Illness never sleeps, so neither do we
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Introduction

A focus on collaboration

The challenges faced by healthcare in Europe is often the subject of debate in Brussels. And despite the many challenges, it really is worth remembering that the rising demand for health services driven by an ageing population is the result of a European success story.

Over the last 50 years, life expectancy across the EU has risen by over a decade. We have seen dramatic advances in prevention and in treatment for diseases such as cancer, heart disease, HIV, inflammatory disease and hepatitis C. With over 7000 medicines in development and rapid advances in diagnostics, devices, imaging and data analytics there are many reasons to be optimistic about the future health of Europe.

To realise this potential will require new levels of partnership and collaboration. No one sector has all the answers and by working together we can continue to transform the lives of patients and their families, make Europe a world leader in medical R&D and drive the growth of the European economy.

Much of the focus in 2018 has been on partnership and collaboration to tackle some of these grand challenges together. For example, the EU Health Summit, in which EFPIA was a contributing partner, brought together 29 organisations from across healthcare and the life sciences sector, developing concrete recommendations for the new EU Commission and Parliament to action on health.

Discussions around Horizon Europe and Europe’s new Public Private Partnership for Health have focused on going beyond medicines to include partners from diagnostics, devices and data analytics. EFPIA entered into a strategic partnership with the International Consortium for Health Outcomes Measurement to standardise definitions of outcomes to facilitate more patient-centred, outcomes-focused health systems. There are many more examples included in this Annual Report.

During 2019, EFPIA will look to continue to promote collaboration as a partner in the fight against disease. Our role in that fight is to develop new treatments and cures that can transform the lives of patients. Access to those new treatments is a goal we share with everyone in healthcare. We need to create an environment that fosters and supports the development of new treatments for diseases like dementia, diabetes, AMR and cancer knowing that innovation is only meaningful when patients get access to it. In 2019 we will continue to work with governments and health system stakeholders to find solutions that ensure patients get access to the new wave of treatments coming through and we can continue to drive Europe’s health success story.
When I took the reins as EFPIA president, we focused on three factors: patient engagement, data and collaboration.

**European Healthcare:**

So much we can build on, so much left to do

Europe has made great progress in healthcare. An EU citizen born today can expect to live 30 years longer than his or her ancestors a century ago. And there is much to suggest that this trend will persist. From immuno-oncology to gene and cell therapy, we are currently seeing the emergence of new medicines that give hope to patients who until recently had no treatment options.

I am personally convinced that there has never been a more promising time for pharmaceutical innovation. However, Europe also faces major healthcare challenges. Demographic change will see ageing societies exert significant cost pressure on healthcare systems. At the same time, high unmet medical need remains in diseases like cancer or Alzheimer’s. This requires continued large-scale investments in research and development. The pharmaceutical industry has a critical role to play in tackling these challenges.

When I took the reins as EFPIA president, we focused on three factors: patient engagement, data and collaboration.

Patients must play a central role in shaping how medicines are developed, how services are designed and how chronic conditions are managed. As an industry, we are committed to engaging patients in all of these processes.

Working through collaborative vehicles we have moved from talking about patients to talking with patients to help shape policy and practice. This approach was typified by last year’s EU Health Summit, where organizations from across healthcare came together to make recommendations to support the creation of patient-centred health systems.

Furthermore, the broad availability of health data and digital technologies open new possibilities. Just one example: by using data more effectively, we can accelerate the transition to outcomes-focused healthcare systems.

Finally, collaboration is and remains key. During my presidency, we celebrated the 10th anniversary of the Innovative Medicines Initiative (IMI). Under this initiative, which was jointly launched by the European Commission and EFPIA, partners have initiated projects across a huge range of therapeutic areas. It has led to big advances in identifying biomarkers, developing a vaccine for the Ebola crisis and contributed to our understanding of - and how we manage - disease.

Two years ago, we launched the #WeWontRest story that underlines our commitment, dedication and passion to discover, develop and deliver new medicines for patients. That commitment remains as strong as ever. Today, we can look forward to continuing to work with partners across the research and health communities to meet the needs of patients across Europe.

Stefan Oschmann
About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 36 national associations and 39 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.

OUR VISION
EFPIA’s vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.

OUR MISSION
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.

