



European Federation of Pharmaceutical
Industries and Associations

Annual Review of 2011 and Outlook for 2012



* Understanding
human needs is
half the job of
meeting them

Contents

- 04 **Foreword**
- 07 **People and Health**
- 08 Meeting patient needs in challenging times
- 10 Getting medicines to the patient
- 14 Getting ready for the new science and the benefits it can bring to patients
- 16 What needs to be done? Time for new thinking
- 19 **The Pharmaceutical Industry and the European Economy**
- 20 Shared destinies: The performance of the pharmaceutical industry and the European economy are inextricably linked
- 22 Navigating the current crisis
- 26 New models to research unmet needs
- 27 Supporting European competitiveness on a global scale
- 30 What needs to be done? Investing in long-term solutions
- 33 **Building Trust – A Responsible Pharmaceutical Industry**
- 34 The pharmaceutical industry and corporate responsibility – more than a “nice to have”
- 36 Improving our environmental record
- 37 Going the extra mile – the pharmaceutical industry’s contribution to global health
- 41 What needs to be done? Working with others to do better
- 43 **Annexes**
- 43 Glossary of Terms
- 44 EFPIA Governance

Foreword

I am delighted to welcome you to EFPIA's first Annual Review. It is a first: for me as Director General of our industry's trade association in Europe, and for the Association itself. The Review comes at the right time. Our industry is going through a period of unprecedented change, as well as coping with an economic crisis. In these times, it is all the more important that we demonstrate the value of our medicines to people's lives, and the value of the industry to Europe's economy. Also, we need to stay on course with our commitment to be more open, transparent and accountable in what we do. This Review is part of that commitment to patients, to Europe and to transparency. It will be issued every year, so that our key stakeholders can share in the fast-moving developments affecting the pharmaceutical industry in Europe, and to show how these developments, in turn, affect all of us.



I am excited about current advances in research and innovation. It is hard not to be enthused about the new science such as personalised medicines and all the "omics". These have huge potential to transform people's lives for the better, as long as we find a way to translate the science into products that are readily available to patients. And while the low hanging fruits of medicines discovery may have been picked, there are still high quality innovations being made available by our industry. In 2011, these included two new medicines to treat melanoma and two ground-breaking treatments for Hepatitis C. We need to talk more about our successes and opportunities, and we will do some of that in this Review. I will come back to this issue, because it is key.

At the same time, I am also concerned. Shrinking healthcare budgets and growing demands of ageing populations mean that governments are under pressure to make ends meet. This situation also puts pressure on the pharmaceutical industry. In the short-term, there are unpaid bills and unilateral cuts in prices. Clearly, our industry should not be immune to the cold winds of austerity. But I am concerned that if we continue on the current path, Europe's pharmaceutical industry will not be able to continue to develop the innovative medicines and vaccines that are needed in the long-term. The industry will continue on its quest, but maybe with much less activity in Europe, to the benefit of other parts of the world.

“ It is hard not to be enthused about the new science such as personalised medicines and all the "omics". These have huge potential to transform people's lives for the better, as long as we find a way to translate the science into products that are readily available to patients. ”

“ Doing things differently involves working together more than ever before. An outstanding example of this is the Public Private Partnership that our industry has engaged in with the European Commission, the Innovative Medicines Initiative (IMI). ”

We will also look at some hard facts and figures about our industry that are sometimes overlooked, and the sector's economic and social contribution to Europe. Despite challenging times, our industry continues to outstrip all other sectors in terms of its investment in research and development, its generation of high quality research jobs, and exports. How are we going to continue to be competitive in a globalised world, where our future growth will come from emerging economies?

We therefore need to have frank discussions with governments about how sustainable innovation, and a vibrant and productive pharmaceutical industry, can continue to operate in Europe. Most importantly, we must ensure that patients are not the ones to suffer. So this Review talks a bit about the crisis, the choices that need to be made, and what we need to consider in trying to get the balance right in terms of a fair return for the industry, and most importantly, delivering innovative medicines and vaccines to the patient.

I am pleased to say that our industry's CEOs have tasked me and EFPIA to plan for the long-term. Our industry has had to readjust, including a painful exercise of aligning the industry's research and development pipeline with what society considers it actually needs, and is able and willing to pay for. Although, we as an industry often hear different, and therefore, confusing messages on what this is, from payers, the medical profession and patient groups. There is sometimes a misalignment of what is needed by society, and where the research of our companies is focused. This is why we need to look at doing things differently, and see how we can fill the gaps. And once we have delivered what is needed, the added value should be properly rewarded, and the new medicines made available to all patients that need them.

Doing things differently involves working together more than ever before. An outstanding example of this is the Public Private Partnership that our industry has engaged in with the European Commission. This Review will talk about the Innovative Medicines Initiative (IMI) and the

exciting work it is doing to fill the gaps in the antibiotics pipeline as well as in a number of other disease areas such as Alzheimer's disease and depression. No review of what we are doing would be complete without trumpeting the ground-breaking IMI initiative.

