



European Federation of Pharmaceutical Industries and Associations

EFPIA Annual Report 2016

Unlocking tomorrow's cures

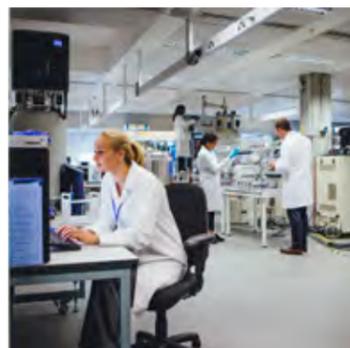
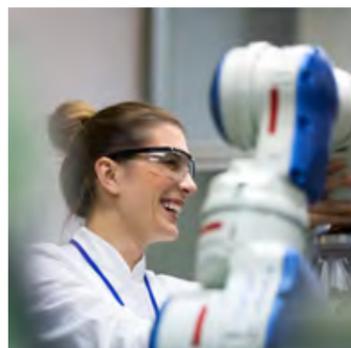
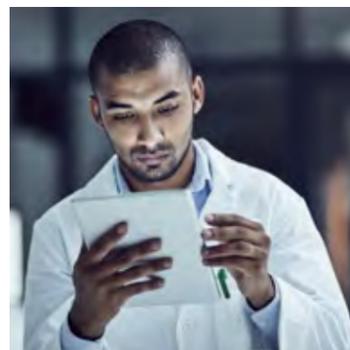




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As I look to the future with EFPIA, we are committed to working with EU institutions and member states to find solutions to make medicines accessible and healthcare more sustainable

Introduction

An age of innovation, challenges and opportunities



NATHALIE MOLL
Director General
EFPIA

Innovation is at the heart of everything we do. Our industry employs over 100,000 scientists and researchers in Europe, working to find new treatments and cures to alleviate suffering, extend life and improve the quality of life for patients across the globe.

It requires vision, commitment, dedication and often endless experimentation with no guarantees of success, but the results of all this endeavour are exciting. We have witnessed transformational change in how we treat diseases like cancer, hepatitis C, HIV and cardiovascular disease. Over the next 5 years, we will see new therapies emerge, such as combination therapies for cancer, disease modifying therapies for Alzheimer's, antibacterial monoclonal antibodies to target antimicrobial resistance, gene therapies against haemophilia, cell therapies against diabetes type 1 and CAR-T therapies targeting blood cancers. These innovative treatments have the potential to bring great benefits to patients and their families in terms of survival and quality of life, saving resources in healthcare systems and offering benefits to the broader society in terms of a healthier workforce.

At the same time, we recognise that introducing high-impact innovation can create challenges for healthcare systems under pressure from an ageing population and increased levels of chronic disease. The key to managing these challenges is partnership in identifying new breakthroughs and transformative technologies well in advance, thus allowing time for industry and governments to work together to plan their introduction into healthcare systems.

As I look to the future with EFPIA, we are committed to working with EU institutions and member states to find solutions to make medicines accessible and healthcare more sustainable, whilst securing future medical innovation and contributing to economic growth. That means realising the potential of healthcare data to support outcomes-focused approaches, developing more flexible solutions to financing new technologies and ensuring that the incentives framework continues to support the level of medical innovation, research and development that will help patients, healthcare systems and society address the challenges they face.

The annual report underlines in numbers, the impact of the therapies we discover, develop and deliver to patients, as well as the commitment of our industry to innovation and economic growth. EFPIA will continue to work with partners across the spectrum of issues that relate to our industry, from science and regulation, to manufacturing, healthcare, ethics and trade.

Nathalie Moll

Foreword by the President



As there remains significant unmet medical need in Europe and across the globe, our industry is determined to continue the search for effective solutions ”

2016 marked another year of impressive scientific progress for our industry. EMA approved 81 new medicines, including 16 medicines for rare diseases, which affect less than 5 in 10,000 Europeans.



JOE JIMENEZ
EFPIA President
CEO Novartis

Additionally, 59 existing products were approved in new indications. These recent successes are the result of continued investment and dedication of pharmaceutical companies in the fight against disease. And they are only the beginning of an exciting wave of medical innovation expected to come to market in the coming years. Cell and gene therapy, combination treatments or immunotherapy could provide much needed breakthroughs for patients in Europe and beyond. Many companies are also investing beyond the pill, providing digital offerings that further contribute to improved care and better outcomes for patients.

As there remains significant unmet medical need in Europe and across the globe, our industry is determined to continue the search for effective solutions, whether for chronic diseases that affect millions or for rare disease that affect only a few. But medicines innovation remains complex and is unavoidably rife with failure, and it can only continue in an innovation-friendly environment, with strong intellectual property protection. Its competitive incentive system has so far allowed Europe to be at the forefront of medical research. However, this competitive position and the great potential of the

7,000 medicines that reside in industry pipelines have been put at great risk with the recent initiation of the European incentives review.

The incentive system we have today is by no means perfect. In fact it needs to be strengthened and become more tailored to the specific public health challenges we face. The orphan disease incentive that was introduced to drive development of medicines for small patient populations is a great example of such a tailored approach, and it works. Following its introduction in 2000, investment in rare disease R&D grew by 210% in just 8 years. 119 medicinal products for about 90 rare conditions were developed since, addressing the needs of many patients who previously had no treatment options.

But more needs to be done. Take the example of anti-microbial resistance (AMR), possibly one of the largest public health threats of our time. The key to addressing AMR is the use of antibiotics only in patients who need them and strict limits on volumes sold. However, this by definition creates a disincentive to develop these new medicines, as they are held in reserve and not used. Targeted incentives are needed to drive investment into this area and to

reward innovators. We also still don't have effective treatments for debilitating diseases such as Alzheimer's, an increasing challenge, given our ageing populations. And while we have made great progress in the area of rare diseases, the search for solutions has to continue, an enormous task given that about 6,000 such rare diseases exist.

We know that innovation is our best means of tackling those challenges and incentives are the most effective tool we have to unlock new solutions by attracting investment and the brightest minds to fight disease. At EFPIA we are proud of the successes of our industry, and we remain fully committed to work hard to deliver the healthcare solutions that our citizens and healthcare systems need. We look forward to continued collaboration with all stakeholders to ensure Europe remains at the forefront of medicines innovation.

Joe Jimenez



About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

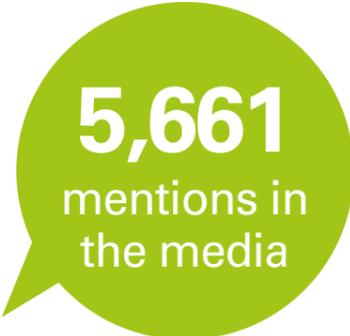
EFPIA specialised groups

European Biopharmaceutical Enterprises (EBE) represents the voice of biopharmaceutical companies of all sizes in Europe. Established in 2000, EBE is recognised as the leading biopharmaceutical association in Europe.