OUR VALUES
Professionalism
Openness
Integrity
Respect

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.
INTERNATIONAL AFFAIRS

• EFPIA joined 40th Anniversary
• Health Collaboration Awards Call for Applications

INTERNATIONAL AFFAIRS

• Turkey’s observer membership of ICH was approved at the ICH general assembly
• Russian authorities approved amendments to Federal Law 61, making it possible for international firms to carry out the GMP certification process in parallel with marketing authorization procedures

LEGAL AFFAIRS

• EFPIA response to the EU consultation on funding for research and innovation
• IMI ADAPT SMART project which EFPIA was a member of held its closing event in Budapest

EUROPEAN BIOPHARMACEUTICAL ENTERPRISES

EBE published a reflection paper on “Medicinal product incorporating a drug delivery device component: An industry perspective on the EU marketing application technical requirements, regulatory review process and post-approval device related change assessment”

VACCINES EUROPE

• An article was published in the journal Vaccine on “Innovation Partnership for a Roadmap in Vaccines in Europe (PROVE): A vision for the vaccines of tomorrow”

EUROPEAN BIOPHARMACEUTICAL ENTERPRISES

• EBE published together with EFPIA an evidence-based approach to the classification in patients, society and healthcare systems

SCIENCE POLICY AND REGULATORY AFFAIRS

• Kick-off of the IMI 4 EQUaION project

INTERNATIONAL AFFAIRS

• EFPIA together with ICHOM and pharma. organisations organised the EU Health Summit in Brussels, to present and discuss 20 recommendations on EU policy for the next European Commission and Parliament that they had developed jointly over 9 months

INTERNATIONAL AFFAIRS

• EFPIA joined forces calling for a future health Public Private Partnership
Illness never sleeps, so neither do we. The research-based pharmaceutical industry is working tirelessly to develop new treatments and cures for patients and #WeWontRest until we win the fight against disease.

With nearly 7,000 medicines in development, 74% of which are potentially first-in-class, the exciting new wave of medical innovation will play a key role in addressing the challenges faced by patients and healthcare systems.

Source: PhRMA

EFPIA shares a common goal with all partners in healthcare: to ensure that patients across Europe get rapid access to the latest, effective and life-saving medicines.

#WeWontRest

CANCER

Every year, more than 3.4 million people are diagnosed with cancer in Europe.[5]

558,000 breast cancer patients treated between 2007-2017 resulted in a gain of 1,180,000 Healthy Life Years (HLYs)* across the patient population.[5]

The EFPIA Oncology Platform aims to transform the lives of patients diagnosed with cancer. #WeWontRest until cancer is nothing to fear.

ALZHEIMER’S

Today, over 11 million people in Europe are living with Alzheimer’s Disease and other forms of dementia, with the number expected to increase to 14 million by 2030.[4,5]

There are currently 135 investigational trials ongoing in treatments for Alzheimer’s disease.[6]

The EFPIA Alzheimer’s Platform aims to ensure a brighter today and tomorrow for people with Alzheimer’s disease. #WeWontRest until Alzheimer’s patients have a brighter future.

DIABETES

Nearly 1 out of 10 people in Europe have diabetes, amounting to around 60 million people.[7]

By 2045 this number is expected to increase by 22% to 81 million people.[6]

The EFPIA Diabetes Platform aims to improve the lives of everyone affected by diabetes. #WeWontRest in the fight against diabetes.

* Healthy Life Years (HLYs), also called disability-free life expectancy (DFLE), is defined as the number of years that a person is expected to continue to live in a healthy condition.[8]
Collaboration

Europe is facing significant challenges across its healthcare systems. No one sector has all the answers. Collaboration is key. By working together, we can win the fight against disease. #WeWontRest in working with partners across the health and research sectors to better the lives of patients. Here are just some of the examples of EFPIA working with partners to deliver more for patients.

IMI projects (signed grant agreements) as of end 2018

119

grants for a total value of EUR 546 million

20

projects kicked off in 2018

13

- PARADIGM
- EHDPEN
- c4c
- Hypo-Resolve
- iConsensus
- PIONEER
- EBOVAC3
- AIMS-2-

Partners in Research that committed EUR 36.7 million to IMI2 projects as of 31 December 2018

26

calls were launched, including 19 topics, with a total budget of EUR 600 million for which 17 proposals were selected for funding

3

active industry members

20+

active patient organisations

20+

overarching topics covered through 2018

11

“Working Together” national workshops to date (CEE Region, Germany, Greece, Turkey)

4

projects applied for the Patient Think Tank-initiated Health Collaboration Awards

80+

partner organisations

28

participants

400

recommendations

20

prioritised recommendations by the audience on outcomes, prevention and collaboration

3

Continuation of the initiative beyond the Summit - EU Health Coalition with growing number of partner organisations

workshops organised in 2018 in Helsinki, Madrid, Brussels and London. Always in collaboration with our national trade association members

2

workshops to be organised in 2019 in Lisbon and Warsaw

450

participants with a diversified composition of patients, industry, payers, healthcare professionals, hospitals, national medicines agencies, national and EU policymakers


The economic impact of the industry

The research-based pharmaceutical industry can play a critical role in restoring Europe to growth and ensuring future competitiveness in an advancing global economy.