The challenges are huge but so are the opportunities. So big in fact that we all have to take a step back and look at the picture as a whole. This will require leadership at the highest level, and a long-term view. How can we get better at joining up our thinking and our efforts – industry, regulators, policy-makers, payers, the scientific community, the medical profession and of course patient representatives, to keep pace with the new science? I am also anxious to know your thoughts.



Richard Bergström
Director General of EFPIA

“

A key challenge we are facing today is to prevent the economic crisis from triggering a health crisis... we must seize the opportunities to push reforms, embrace and develop new ideas and find better innovative models to address the unfolding challenges not least the ageing society.

”

John Dalli

Commissioner for Health and Consumer Policy, European Commission



People and Health

Lessons.

What did 2011 teach the pharmaceutical industry?

- * **Quality not quantity.** The quality of medical innovation remains high, but health systems are struggling to respond.
- * **Quicker delivery of innovation to patients.** Patients need medicines to get to the market more quickly and more extensively. The revision of the EU's Transparency Directive can play a key role in this regard.
- * **Gaps in research.** Despite exciting innovations, the industry recognises the need to address significant research gaps in important therapeutical areas.
- * **Stamping out falsified medicines.** Patients should receive the medicines they need to get well and stay well. Systems are needed to rid the medicines supply chain of falsified medicines.

Beliefs.

What values have shaped the way the pharmaceutical industry has addressed issues in 2011?

- * **Partnering in developing a shared agenda.** The pharmaceutical industry believes partnering with other stakeholders can help tackle the health and societal challenges facing Europe and patients throughout the world.
- * **New science calls for new policies.** We are on the cusp of a new paradigm in medical science. Advances in personalised medicines will transform the patient's prospects of recovery in many disease areas. A new regulatory approach is essential to ensure the benefits of these developments are delivered to the patient.
- * **Collaboration on Health Technology Assessment.** Best practice sharing on HTAs at European level can bring added value by streamlining processes and reducing unnecessary duplication.
- * **Facilitating clinical trials.** A simplified and efficient regulatory framework for clinical trials is vital to enhance Europe's attractiveness as a location for clinical research.

Actions.

What did the pharmaceutical industry do in 2011?

- * **Promoting new models of research.** Examples of new forms of research collaboration include, the Innovative Medicines Initiative (IMI) focus on antibiotics, and pooled research among companies on Alzheimer's.
- * **Serving Europe's ageing population.** The industry is helping address Europe's major challenge of an ageing population through its involvement in the European Innovation Partnership on Active and Healthy Ageing.
- * **Putting safety first.** Significant progress was made by the industry towards establishing an EU-wide coding and serialisation system to ensure the safety of medicines supplied to patients.
- * **Ensuring medicines are used.** The industry is promoting new thinking about how to improve patient's adherence to treatment, which is one of the most pressing challenges facing healthcare systems in Europe.

Impact.

What did the pharmaceutical industry achieve in 2011?

- * **Meeting unmet needs with new medicines.** Patients in 2011 benefited from the successful R&D efforts of the pharmaceutical industry in producing new medicines for skin cancer and hepatitis C and the first new treatment in 50 years for Lupus.
- * **Investing in ground-breaking science.** Advances such as epigenetics are encouraging the pharmaceutical industry and policymakers to look at new ways of bringing the benefits of scientific developments to patients as quickly as possible.
- * **Re-targeting existing treatments.** Innovation need not always mean starting from scratch. Many existing medicines which have long since gone off patent are being re-purposed for different treatments as the result of new research.
- * **Progress on vaccines.** The first-ever large scale trial of a malaria vaccine in children in sub-Saharan Africa produced promising results, cutting the risk of infection by about 50%. In addition, a vaccine against dengue fever is in late stage development.

Meeting patient needs in challenging times

Getting medicines to patients has always been the focus of what we do. 2011 was no exception. Our industry continued to innovate, by making new medicines available, but also by working in new ways – in Public Private Partnerships – by pressing for integration of new information technologies, and by looking at new ways to use old treatments. We moved closer to personalising medicines and to making the medicines supply chain safer. Last but not least, we addressed the issue of encouraging patients to stick to the treatments they need to get well, and stay well.

2011: Innovation in medical science

Amid all the gloom of the economic crisis and concerns about ageing populations, the European pharmaceutical industry is continuing to develop ground-breaking new medicines to treat unmet patient needs. This includes advances in major diseases like skin cancer as well as investment in new models of collaboration to address innovation gaps in areas such as resistance to antibiotics. Particularly in times of austerity, the industry recognises that innovation for innovation's sake is not enough, and that new medical developments must demonstrate a clear added value to society. At the same time, genuine breakthroughs that have a real impact on patients' lives must continue to be incentivised.

New treatments provide hope to patients

First and foremost, 2011 saw ground-breaking new medicines being made available to patients who need them most. For example, people suffering from the hardest-to-treat form of Hepatitis C can now significantly improve their chances of overcoming the disease.