Vaccines Europe (VE) represents major innovative research-based global vaccine companies as well as small and medium-sized enterprises operating in Europe.



2 specialised groups



3000 subscribers to the EFPIA newsletter



EFPIA Activity 2016

TRADE

Director-General Richard Bergström participated in the high-level Gaidar Forum in Moscow with the Deputy Prime Minister Shuvalov, Health Minister Skvortsova and Trade Minister Manturov.

AMR

EFPIA and over 85 pharmaceutical, biotech and diagnostic companies published the so-called Davos Declaration on combating antimicrobial resistance.

BIOSIMILARS

EFPIA, along with EBE and IFPMA, launched a position paper on “Considerations for physicians on switching decisions regarding biosimilars”.

OUTCOMES-FOCUSED HEALTHCARE

Launch of the consensus document “Enhancing Value in European Health Systems – the role of outcomes measurement”, in the European Parliament, developed by a broad coalition of stakeholders, including patient organisations, academics, healthcare institutions and industry, together with EFPIA and a number of EFPIA members.

HEALTHCARE SYSTEMS

EFPIA supported the BIAC Forum on Innovation, Health and Well-Being held at OECD in Paris, with participation from Richard Bergström.

TRADE

EFPIA launched its TTIP Economic Study, conducted by Copenhagen Economics, with the participation of TTIP negotiators, MEPs and other key stakeholders in the European Parliament.

EFPIA Joint Industry Strategy Session, together with global sister associations in Beijing, which included high level meetings with Chinese authorities from 5 different ministries, and EU and US officials.

HEALTHCARE DATA

The Data Protection Regulation was adopted and contains positive provisions to support the use of data in research.

TRADE SECRETS DIRECTIVE

Adoption of the Trade Secrets Directive by the European institutions, establishing standard rules against the unlawful acquisition, disclosure and use of trade secrets.

REGULATORY AFFAIRS

Regulatory Team compiled the response on behalf of Innovation Board Sponsored Committee of EFPIA, Vaccines Europe and EBE on Commission survey DDG2/RS/(2016) Impact of Regulation on Innovation.

HEALTHCARE SYSTEMS

EFPIA organised a roundtable event on the future of cancer care with key stakeholders. In parallel a series of national roundtable discussions have occurred in 10 Member States over the course of 2016/17.

TRADE

For the first time, and following dedicated EFPIA advocacy, an industry workshop was organised along the margins of the EU-India High Level Regulatory Dialogue (HLRD). EFPIA coordinated a joint industry presentation with AESGP and Medicines for Europe, which highlighted key regulatory issues in India.

REGULATORY AFFAIRS

EFPIA Clinical Trials and Transparency priority working group coordinated the launch of a comprehensive survey jointly with PhRMA on the membership implementation of Principles of Responsible Clinical Data Sharing.

HEALTHCARE SYSTEMS

EFPIA organised a roundtable on outcomes measurements in Health Systems Performance Assessment, hosted by the Belgian National Institute for Health and Disability Insurance, with participation from the Commission, the OECD and WHO Europe.

EFPIA organised a workshop, chaired by Richard Bergström, on “personalised prevention” during European Health Forum Gastein, to discuss the future of prevention in the light of developments in big data, digital health and personalised medicine.

OUTCOMES-FOCUSED HEALTHCARE

Launch of “Healthier future – The case for outcomes-focused, sustainable healthcare”

TRANSPARENCY

EFPIA engagement in the debate with policy makers in the context of the European Commission proposal for an Interinstitutional Agreement on a mandatory Transparency Register.

TRADE

Director-General Richard Bergström led the EFPIA team participating in the Pharma Vision 2016 Joint Strategy Session in Ankara, organised together with AIFD and PhRMA, which included a high-level meeting with the Deputy Prime Minister of Turkey, Mehmet Simsek.

AMR

Following the Davos Declaration in January and ahead of the UN General Assembly High-Level Meeting on Antimicrobial Resistance, 13 leading companies, including EFPIA members presented a new roadmap that lays out four key commitments they will deliver by 2020, to reduce antimicrobial resistance.

ACCESS TO MEDICINES

EFPIA engagement in the debate with policy makers and stakeholders in the context of the European Parliament INI report on EU options for improving access to medicines.

PATIENT ACCESS PARTNERSHIP (PACT)

EFPIA as a member of the PACT Steering Committee, helped organise the PACT Regional Conference in Sofia.

REGULATORY AFFAIRS

ICH Assembly approves Brazilian drug regulatory authority ANVISA and Korean drug regulatory authority MFDS as new members of ICH, which is the first step towards ICH globalisation.

PATIENT ACCESS PARTNERSHIP (PACT)

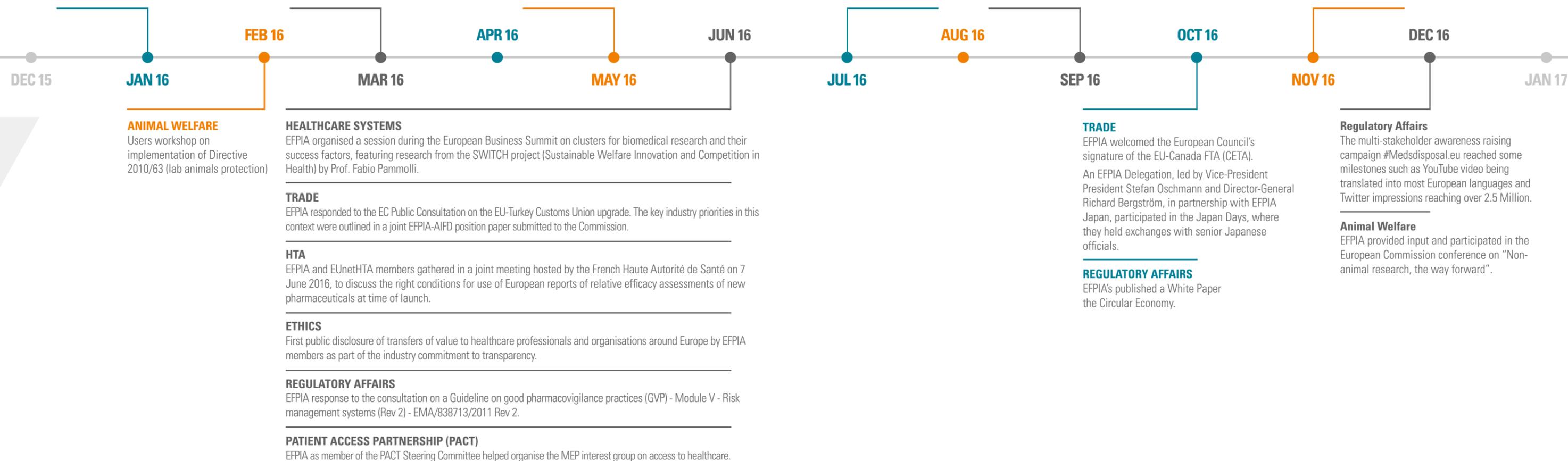
EFPIA, as a member of the PACT Steering Committee, helped organise the MEP interest group on access to healthcare.

