and societal footprint of the pharmaceutical industry in Europe, June 2019).

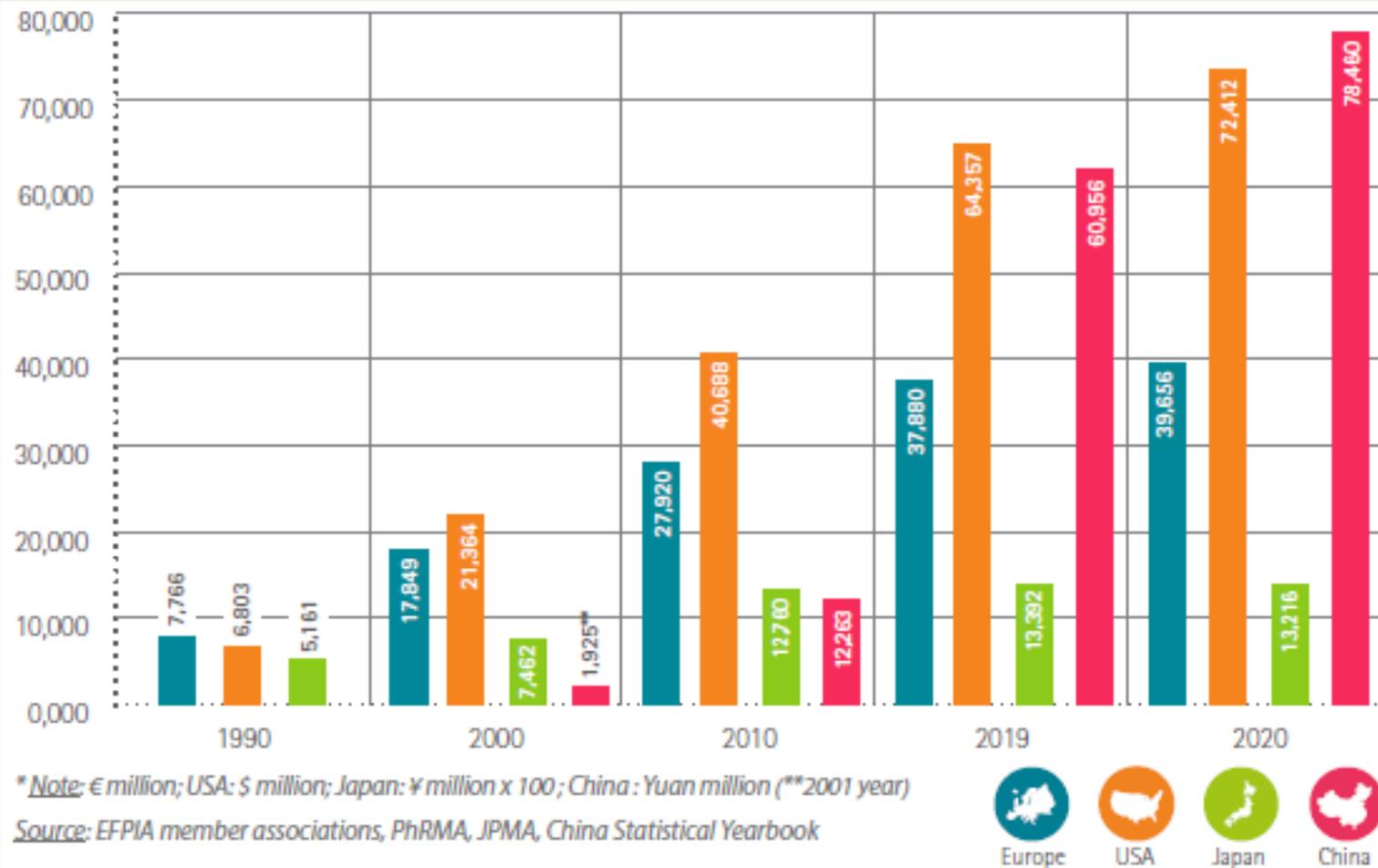
However, the sector faces real challenges. Besides the additional regulatory hurdles and escalating R&D costs, the sector has been severely hit by the impact of fiscal austerity measures introduced by governments across much of Europe since 2010. There is rapid growth in the market and research environment in emerging economies such as Brazil, China and India, leading to a gradual migration of economic and research activities from Europe to these fast-growing markets.