Meanwhile not one but two products came on the market to help melanoma patients. For the first time, patients with the deadliest form of skin cancer have two new treatment options that prolong survival. New technologies are also helping to improve the day-to-day lives of people dealing with long-term chronic diseases. An example is a new solution for type 2 diabetes sufferers, which only needs to be administered once a week. However, a key challenge is for these innovative medicines to be reimbursed so that the patient can benefit from them.

There were also new developments in the field of vaccines in 2011. The global effort to protect millions against malaria received a major boost when the first-ever wide-scale trial of a malaria vaccine tested in children in sub-Saharan Africa produced promising results. The candidate vaccine cut the risk of infection by about half – a remarkable achievement, considering there has never been a vaccine against a human parasite before.

THE FRUITS OF INNOVATION – new treatments made available to patients in 2011

In 2011, 49 innovative medicines were approved in the EU covering several disease areas. In just one year, the European Medicines Agency (EMA) approved 37 new non-orphan medicines, 11 new orphan medicines and 1 advanced-therapy medicine (EMA Monthly statistics report: December 2011) for the EU market (not including national authorisations). According to SCRIP Intelligence, the market newsletter *"a large proportion of these drugs are truly original: one third of drugs launched in 2011 were first in class..."*

Orphan medicinal products are used for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect not more than 5 in 10,000 persons in the European Union. Approvals for new orphan medicines offer hope to patients with diseases that often have no other existing treatment options.

In addition, among the 37 non-orphan medicines, the first new medicine for lupus in over fifty years was authorised in 2011. We have also seen approvals for two new treatments for melanoma both of which can help patients who have had few treatment options in the past. The commitment to personalised medicine was demonstrated through the approval of two new cancer medicines to be applied only after the right patients have been selected using a companion diagnostic. 2011 also saw the introduction of a new medicine for epilepsy, several blood thinners and new treatments for schizophrenia patients. In addition to new molecules, there are several new products that enable patients to take their medicine less frequently or in an easier way, helping patient adhere to therapy and therefore benefit more.

Pooling knowledge and expertise

Despite these exciting new developments, the industry recognises there are still significant gaps in the focus areas of pharmaceutical research in Europe. There are research bottlenecks but also societal problems, such as prudent use of antibiotics, and the management of chronic disease, which are too big for individual companies to address on their own. At the same time, these critical issues hold back progress for all, and need to be addressed.

In order to tackle some of the most pressing gaps in current knowledge, industry has partnered with the European Commission to form the world's largest Public Private Partnership – the Innovative Medicines Initiative (IMI).

New models of collaboration are not confined to the IMI. European pharmaceutical companies have also recognised the need to pool research efforts to tackle complex conditions such as dementia. The importance of finding more effective ways of treating diseases like Alzheimer's, reflects the long-term challenges posed by demographic change. Europe's ageing population is leading to increasing demands for access to treatment, new treatment needs and a redefinition of unmet need.

In 2011, across Europe, health experts, governments, civil society, and in particular, the pharmaceutical industry looked for solutions to reduce the impending impact of such powerful changes in society. Many of the research targets of most relevance to our ageing population are particularly difficult to address, both because of challenging science and because the elderly have unique treatment needs. Progress continues to be made, for example, by companies carrying out ground-breaking research targeting the CETP gene, which has been linked to long life, good heart health, and a reduced risk of cognitive decline with age. It is also believed to reduce the chance of developing Alzheimer's disease.

The European pharmaceutical industry is involved in various aspects of the European Union's flagship Innovation Partnership on Active and Healthy Ageing to help produce better medicines, make better use of currently available medicines, and address unmet needs.

Demographic facts: Did you know?

- * By 2025, about one-third of Europeans will be aged 60 years and over and there will be a steep increase in the number of people aged 80 years and older. Across Europe, the working-age population will fall as the ageing population swells.
- * By 2050, the world population will reach 9 billion – marking the first time in history when people aged 60 and over will outnumber children aged 14 and under. With 35% of the European population estimated to be over the age of 60, compared to 20% today¹.

INNOVATIVE MEDICINES INITIATIVE (IMI) – a case study in collaboration

The Innovative Medicines Initiative (IMI) is a unique collaborative venture – a Public Private Partnership - between the European Commission and European pharmaceutical companies, small and medium-sized companies (SMEs), regulators, academia and patient groups. The goal of the IMI is to speed up the development of better and safer medicines in under-researched therapeutic areas. Teams of world-class experts are pooling their data and knowledge to tackle today's major scientific challenges in large scale pre-competitive projects building new methods, models and tools that will speed up the development of novel therapies. With a total budget of €2 billion, IMI is the world's largest public-private partnership in life science funded jointly by the European Union (€1 billion in cash) and EFPIA (€1 billion in in-kind contributions). Projects cover the entire value chain, from discovery, through preclinical and clinical research, to Health Technology Assessments (HTA) and pharmacovigilance. The first ongoing projects are already delivering impressive results, at a pace that could not be achieved by a single company or under another funding scheme.