Regulatory Affairs

The multi-stakeholder awareness raising campaign #Medsdisposal.eu reached some milestones such as YouTube video being translated into most European languages and Twitter impressions reaching over 2.5 Million.

Animal Welfare

EFPIA provided input and participated in the European Commission conference on “Non-animal research, the way forward”.

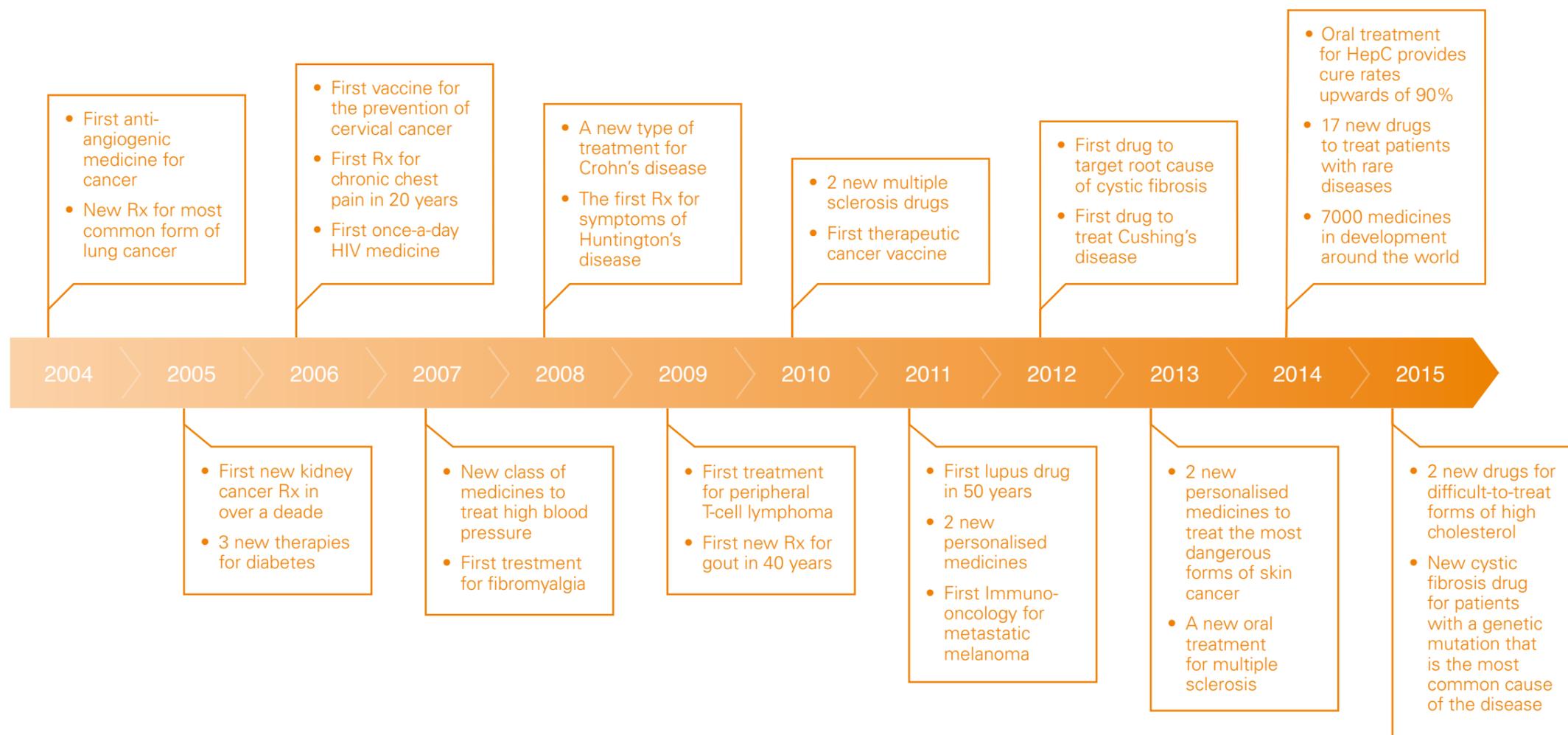


Innovation in numbers

Innovation is in our industry's DNA. It's the vehicle by which we improve patients' lives, evolve the way we manage healthcare and benefit wider society. But our innovation gene is just the start. Expressing it requires time, great people, significant resources, collaboration across sectors and borders and often-endless experimentation to search out new breakthroughs.

The prize: discovering and developing treatments that mean alleviating suffering, extending life and improving its quality is something EFPIA, EBE and Vaccines Europe members are dedicated to realising.

Biopharmaceutical companies around the world have driven a decade of advances in medicines



Note: Dates of innovation provided by the US Food and Drug Administration (FDA). Source: Health Advance analysis; PhRMA 2015 Biopharmaceuticals in Perspective.



Innovation in numbers

With over 7000 medicines in development, the exciting new wave of medical innovation will play a key role in addressing the challenges faced by patients and healthcare systems



CANCERS



CARDIOVASCULAR DISORDERS



DIABETES



HIV/AIDS



IMMUNOLOGICAL DISORDERS



INFECTIOUS DISEASES

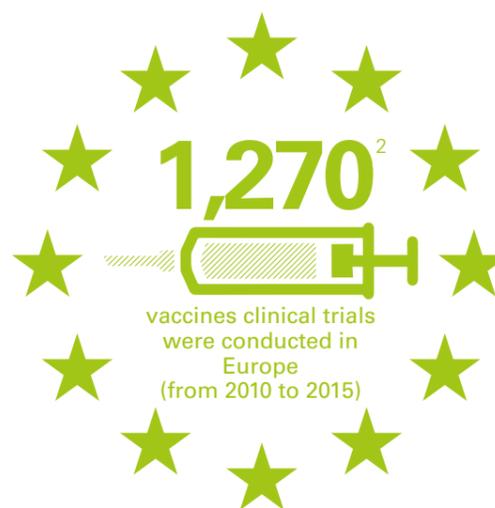
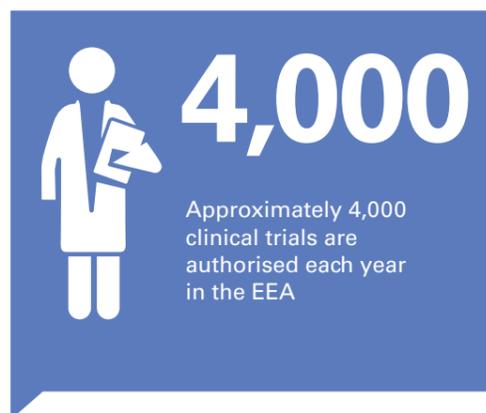