During the period 2016-2021 the Brazilian, Chinese and Indian markets grew by 11.7%, 6.7% and 11.8% respectively compared to an average market growth of 5.8% for the top 5 European Union markets and 5.6% for the US market (source: IQVIA MIDAS, May 2022). In 2021 North America accounted for 49.1% of world pharmaceutical sales compared with 23.4% for Europe.

According to IQVIA (MIDAS May 2022), 64.4% of sales of new medicines launched during the period 2016-2021 were on the US market, compared with 16.8% on the European market (top 5 markets). The fragmentation of the EU pharmaceutical market has resulted in a lucrative parallel trade.

This benefits neither social security nor patients and deprives the industry of additional resources to fund R&D. Parallel trade was estimated to amount to € 6,070 million (value at ex-factory prices) in 2020.

## PHARMACEUTICAL R&D EXPENDITURE IN EUROPE, USA, JAPAN AND CHINA (MILLION OF NATIONAL CURRENCY UNITS \*), 1990-2020



All new medicines introduced into the market are the result of lengthy, costly and risky research and development (R&D) conducted by pharmaceutical companies:

- By the time a medicinal product reaches the market, an average of 12-13 years will have elapsed since the first synthesis of the new active substance;
- The cost of researching and developing a new chemical or biological entity was estimated at € 1,926 million (\$ 2,558 million in year 2013 dollars) in 2014 (DiMasi et al, Journal of Health Economics, January 2016);
- On average, only one to two of every 10,000 substances synthesised in laboratories will successfully pass all stages of development required to become a marketable medicine.

# PHARMACEUTICAL INDUSTRY RESEARCH AND DEVELOPMENT IN EUROPE

EFPIA 2020	€ million		€ million
Austria	283	Latvia	n.a
Belgium	4,964	Lithuania	n.a
Bulgaria	91	Malta	n.a
Croatia	40	Netherlands	642
Cyprus	85	Norway	126
Czech Rep.	72	Poland	431
Denmark	1,486	Portugal	90
Estonia	n.a	Romania	69
Finland	258	Russia	706
France	4,451	Slovakia	35
Germany	7,813	Slovenia	334
Greece	102	Spain	1,161
Hungary	298	Sweden	1,104
Iceland	n.a	Switzerland	7,380
Ireland	305	Turkey	71
Italy	1,620	U.K.	5,639
<b>TOTAL</b>			<b>39,656</b>

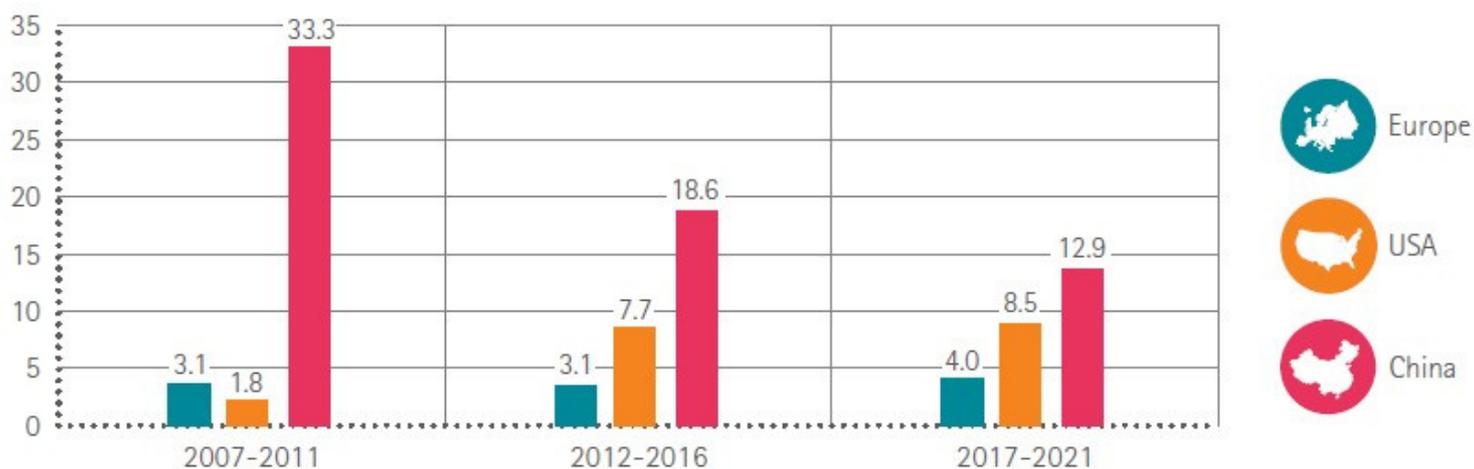
*Note:*  
 The figures relate to the R&D carried out in each country.  
 Austria, Slovenia: 2019; Bulgaria, France: 2017 data; Norway, Sweden: 2015 data; Cyprus, Ireland: 2013 data; Croatia, Netherlands: 2011 data  
 Belgium, Croatia, Denmark, France, Greece, Ireland, Italy, Netherlands, Norway (LMI members), Poland, Romania, Slovenia, Sweden (LIF members), Switzerland (Interpharma members), Turkey: estimate