An additional benefit of IMI is the relationships being made within the teams. So far, 225 different research groups from 23 major pharmaceutical companies are collaborating with 298 academic teams, 47 SMEs, 11 patient organisations and the European Medicines Agency (EMA). Working with regulators will help pharmaceutical companies to better understand, and thereby meet, regulators' requirements for new medicines approvals. At the other end of the process, patients should benefit from more reliable, up-to-date information thanks to the close involvement of patient organisations in some projects.

¹Source: 2005 Report from the Alliance for Health & The Future, "An Ageing Population: The European Facts and Figures" with the statistics taken from the Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects.

Getting medicines to the patient

Developing new medicines is only part of the picture. Ensuring people actually benefit from these solutions is even more important. This involves addressing regulatory pricing and reimbursement barriers to access to new medicines, combating trade in falsified medicines and helping ensure that patients adhere to the treatments they have been prescribed. The industry is actively involved in driving progress in all of these areas in collaboration with regulators, payers the medical community and civil society.

“ Involvement in your own health is often the best medicine. So, whenever patients ask for something, it should not only be a possibility for industry to deliver; it should also be an obligation. And I think industry takes this very seriously. ”

Christofer Fjellner
MEP (EPP, Sweden)

Ensuring fair access to treatments

Key to ensuring patients do not have to wait to access potentially life-changing new treatments are more efficient procedures for the pricing and reimbursement of innovative medicines. The same principle applies to generic versions of medicines that come off patent. In both cases, the goal must be to get the necessary medicines to the patient as quickly as possible.

In the current economic climate, more strategic thinking and flexibility is needed to ensure fair access for all patients to pharmaceutical treatment. Speeding up timetables for pricing and reimbursement decisions so that the products get to the market more quickly is one way of achieving this. It also means setting equitable prices that reflect the economic situation in a given country, while continuing to provide pharmaceutical companies with a return on often considerable investments in innovation.

The danger is that emergency price reductions in one market will lead to automatic and arbitrary cuts in other markets. While this may lead to short-term savings for governments, it reduces the industry's ability to respond to the needs of individual Member States and undermines the innovation model, which is based on aligning prices with the ability to pay. This is why, in 2011, the industry has been advocating the uptake of differential pricing from market to market as a means of improving access to medicines across Europe.

Clinical trials should also allow increasing numbers of patients to benefit from innovative medicines that are still in development. Between 2005 and 2010, over 297,000 patients took part in clinical trials in Europe. This represents around 40% of trials conducted globally for that period – with a value of €20 billion per year. Despite this, Europe's clinical trials infrastructure remains fragmented. This discourages investment and limits opportunities for participation.

“ Patients are increasingly impatient to receive new treatments; there has to be a two-way conversation between industry and patients during the developmental stage of new drugs so that industry can properly understand patients' needs. ”

Mary Baker
Patient group advocate, President of the European Brain Council

“ Ageing populations, the economic crisis and rapidly increasing healthcare costs means payers are under extreme budgetary pressure. This is forcing payers to make difficult choices regarding what medical procedures to fund and what medications to reimburse. To ensure a true reflection of the value of products and their innovative qualities for patients we should look towards involving all healthcare stakeholders throughout the medicine development stages. ”

Jo Decock

CEO of the Belgian National Institute for Health and Disability Insurance (RIZIV-INAMI)

Furthermore, with the revision for the Clinical Trials Directive under discussion at EU level, the European pharmaceutical industry will be pushing for more streamlined procedures better adapted to the new science in order to get innovative medicines to the patient more quickly. At the same time, we recognise that in the new drug development paradigm the assessment of efficacy will continue after formal approval, laying the basis for a real dialogue between developers, patients and healthcare professionals.

Safety first

Patient safety is fundamental to everything we do. Great efforts have been put into updating the legislative framework on falsified medicines, not least to take account of the impact of the internet. According to the European Association for Access to Safe Medicines (EAASM), 60% of medicines purchased online are falsified, fake or substandard. The next phase in stamping out falsified medicines is the implementation of the legislation in European countries and ensuring that patients and their physicians are properly informed. It is equally important that a proper tracking system for medicines be in place to guarantee the reliability of the supply chain. To this end, the pharmaceutical industry has been involved in setting up an ambitious EU-wide coding and serialisation system, the European Medicines Verification System (EMVS), aimed at ensuring the safety of the supply chain.

Doctor's orders: boosting adherence to medicines and health literacy

The industry is also promoting new thinking about how we improve patients' adherence to treatment. The issue is one of the most pressing facing healthcare systems in Europe. Too often medicines are filling up bathroom cabinets rather than being used by the patient as prescribed by their doctor.

THE RIGHT TRACK: The European Medicines Verification System (EMVS)

In 2011, with the adoption of the EU Falsified Medicines Directive, significant progress was made towards establishing an EU-wide coding and serialisation system, which will assist in ensuring the safety of medicines supplied to patients. In order to comply with the new EU legislation and enhance patient safety, an initiative has been developed by EFPIA in collaboration with key supply chain partners representing pharmacists (PGEU), wholesalers (GIRP), and parallel distributors (EAEPD) at EU level. The planned system sticks closely to the model tested in a pilot scheme in Sweden in 2009 which relied on placing 2D codes onto packs and verifying them in the pharmacy as they were being dispensed to patients.