MENTAL HEALTH DISORDERS

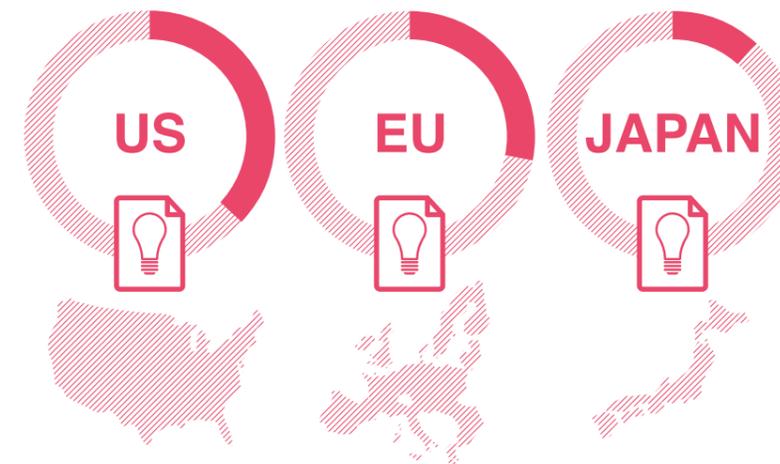


NEUROLOGICAL DISORDERS

16 of the 27 medicines are biologic medicines, including one vaccine and 2 advanced therapies. 1 of the remaining 11 new substances is a personalised (precision) medicine



Share of countries in biotechnology patents for the time period 2010-2013 (published by OECD in 2016):³



¹http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2017/01/WC500219736.pdf

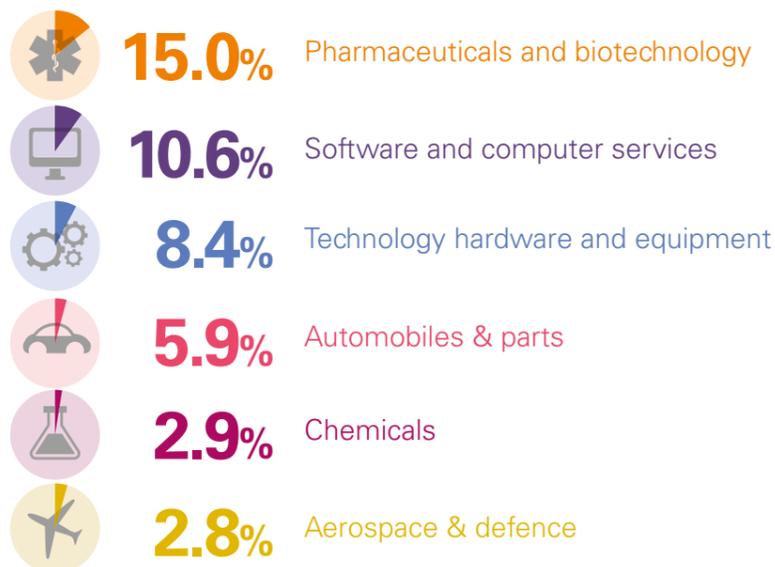
²A STRATEGIC EUROPEAN ROADMAP FOR THE VACCINES OF TOMORROW: A JOINT STAKEHOLDER REFLECTION http://iprove-roadmap.eu/wp-content/uploads/2016/06/IPROVE-ROADMAP_JUNE2016_WEB.pdf

³<http://www.oecd.org/sti/biotech/keybiotechnologyindicators.htm>

Innovation in numbers

The biopharmaceutical industry invests more of its revenue in generating **new knowledge through research and development than other sectors**

R&D SPENDING AS A PERCENTAGE OF NET SALES, 2015



Source: The 2016 EU industrial R&D investment scoreboard, European Commission, JRC, DG RTD.

2015 R&D investment at European biotechnology companies rose 11% compared to 2014⁴
11% rise

€900 billion
The pharmaceutical industry is expected to invest close to €900 billion in research and development from 2015-2020.

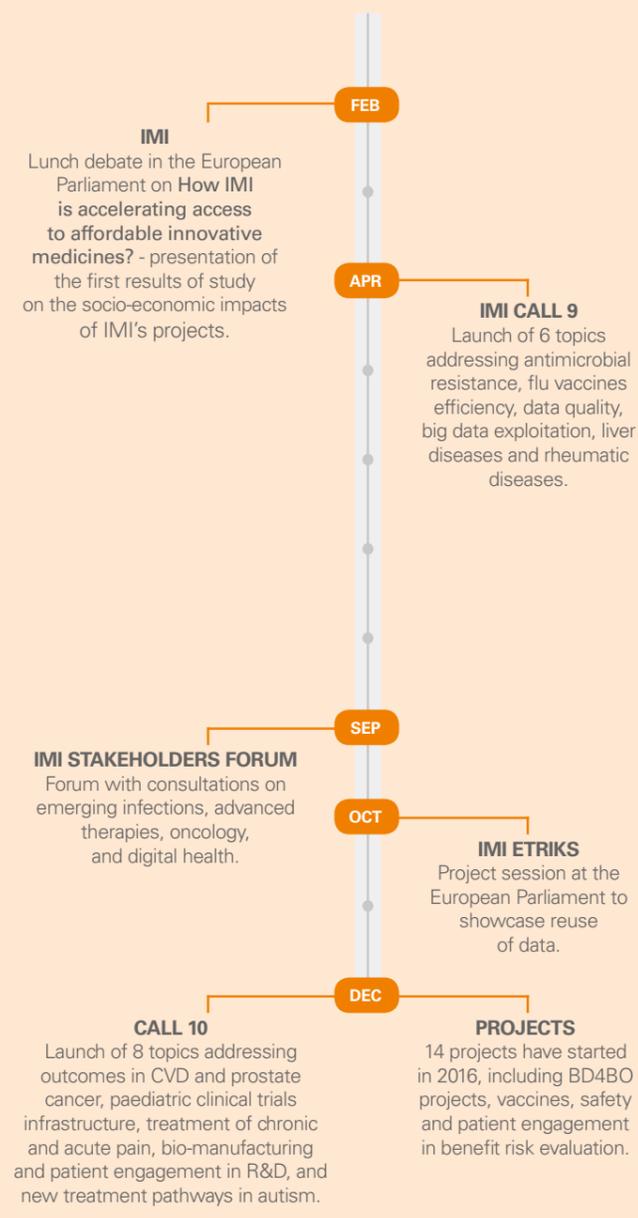
1 out of 6
1 out of 6 people employed by the pharmaceutical industry has a highly skilled R&D position