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

The pharmaceutical industry employs some 765,000 people directly in Europe in 2018 and generates about four times more employment indirectly – upstream and downstream – than it does directly.

In 2018 the pharmaceutical industry invested an estimated €36,500 million in research and development in Europe.

EU-28 trade balance - High technology sectors (€ million) – 2018

The research-based pharmaceutical industry is a key asset of the European economy - one of Europe’s top performing high-technology sectors.

| SITC 54 Pharmaceutical products | 91,270 |
| SITC 71 Power-generating machinery and equipment | 25,587 |
| SITC 87 Professional, scientific controlling material | 25,126 |
| SITC 76 Telecommunications, sound, tv, video | -74,695 |
| SITC 77 Electrical machinery | -16,091 |
| SITC 75 Office machines and computers | -50,886 |
The impact of vaccines

#WeWontRest until we live in a world in which no one suffers or dies from a vaccine-preventable disease

Global measles deaths have declined by 84% from an estimated 550,000 deaths in 2000 to 89,780 in 2016. Accelerated immunisation activities have had a major impact on reducing measles deaths.\(^{(1)}\)

![Image of a baby with a scarf, representing the impact of vaccines.]

**-84% GLOBAL MEASLES DEATHS**

2000: 550,000

2016: 89,780

Immunization currently prevents between 2,000,000 - 3,000,000 deaths every year. Immunization is one of the most successful and cost-effective public health interventions.

An additional of 1,500,000 could be avoid, however, if global vaccination coverage improves.

![Image of a heart and a baby with a syringe, illustrating the effectiveness of vaccines.]

More children are being immunized worldwide than ever before. During 2016, an estimated 116.5 million (about 86%) children under the age of one year worldwide received three doses of diphtheria-tetanus-pertussis (DTP3) vaccine. These children are protected against infectious diseases that can cause serious illness or disability, and be fatal.

An additional of 1,500,000 could be avoided, however, if global vaccination coverage improves.

![Image of a heart and a syringe, illustrating the effectiveness of vaccines.]

VACCINES ARE CRITICAL IN HELPING TO COMBAT THE GROWING ANTIMICROBIAL RESISTANCE (AMR) CRISIS

**INFLUENZA VACCINATION HELPS REDUCE COMPLICATIONS FROM CHRONIC DISEASES\(^{(2)}\)**

- **-28% DEATHS IN DIABETIC PATIENTS**
  - Risk of experiencing a Heart Attack after systemic respiratory infections

- **-50% HEART ATTACK OCCURRENCE**
  - Risk of experiencing a Stroke after systemic respiratory infections

- **-24% THE RISK OF STROKE OCCURRENCE**
  - N°1 of Risk group for influenza mortality

- **-79% HOSPITAL ADMISSION**
  - Universal coverage by a pneumococcal conjugate vaccine could avert 11.4 million days of antibiotic use per year in children younger than five\(^{(3)}\).

**PNEUMOCOCCAL**

Universal coverage by a pneumococcal conjugate vaccine could avert 11.4 million days of antibiotic use per year in children younger than five\(^{(3)}\).

Childhood immunisation against S. pneumoniae is the most effective public health measure for preventing IPD both among vaccine recipients (direct effect), and among unimmunised populations\(^{(4)}\).

**-84% GLOBAL MEASLES DEATHS**

**-28% DEATHS IN DIABETIC PATIENTS**

**-50% HEART ATTACK OCCURRENCE**

**-24% THE RISK OF STROKE OCCURRENCE**

**-79% HOSPITAL ADMISSION**

**ANTIBIOTIQUE USE**

**MOST EFFECTIVE PUBLIC HEALTH MEASURE**


EFPIA Members*

FULL MEMBERS

ABBVIE
ALMIRALL
AMGEN
ASTELLAS
ASTRAZENECA
BAYER
BIOGEN
BOEHRINGER INGELHEIM
BRISTOL-MYERS SQUIBB
CELGENE
CHIESI
GLAXOSMITHKLINE
GRÜNENTHAL
IPSEN
JOHNSON & JOHNSON
LEO PHARMA
MENARINI
MERCK
MSD
NOVARTIS
NOVO NORDISK
PFIZER
PIERRE FABRE
ROCHE
SANOFI
SERVER
SHIRE
TAKE
TEVA
UCB

AFFILIATE MEMBERS

BIAL
DAIICHI-SANKYO
EISAI
ESTEVE
H. LUNDBECK
OTSUKA
ROVI
VIFOR PHARMA

EFPIA Member Associations

FULL MEMBERS

AUSTRIA
Fachverband der Chemischen Industrie Österreichs (FCIO)

BELGIUM
Association Générale de l’Industrie du Médicament (pharma.be)

DENMARK
Laegemiddelindustriforeningen The Danish Association of the Pharmaceutical Industry (LFI)