The codes will include a randomised serial number, product number, batch number and expiry date, and scanning should allow pharmacists to identify fake medicines as well as genuine material that is recalled, expired, or which should not be dispensed for some other reason. The system will require the establishment of a series of national data repositories linked via a European hub. These will serve as the verification platforms, which pharmacies and other registered parties can use to check a product's authenticity. The system will have to handle up to 10 billion individual pack entries per year.

The EMVS will be able to handle parallel distribution of medicines, as well as multi-country recalls. A "blueprint" for the national system architecture will be made available for countries that do not currently have a national system in place.



The reasons for non-adherence are complex, as are the factors that define how well individuals manage their health. Improving health literacy should be a priority, not least in light of the need to address chronic disease. And trust in medicines among patients can be promoted by stamping out falsified or fake medicines in the supply chain.

The ability of citizens and patients to access and use the health information resources now available to them is a key issue. Health information was a prominent concern in 2011 both in terms of discussions about how to enhance patient empowerment, but also in terms of what role, if any, industry can play in providing information to patients, and how to address the digital divide within EU society.

The pharmaceutical industry believes that the idea of an empowered patient in a supportive health system is a powerful model for Europe. But we are still in the early stages of understanding what sorts of informational supports are most useful for patients. EFPIA joined with the European Patients Forum, the CPME doctors' association and the PGEU representing pharmacists to address this issue in a European Parliament seminar in September 2011. We jointly called for a concerted approach at EU and national levels to helping patients adhere to treatments involving carers and health professionals, as well as improved measures on information to patients and health literacy.

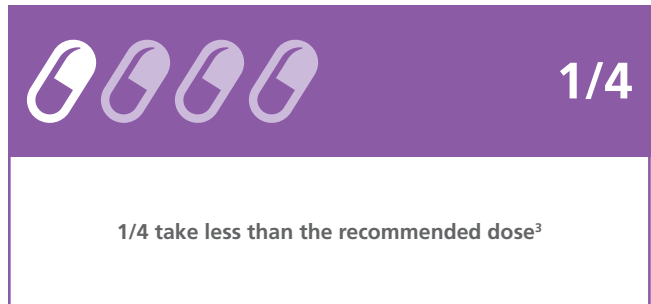
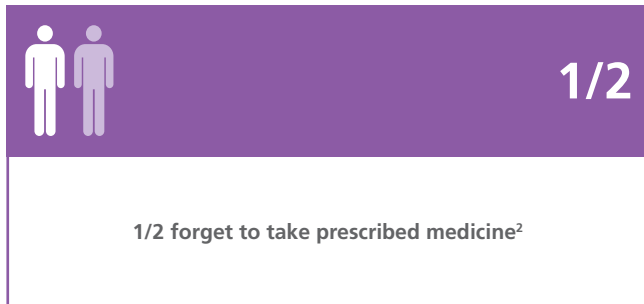
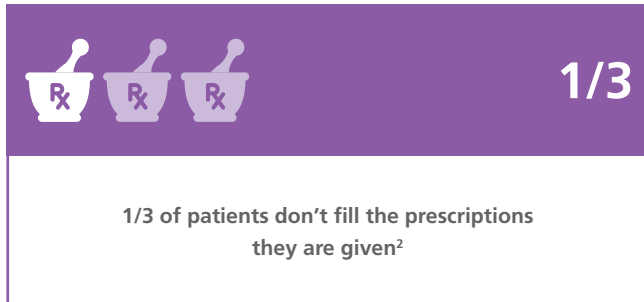
“ We are all fully committed to creating a flexible, practical, cost-effective system that will meet the key objective of protecting patients from fake medicines. ”

Isabelle Adenot

President of the Pharmaceutical Group of the European Union (PGEU)

Non-adherence is a problem of epidemic proportions globally

Adherence among patients with chronic illnesses averages only 50%¹



In Europe, medication non-adherence costs governments an estimated €125 billion and contributes to the premature deaths of nearly 200,000 Europeans a year.

¹World Health Organization, Adherence to Long-term Therapies: Evidence for Action, Switzerland, 2003.

²National Council on Patient Information and Education. Enhancing Prescription Medicine Adherence: A National Action National Plan, USA, August 2007.

³Just what the doctor ordered: An EU Response to Medication Non-Adherence, Tuesday 28 September 2010, Biliothèque Solvay, Brussels.

“ When a long-term medicine is prescribed, around 50% of patients fail to adhere to the prescribed regime... An international patient survey that we ran recently revealed non-adherence to antihypertensives within the range of 38% for Wales to 70% for Hungary. ”

Professor Przemyslaw Kardas

Head of the First Department of Family Medicine at the Medical University of Lodz, Poland and the Scientific Director of the ABC Project

Getting ready for the new science and the benefits it can bring to patients

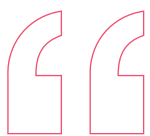
Science has always been at the core of what the medicines sector is about. The research-based pharmaceutical industry has consistently invested in science, knowing that the fruits of R&D can add years to life, and life to years. Progress comes in waves. Right at this moment, we are in the midst of technological advances which promise step-changes in patient care in Europe and beyond. With these advances come challenges to the existing regulatory system, which needs to adapt to ensure the potential of the emerging science translates into real benefits for European citizens.