Fostering Innovation

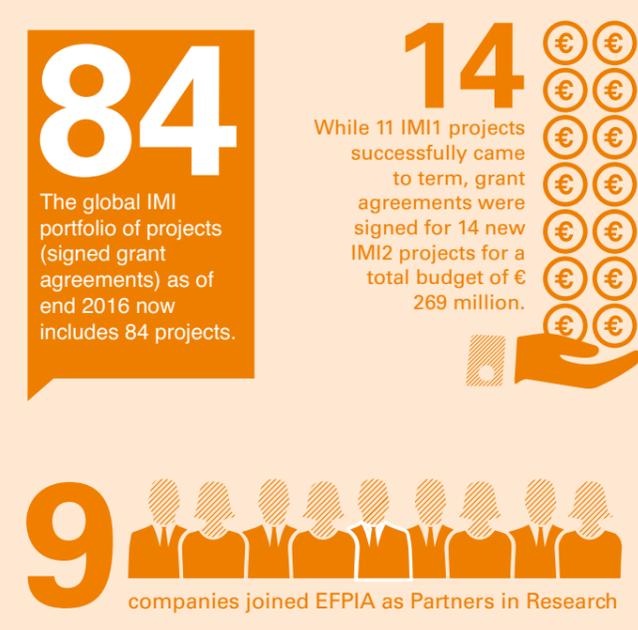


To find out more about the role of intellectual property in fostering innovation, watch our video.

IMI Timeline 2016



IMI Key facts and figures 2016

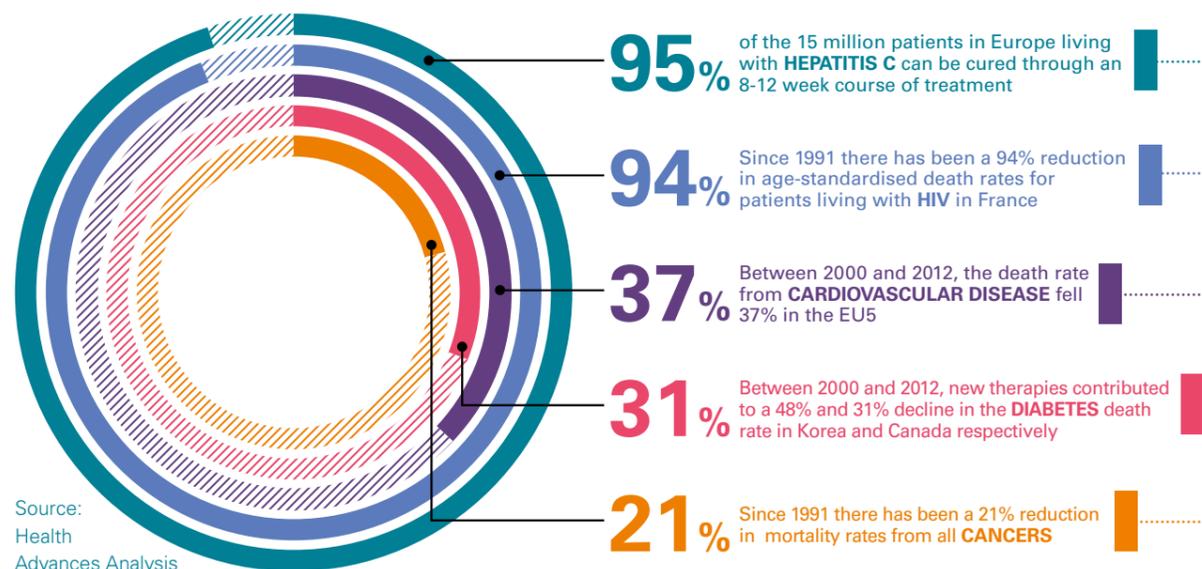


€442.3 million 2 calls were launched, including 16 topics, with a total budget € 442.3 million, for which 19 proposals were selected for funding.

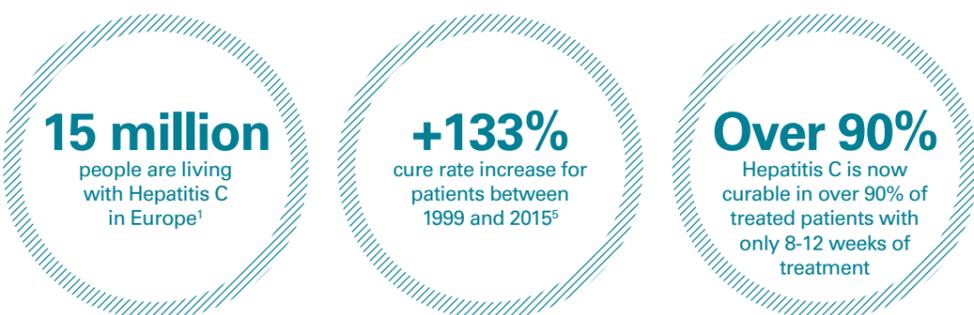
⁴[http://www.ey.com/Publication/vwLUAssets/EYbeyond-borders-2016/\\$FILE/EYbeyond-borders-2016.pdf](http://www.ey.com/Publication/vwLUAssets/EYbeyond-borders-2016/$FILE/EYbeyond-borders-2016.pdf)

The impact of medicines

Medicines are some of the most powerful tools in treating and curing diseases



Hepatitis C (HCV)

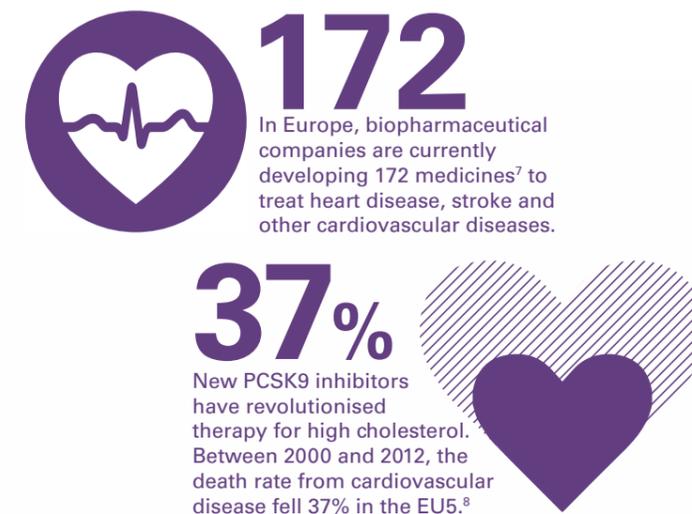
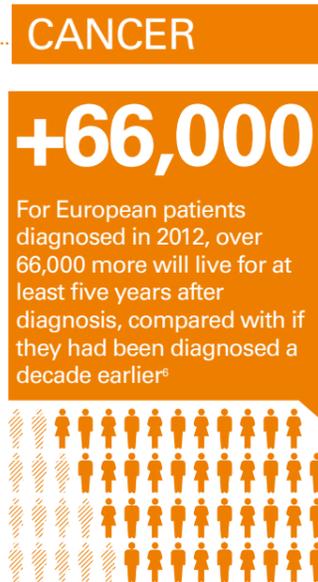