*Source:* EFPIA member associations (official figures)

In 2020 the pharmaceutical industry invested more than € 39,600 million in R&D in Europe. A decade of strong US market dominance led to a significant shift of economic and research activity towards the US during the period 1995-2005, a trend that has been exacerbating since 2015. Additionally, Europe is now facing increasing competition from emerging economies: rapid growth in the market and research environments in countries such as China and Korea are contributing to the move of economic and research activities to non-European markets. In 2021 China nearly equalled Europe as originator of new active substances launched for the first time on the world market, with respectively 18 and 19 new substances, far behind the US leading with 35 on a total of 95. The geographical balance of the pharmaceutical market – and ultimately the R&D base – is likely to shift gradually towards fast-growing emerging economies.

## PHARMACEUTICAL R&d EXPENDITURE - ANNUAL GROWTH RATE (%)

### PHARMACEUTICAL R&d EXPENDITURE – ANNUAL GROWTH RATE (%)



*Note: USA, China: data relating to period 2017-2020*

*Source: EFPIA, PhRMA, China Statistical Yearbook 2002-2021*

Source: EFPIA



# Focus on EFPIA

## European Federation of Pharmaceutical Industries and Associations

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 38 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

Source: EFPIA



# SKYMINDER AT A GLANCE PHARMA INDUSTRY



Solutions available for more than **240**  
countries and jurisdictions

Best in class information thanks to more  
than **40** providers, both local and global

**13** available products and solutions

**Web** and **API** integration



# SKYMINDER SOLUTIONS

Requirement	SkyMinder Solution	Description
Know business partners and risk level - have on board new suppliers - understand in depth customers creditworthiness	<b>Full Report and Slim Report</b>	Information, with different level of details, related to all companies in the world, including firmographics, credit limit, risk indicator, management, shareholders, negative events etc.
Receive immediate notification with related details if a change affects a company	<b>Full Monitoring</b>	Detailed information about changes affecting a company as soon as happened. Combined possibility to request for free updated report.
Be alerted if there is change in company's information	<b>Alert</b>	Information related to the area involved by a change as soon as an event happened.
Periodically checks if there are changes involving companies	<b>Planned Revision</b>	Scheduled revision with updated report including company's changes if applicable
Obtain documents from Official Registry and LEI repository	<b>Official Registry and LEI</b>	Product range including documents coming from public sources or from LEI Registry
Company ownership overview	<b>Verification Report</b>	List of shareholders to understand company's structure
Compliance requirements and fraud checks	<b>Compliance Report and Extended Check Report</b>	Anti Bribery and Money Laundering lists checks related to financial crimes.
Risk of Cyber attack	<b>Cyber Risk Report</b>	Assess the level of risk related to a business partner in being involved in a cyber attack
Understand overall value of intangible assets of a company	<b>Patent Due Diligence Report</b>	Patent Asset Overview with geographical coverage, remaining life of active patent assets, high-value patent assets, technology and patent deployment, technology timeline, peer comparison, key inventors.