Personalised medicines in the digital age

The phrase “Personalised medicines” has become an accepted term to capture the potential benefits for patients of emerging therapies that can be tailored for individual patients or specific population groups. We live in a time when it is now possible to produce a reading of a human genome in less than a day for less than €1000. A few years ago, this was no more than a pipedream. Improved access to this level of genetic information could fuel significant advances in therapies tailored to individual patients. However, the future of personalised medicine has several different aspects, and one of the most important is effective data capture through e-health. Targeted treatments can only be deployed effectively, if the data are available to see how medicines are working with real patients. This new pharmaceutical science is not evolving in a silo, but is a product of innovations in pharmaceutical research, as well as innovation in other sectors, particularly information technology.

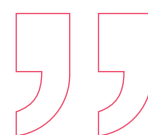
Re-purposing and re-targeting existing treatments

2011 brought major breakthroughs in pharmaceutical innovation in the form of completely new molecules. However, innovation today has many different dimensions. One of the least understood is finding new uses of existing molecules. Our growing understanding of the specificities of individuals and populations urge a re-evaluation of what is sometimes dismissed as secondary innovation. Many tried and tested medicines, which have long since gone off patent are also being researched and repurposed for new treatments. An insight into patients’ genetics can help health professionals figure out which medicines will work best, and in which dosage, for each individual. Selective Serotonin Reuptake Inhibitors (SSRIs), are used in depression, but we do not really understand which ones will be effective on which patients, or how they actually work. So the doctor would need to test with in-vitro diagnostics to see which medicine is best-suited to their patient. Similarly, there are established cancer treatments, that work on an overexpression of a gene, and therefore tests could be conducted to see which patients can best benefit from the treatment.



We have an excellent science base in Europe, but there is a need to remove barriers that prevent discoveries from reaching the market in the form of innovative products and services. This requires effective partnerships between academia and industry, better access to finance and less bureaucracy, but also more flexibility in mobility between the two sectors. More innovation is the key to competitiveness, growth and jobs for the European pharmaceuticals sector.

Máire Geoghegan-Quinn
Commissioner for Research, Innovation & Science, European Commission



“ We are looking to achieve optimal individualised patient care for cancer sufferers by combining diagnostic tools with innovative medicines and targeted radiation therapy. ”

Professor Vincenzo Valentini

President of the European Society for Therapeutic Radiology and Oncology (ESTRO)



Getting the right regulatory framework in place

However, the new paradigm poses problems for regulatory authorities, as the necessary tests are currently not recognised in the medicine approval process. The regulatory framework is not keeping pace with new developments. A new approach is essential if these new therapies are to be made available to the patient safely and quickly. Fresh thinking about how to incentivise innovation in areas such as companion diagnostics is also essential if companies are to continue to invest substantial amounts of money in funding these solutions.

National governments can play their part too. The industry supports the need to assess the added value of new medicines for individual patients and society as a whole, and commits to demonstrating it with high quality, transparent data. Health Technology Assessments (HTAs) when based on sound methodologies and input from all relevant stakeholders can be used as a tool to support efficient healthcare decision-making. Industry will continue to be involved in efforts to promote HTAs among EU Member States, and to promote good practices and efficiencies in HTA.

“ One of the greatest bottlenecks in drug development is that subpopulations of patients cannot be identified. Therefore the U-BIOPRED research project, under IMI, seeks to understand more about individual abnormalities amongst patients with severe asthma. We are mapping out different categories of asthma to better understand HOW we can produce more targeted and effective therapies for patients. ”

Peter Sterk

Chief Investigator at U-BIOPRED (IMI)

from the Department of Respiratory Medicine at the University of Amsterdam, The Netherlands

What needs to be done?

Time for new thinking

The industry will be advocating at the highest political levels for a fresh look at the issues that impact on delivery of healthcare to the patient. This will require a whole new joined-up approach to the regulatory framework to take account of the new science and to ensure that safety, efficacy and quality are safeguarded, whilst at the same time ensuring that new medicines and vaccines reach the patient as quickly as possible.

“ We want to streamline the submission process and create a single submission portal. Information on one clinical trial should be submitted only once. ”

John Dalli
Commissioner for Health and Consumer Policy,
European Commission

2012 sees the start of regulatory processes critical to the pharmaceutical industry. There will be the opportunity to streamline the way clinical trials are regulated in Europe. A simplified and efficient regulatory framework for clinical trials is vital to enhance Europe's attractiveness as a place for clinical research. This will benefit European patients by allowing them faster access to innovative treatments and in reducing the administrative burden and costs for public and private sector researchers as well as for Member States. The system will need to continue to evolve to adopt the new science.