Medicines have transformed HIV/AIDS from a death sentence to **a manageable diseases**

HIV/AIDS - Age Standardised Death Rate (ASDR)



Cardiovascular Disease



⁶Calculations based on incidence figures quoted in Bengt Jönsson et al., Comparator Report on Patient Access to Cancer Medicines in Europe Revisited, 2016 - page 16: 2000-2002 5-year survival rate in all cancers in Europe: 51.55% 2000-2007 5-year survival rate in all cancers across Europe: 54%; Incidence in 2012 in Europe: 2,707,000
⁷Medicines in Phase I through III of development. Source: 1) Health Advances analysis; PharmaProjects (accessed February 2016)
⁸2) WHO Mortality Database (accessed February 2016)

The impact of vaccines

Vaccines keep people **healthier for longer** and across all ages **preventing death and illness** from vaccine-preventable diseases

Vaccination programmes have had a significant impact on reducing mortality and morbidity throughout life from numerous infectious diseases

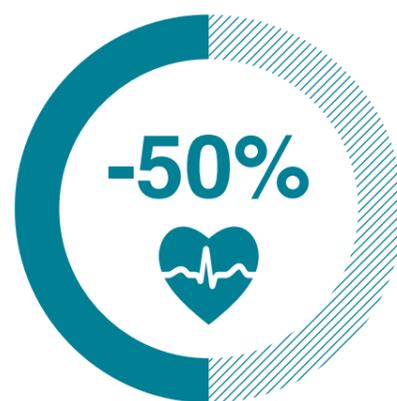


2,000,000 - 3,000,000 lives saved every year worldwide⁹

Vaccination protects patients with chronic diseases. Influenza vaccination reduces by¹⁰



The risk of strokes after respiratory disease



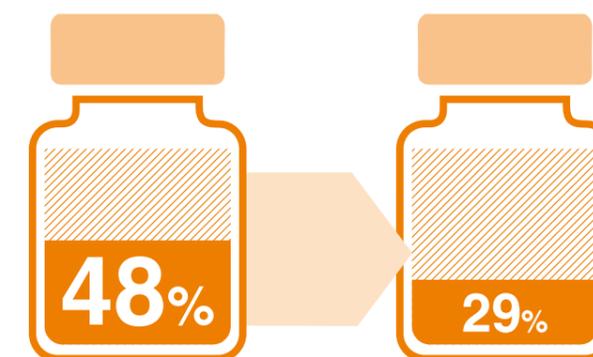
Heart attack occurrence



Death in diabetic patient

Vaccination helps fight against antimicrobial resistance (AMR)

The use of pneumococcal vaccine in France has reduced the use of antibiotics¹¹



Vaccination is one of the most cost-effective public health interventions



Saved by avoiding 715,000 lost days of work and productivity thanks to Influenza vaccination.¹²



25,000 lives spared per year

⁹WHO (2017) Immunization coverage Fact sheet <http://www.who.int/mediacentre/factsheets/fs378/en/>
¹⁰Udell et al (2013); Association Between Influenza Vaccination and Cardiovascular Outcomes in High-Risk Patients, JAMA. 2013;310(16):1711-1720. doi:10.1001/jama.2013.279206

¹¹Wilby et al. (2012), A review of the effect of immunization programs on antimicrobial utilization, Vaccine. Oct 12;30(46):6509-14. doi: 10.1016/j.vaccine.2012.08.03
¹²Préaud et al. (2014), Annual public health and economic benefits of seasonal influenza vaccination: a European estimate, BMC Public Health 2014, 14:813 <http://www.biomedcentral.com/1471-2458/14/813>

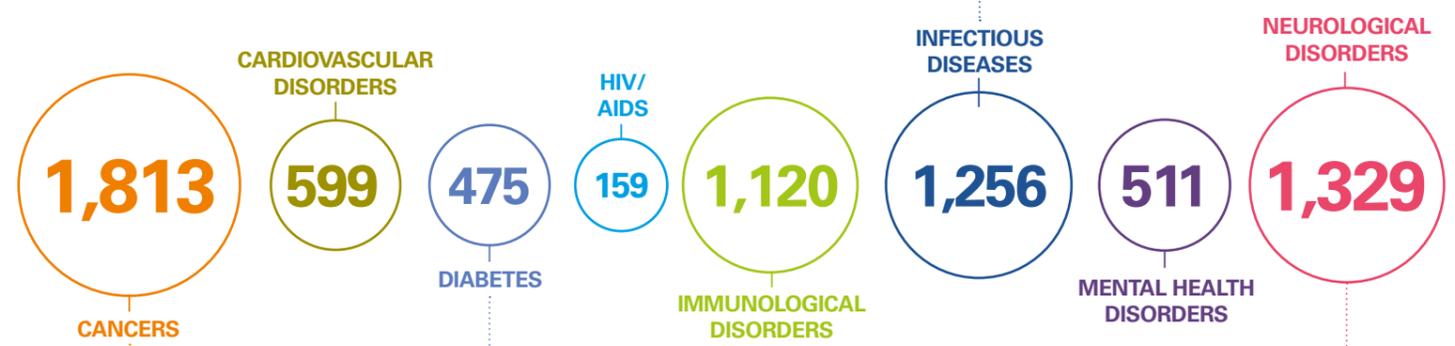
The impact of medicines

With over 7000 medicines in developments over the next 5-10 years, we see **major innovations** that will address this unmet need and bring **benefits** to **patients** and **society**



Antibacterial treatments –
neutralise highly pathogenic bacterial surface proteins or secreted toxins and activate the immune system to kill the bacteria directly

25,000 patients die from a serious, resistant bacterial infection every year, most of them in hospital	€1.5 billion are lost each year in extra healthcare costs and productivity losses from infections due to these selected MDR bacteria in the EU	300 million people worldwide are expected to die prematurely because of drug resistance over the next 35 years ³
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CAR-T therapies –
CAR-T cells that have been genetically modified to allow the T cell to recognise and destroy tumour cells

55-100% CAR-Ts can reduce expenditure on targeted therapy by 55-100%	Increased life expectancy The curative impact of CAR-Ts is greatest in ALL* where median age at diagnosis is 14 and could increase average life expectancy by 68 years
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Combination therapies –
increasing quality and quantity of life by combining targeted cancer treatments to increase their effectiveness