FINLAND
Lääketieteellinen ry Pharma Industry Finland (PiF)

FRANCE
Les Entreprises du Médicament (LEEM)

GERMANY
Verband Forschender Arzneimittelhersteller (VFA)

GREECE
Hellenic Association of Pharmaceutical Companies (SFEE)

IRLAND
Irish Pharmaceutical Healthcare Association (IPHA)

ITALY
Associazione delle imprese del farmaco (FarmaIndustria)

NETHERLANDS
Vereniging Innovatieve Geneesmiddelen

NORWAY
Legemiddelindustriforeningen Norwegian Association of Pharmaceutical Manufacturers (LMI)

POLAND
Emploiers Union of Innovative Pharmaceutical Companies (Inarma)

PORTUGAL
Associação Portuguesa da Indústria Farmacêutica (AIFP)

RUSSIA
Association of International Pharmaceutical Manufacturers (AIPMI)

AFILIATE MEMBERS

BOSNIA & HERZEGOVINA
Association of Research-based Medicine Producers (UIPL)

BULGARIA
Association of the Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharm)

CROATIA
Innovative Pharmaceutical Initiative (IFI)

CYPRUS
Cyprus Association of Pharmaceutical Companies (KEFEA)

CZECH REPUBLIC
Association of Innovative Pharmaceutical Industry (AIPFI)

ESTONIA
Association of Pharmaceutical Manufacturers in Estonia (APME)

HUNGARY
Association of Innovative Pharmaceutical Manufacturers (AIPMI)

ICELAND
The Icelandic R&D Pharmaceutical Association (FIROVAK)

LATVIA
Association of International Research-based Pharmaceutical Manufacturers (SIFFA)

LITHUANIA
The Innovative Pharmaceutical Industry Association (FIPA)

MALTA
Maltese Pharmaceutical Association (PRIMA)

ROMANIA
Association of International Medicines Manufacturers (APRIM)

SLOVAKIA
Slovak Association of Innovative Pharmaceutical Industry (AIFP)

SLOVENIA
Forum of International Research and Development Pharmaceutical Industries (EIG)

SERBIA
Innovative Drug Manufacturers Association (IONV)

SLOVAKIA
Slovak Association of Innovative Pharmaceutical Industry (AIFP)

TURKEY
Araştımçı İlacı İşletmeleri Senyoralıları Derneği (AIFD)

UNITED KINGDOM
The Association of the British Pharmaceutical Industry (ABPI)

*CORRECT AT DATE OF PUBLICATION
EFPIA Specialised Groups

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 BIOLOGICALS | MSD | TAKEDA |
| ASTRAZENECA | NOVAVAX | VAXEAL |
| CUREVAC | PFIZER VACCINES | |
| JANSSSEN | SANOFI PASTEUR | |
| GLAXOSMITHKLINE VACCINES | SEORUS |

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 | ERYPHARM | NOVARTIS AG |
| ACHAOGEN* | EVOTEC | NOVIMMUNE |
| AC IMMUNE | FHOFFMANN-LA ROCHE | ORPHAN EUROPE* |
| AICURIS GMBH & CO. KG | GENESIS PHARMA | PATHOQUEST |
| ALK | GENFIT SA | PHARMA MAR |
| AMGEN | GENOMIC HEALTH | POLYPHOR |
| AND BIOPHARMA | GLAXO SMITH KLINE | PREGLEM SA |
| ASTRAZENECA | HEPATEST THERAPEUTICS | ROKALL* |
| BASILEA PHARMACEUTICA | HRA PHARMA | SANOFI |
| BAYER | IDOGEN | SPERO THERAPEUTICS |
| BIO DEUTSCHLAND | IDORSIA | STALLERGENES-GREER |
| BIOGEN | INTREXON | SYMPHOGEN A/S |
| BIOHYTIS | IPSEN | SYNTHON |
| BOEHRINGER INGELHEIM | IXALTIS | TIGENIX |
| CELLECTIS | JOHNSON & JOHNSON | TRANSGENE |
| CHIESI FARMACEUTICI* | LABORATORIODI LETI | UCB PHARMA |
| CUREVAC | LFB BIOTECHNOLOGIES | UNIQURE |
| DA VOLTERA | LYSOGENE | VAXEAL |
| DOMPE* | MEDIMMUNE (ASTRAZENECA) | VISCOFAN |
| ELI LILLY | MERCK KGA | ZYMENEX* |

* CORRECT AT DATE OF PUBLICATION

* LEFT EBE IN JANUARY 2019
EFPIA represents the pharmaceutical industry in Europe. Through its direct membership of 36 national associations and 39 leading pharmaceutical companies, 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. Our vision is for a healthier future for Europe - a future based on prevention, innovation, access to new treatments and better outcomes for patients.