The industry will also be pressing for swifter timetables on pricing and reimbursement of medicines by national authorities. As Europe looks to review the Transparency Directive in 2012, there is an opportunity to shorten the time it takes for both innovative and generic medicines to go through pricing and reimbursement assessment in Member States. The goal must be to get the necessary medicines to the patient as quickly as possible.

This process should also be reformed to take account of the new science with initial pricing and reimbursement decisions being flexible and updated, as the full utility of new medicines for various population groups becomes evident. This requires a more dynamic and responsive

system. In relation to antibiotics, it may be necessary to go one step further and think about completely new ways of incentivising innovation which do not rely on volume sales. Many of the required changes can only be achieved through a more coherent and integrated approach, which replaces current highly inequitable practices, such as international referencing with other more sustainable means of guaranteeing value for money for Member States.

Since their inception, Health Technology Assessments (HTAs) have gradually evolved to represent an important evidence-based support to healthcare decision-making. The potential to streamline and align evidence requirements, promote good practice and improve efficiency by reducing unnecessary duplication, explains why industry supports the setting up of a permanent European network connecting HTA agencies by 2013. Through discussions with regulatory agencies, there is also an opportunity to streamline clinical evidence requirements, and support the separate processes of medicines regulation and HTA.



“ Implementing personalised medicine will require a higher degree of collaboration amongst the many stakeholders in the life science and medical sectors than has ever been achieved in the past. ”

Marc de Garidel

President of European Biopharmaceuticals Enterprises (EBE)
Chairman and Chief Executive Officer, Ipsen Group

However, the biggest challenge facing Europe's health systems is sustainability. The EU's reflection process on chronic diseases is an opportunity for change that must be taken. These diseases make up a large proportion of healthcare costs, and a much greater (and hidden) drain on competitiveness. Building on the EU competence in the field of public health, the European Commission could take a more active role in facilitating and co-ordinating the exchange of national and regional best practices in the field of prevention of chronic diseases, and benchmarking progress. This could include experiences with health promotion programmes, involving multiple relevant stakeholders – employers, the workforce, and health insurers – or with the implementation of patient registries. Along with the transfer of ideas and knowledge on chronic conditions, models, tools and solutions that can be used in other countries could be developed, promoted and implemented.

When it comes to ensuring patient safety, the pharmaceutical industry and its partners will launch its pioneering coding and serialisation system – European Medicines Verification System (EMVS) – in 2012. This should greatly assist in stamping out dangerous falsified medicines from the supply system in the EU.

We can also look forward to the launch of an e-Health Action Plan from the European Commission in 2012, which will aim, among other things, to establish an “e-health network” in order to afford better access to care across the EU for patients, and to place e-health at the forefront of European Health Policy.

Finally, the industry will continue to work together and in Public Private Partnerships, notably in the Innovative Medicines Initiative (IMI), to fill the gaps in research and innovation. A key focus area for the coming year will be the roll out of the next phase of IMI.

““

While there are no easy quick-fix solutions to current challenges, behind every crisis there is an opportunity to challenge traditional ways of thinking, promote collaboration among different players in society and develop innovative models of working.

””

Panos Kanavos

Reader in International Health Policy in the Department of Social Policy, London School of Economics (LSE) and Programme Director of the Medical Technology Research Group (MTRG) at LSE Health, London, United Kingdom



The Pharmaceutical Industry and The European Economy

Lessons.

What did 2011 teach the pharmaceutical industry?

- * **Cost containment.** Governments are looking to make savings across the board to cope with the economic crisis and are less willing to pay for innovative medicines.
- * **Unpaid bills.** The crisis has led to unpaid bills with the industry owed over €12.5 billion by four countries alone at the end of 2011.
- * **Global competition.** Europe continues to face increasing competition for investment from fast-growing and rapidly changing emerging economies.
- * **Availability does not necessarily mean access.** Huge disparities in uptake of innovative medicines from market to market across the EU are linked to economic factors rather than the availability of the products themselves.

Beliefs.

What values have shaped the way the pharmaceutical industry has addressed issues in 2011?

- * **Added value.** The industry is committed to developing new products and solutions with a clear added value for society.
- * **Long-term thinking.** The crisis presents an opportunity to develop new ways of promoting and incentivising innovation.
- * **Flexible solutions to get medicines to patients.** The industry is advocating differential pricing to address disparities in purchasing power across EU Member States.
- * **Working together.** Public Private Partnerships will have a crucial role in delivering ongoing healthcare innovation in Europe, through programmes such as the IMI and Horizon 2020.

Actions.

What did the pharmaceutical industry do in 2011?

- * **Investment in innovation.** The pharmaceutical industry is the second sector - just after the automobile industry - in terms of R&D investments in the EU.
- * **Europe remains a priority market.** Despite the growth of emerging economies, the EU remained the second largest market for investment in pharmaceutical R&D.
- * **Sharing the pain.** The industry contributed over €7 billion in savings to national budgets in Greece, Ireland, Italy, Portugal and Spain through price cuts and discounts.
- * **Significant employer.** The pharmaceutical industry employed about 660,000 people in Europe.