30,000 deaths could be avoided in NSCLC** through combination treatment	685 million EUR could be generated in GDP each year for those NSCLC** patients diagnosed in 2020
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Cell therapy –
insertion of living cells into patients to replace or repair damaged tissue, in order to facilitate improved organ or tissue functionality

~ 650,000 sick days due to hospitalisation could be avoided per year, which could lead to an increase in nominal GDP of ~ €16 billion	~ 12,000 new cases of blindness across the EU every year are estimated to be caused by diabetic retinopathy	-30% in the number of cardiovascular events in patients that do not receive intensive treatment
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Alzheimer's treatments –
seek to breakdown or inhibit the formation of protein plaques, helping to delay the onset and progression of Alzheimer's disease

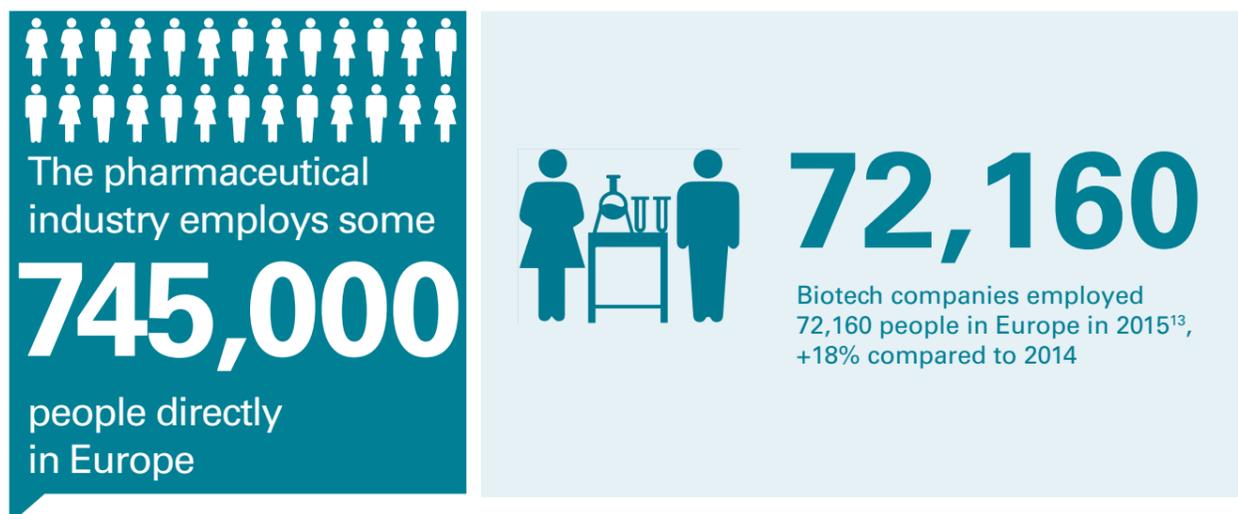
€17 billion
is the current social care costs for Alzheimer's in Europe; new treatments may result in substantial savings

* ALL - Acute Lymphoid Leukaemia
**NSCLC - Non small cell lung cancer

The economic impact of the industry

The research based pharmaceutical industry is one of Europe's major high-technology industrial employers.

Europe is a global leader in highly-skilled, science-based workforce

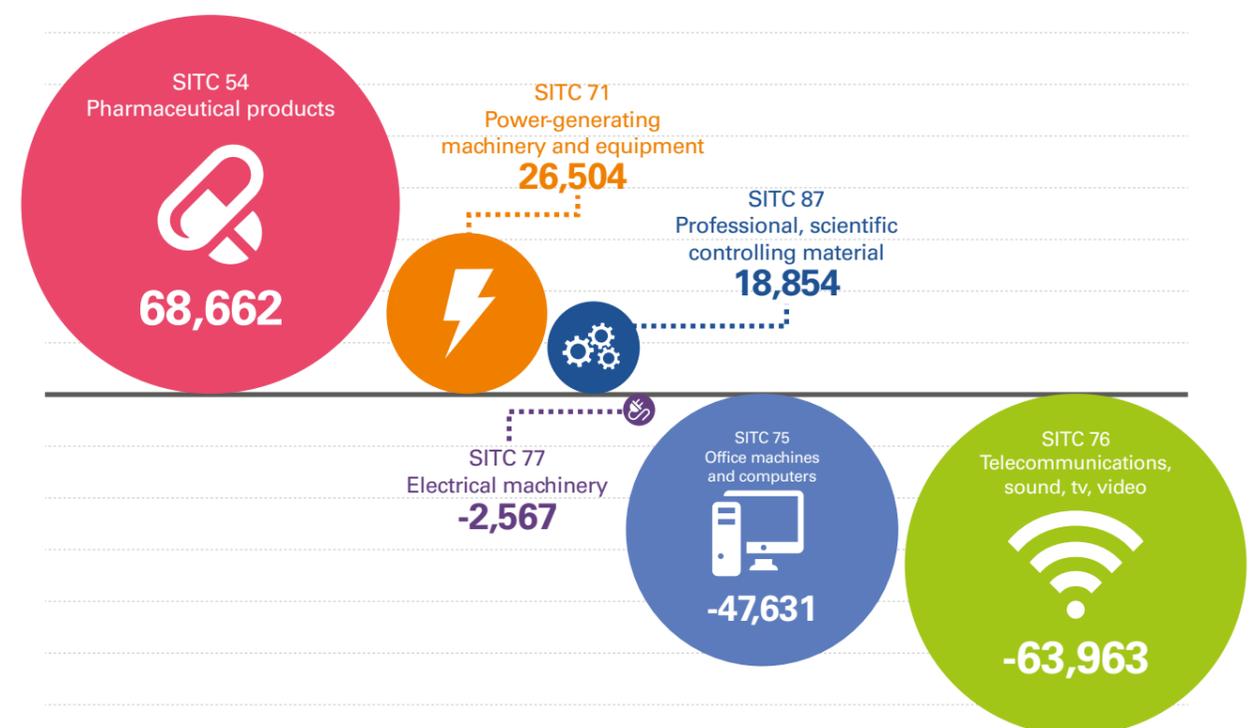


Total worldwide employees of Vaccines Europe members in 2014



EU-28 Trade balance - High Technology Sectors

The biopharmaceutical industry makes a significant contribution to the European economy.



Source: EFPIA member associations (official figures) - (e): EFPIA estimate.
¹³http://www.ey.com/Publication/vwLUAssets/EY-beyond-borders-2016/\$FILE/EY-beyond-borders-2016.pdf

The economic impact of the industry

Driving employment in Europe



KEY DRIVER
The pharmaceutical industry is a key driver of growth in the European economy

5 Every job in the pharmaceutical industry supports 5 other jobs

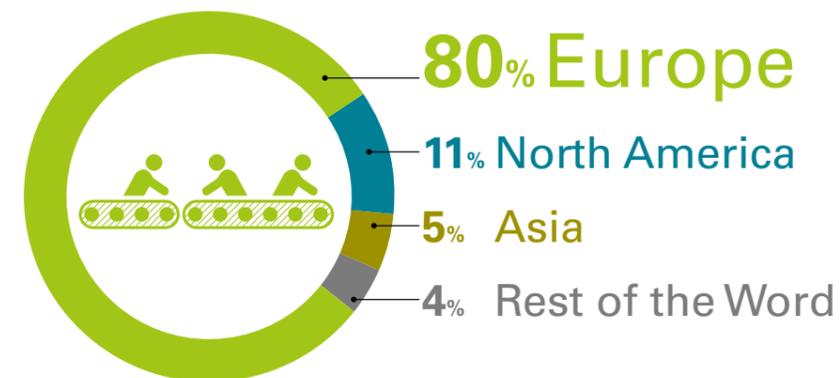
For every Euro of direct gross value added by the pharmaceutical industry, 1.3 Additional Euros are generated for the European economy

To find out more about the economic impact of the industry, view our animated infographics online.



Europe is a long-standing leader in vaccines

Doses of vaccines produced by Vaccines Europe members by region in 2014, across 23 production sites



EFPIA Members

FULL MEMBERS

ABBVIE	ELI LILLY	PFIZER
ALMIRALL	GLAXOSMITHKLINE	PIERRE FABRE
AMGEN	GRÜNENTHAL	ROCHE
ASTELLAS	IPSEN	SANOFI
ASTRAZENECA	JOHNSON & JOHNSON	SERVIER
BAYER	LEO PHARMA	SHIRE
BOGEN	MENARINI	TAKEDA
BOEHRINGER INGELHEIM	MERCK	TEVA
BRISTOL MYERS SQUIBB	MSD	UCB
CELGENE	NOVARTIS	
CHIESI FARMACEUTICI	NOVO NORDISK	

AFFILIATE MEMBERS

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DAIICHI-SANKYO
EISAI
ESTEVE
H. LUNDBECK
ORION PHARMA
OTSUKA
THE MEDICINES COMPANY
VIFOR PHARMA

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BRUKER	NOKIA
CLARIVATE ANALYTICS	PIRAMAL
COVANCE	PMB ALCEN
DETECOM	PSYCHOGENICS
DEXCOM	QUINTILES
ELLEGARD MINIPIGS	SAS
FUJIFILM	SOMALOGIC
GE HEALTH	VARIAN
ILLUMINA	ZEISS
INSTITUT MERIEUX	ZOETIS
INTERSYSTEMS	

EFPIA Member Associations

FULL MEMBERS

AUSTRIA Fachverband der Chemischen Industrie Österreichs (FCIO)	IRELAND Irish Pharmaceutical Healthcare Association (IPHA)	SPAIN Asociación Nacional Empresarial de la Industria Farmacéutica (Farmaindustria)
BELGIUM Association Générale de l'Industrie du Médicament (pharma.be)	ITALY Associazione delle imprese del farmaco (Farmindustria)	SWEDEN Läkemedelsindustriföreningen / The Swedish Association of the Pharmaceutical Industry (LIF/Sweden)
DENMARK Laegemiddelindustriforeningen The Danish Association of the Pharmaceutical Industry (LIF)	NETHERLANDS Vereniging Innovatieve Geneesmiddelen / Association Innovative Medicines	SWITZERLAND Verband der forschenden pharmazeutischen Firmen der Schweiz (Interpharma)
FINLAND Lääketeollisuus ry / Pharma Industry Finland (PIF)	NORWAY Legemiddelindustriforeningen / Norwegian Association of Pharmaceutical Manufacturers (LMI)	TURKEY Turkey Arastirmaci Ilac Firmalari Dernegi (AIFD)
FRANCE Les Entreprises du Médicament (LEEM)	POLAND Employers Union of Innovative Pharmaceutical Companies (Infarma)	UNITED KINGDOM The Association of the British Pharmaceutical Industry (ABPI)
GERMANY Verband Forschender Arzneimittelhersteller (VfA)	PORTUGAL Associação Portuguesa da Indústria Farmacêutica (Apifarma)	
GREECE Hellenic Association of Pharmaceutical Companies (SfEE)	RUSSIA Association of International Pharmaceutical Manufacturers (AIPM)	

AFFILIATE MEMBERS

BULGARIA Association of the Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM)	HUNGARY Association of Innovative Pharmaceutical Manufacturers (AIPM)	SERBIA Innovative Drug Manufacturers' Association (INOVIA)
CROATIA Innovative Pharmaceutical Initiative (IFI)	LATVIA Association of International Research-based Pharmaceutical Manufacturers (SIFFA)	SLOVAKIA Slovak Association of Innovative Pharmaceutical Industry (AIFP)
CYPRUS Cyprus Association of Pharmaceutical Companies (KEFEA)	LITHUANIA The Innovative Pharmaceutical Industry Association (IFPA)	SLOVENIA Forum of International Research and Development Pharmaceutical Industries (EIG)
CZECH REPUBLIC Association of Innovative Pharmaceutical Industry (AIFP)	MALTA Malta Maltese Pharmaceutical Association (PRIMA)	UKRAINE Association of Pharmaceutical Research and Development (APRaD)
ESTONIA Association of Pharmaceutical Manufacturers in Estonia (APME)	ROMANIA Association of International Medicines Manufacturers (ARPIM)	

EFPIA Board Members*

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* UNTIL 13 JUNE 2017

EFPIA Specialised Groups

European Biopharmaceutical Enterprises (EBE) represents the voice of biopharmaceutical companies of all sizes in Europe and is a specialised group within EFPIA. Established in 2000, EBE is recognised as the leading biopharmaceutical association in Europe.

EBE MEMBERS

ABBVIE BIOPHARMACEUTICALS SARL	ELI LILLY SA	NETSCIENTIFIC
AC IMMUNE SA	ENTASIS THERAPEUTICS	NOVARTIS
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ALK-ABELLÓ A/S	GENFIT SA	PHARMA MAR SA
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Vaccines Europe (VE) is the specialised vaccine industry group within EFPIA. It represents major innovative research-based global vaccine companies as well as small and medium sized enterprises operating in Europe.

VACCINES EUROPE MEMBERS

ABBOTT PRODUCT OPERATIONS AG	IMMUNOBIOLOGY LTD	SEQIRUS
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* WILL LEAVE EBE ON 31 JUNE 2017

** WILL LEAVE EBE ON 31 DECEMBER 2017

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European Federation of Pharmaceutical
Industries and Associations

EFPIA represents the pharmaceutical industry in Europe.

Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA provides the voice of 1,900 companies committed to researching, developing and bringing new medicines to improve health and quality of life around the world.



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