Impact.

What did the pharmaceutical industry achieve in 2011?

- * **Trade balance.** With a €48.3 billion contribution to the EU's trade surplus, no other high-technology industry made a more significant contribution to Europe's trade balance.
- * **R&D intensity.** The pharmaceutical industry had a higher ratio of R&D investment to net sales than any other European sector.
- * **High quality jobs.** With almost 20% of these people working in R&D, the industry provides the highest value added per employee, according to Eurostat.
- * **World leader in vaccines.** 77.4% of the production of the world's largest vaccine manufacturers was carried out in Europe.

Shared destinies – The performance of the pharmaceutical industry and the European economy are inextricably linked

From an economic perspective, pharmaceuticals are an area in which Europe has traditionally been a world leader. Few other sectors can match the industry's contribution to investment in R&D, trade balance and creation of skilled employment in Europe.

Economic facts: Did you know?

- * The pharmaceutical industry is Europe's 5th largest industrial sector.
- * The pharmaceutical industry is the sector with the highest rate of R&D intensity in Europe and the highest rate of private investment in R&D.
- * No other high technology industry makes a more significant contribution to Europe's trade balance.
- * The pharmaceutical industry provides the highest value added per employee in Europe.
- * Europe was home to 77.4% of the output of the world's largest vaccines manufacturers in 2011.

If the pharmaceutical industry is important to European global competitiveness, the fundamental source of competitiveness lies in conditions at home. In 2011, Europe remained the second largest market for pharmaceutical sales after the USA. Meanwhile, the presence of a highly-skilled workforce and robust framework for the protection of intellectual property rights are key factors in the industry investing €27.5 billion in R&D in Europe last year. In the next stage of the evolution of what is now a genuinely globalised industry, the links between the industrial base and the healthcare systems in which new technologies are used, will become more important than ever as an influence on competitiveness.

However, it is clear that both the pharmaceutical industry and the European economy are facing real challenges. These range from pressures on public purses due the current financial crisis to ongoing regulatory hurdles. Add to this the rising costs of R&D in Europe and competition from emerging economies vying for R&D investment, and working to become market players in their own right.

Some of the pressure on public finances was relieved by an unprecedented wave of patent expiries, resulting in significant losses of revenue for the affected companies. At the same time, payers continue to increase demands for companies to demonstrate the added value of new products and solutions they bring to the market, particularly in times of austerity.

The European Pharmaceutical Industry in Figures in 2011

€48.3 billion Contribution to EU trade surplus.

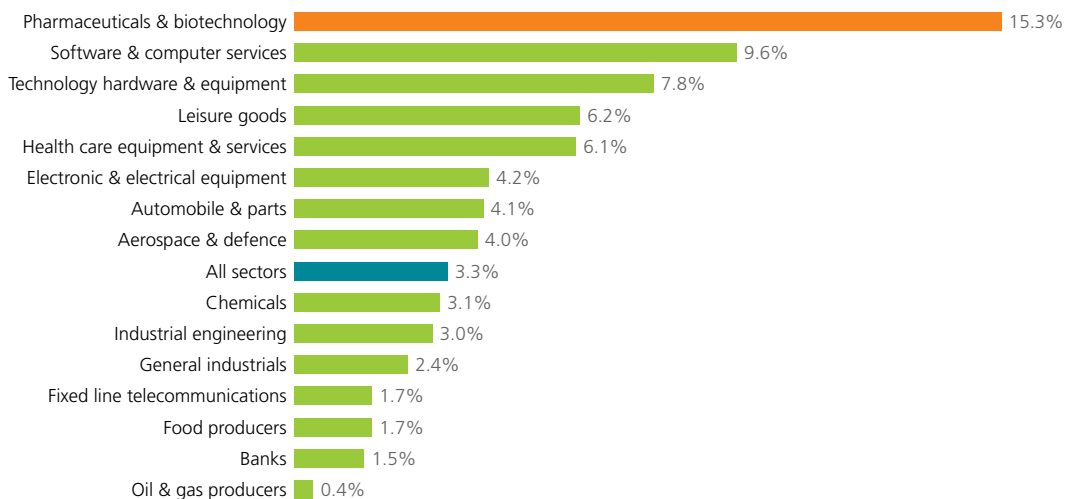
€27.5 billion Amount invested by the industry in Europe.

660,000 Number of people employed by the industry, with three or four times more jobs indirectly reliant on the sector.

116,000 Number of these people in R&D-related positions.



The EU Industrial Innovation Scoreboard ranked the pharmaceutical industry as the sector with the highest ratio of R&D investment to net sales on a global scale in 2010



Source: The 2011 EU Industrial R&D Investment Scoreboard, Joint Research Centre, Directorate General Research & Innovation, European Commission.

Navigating the current crisis

The economic crisis is impacting every aspect of our lives – and health in particular. Financial insecurity means that people are less able to put health considerations first; putting pressure on Europe's social and economic fabric and jeopardising prospects of recovery. However, it is only through long-term thinking and investment in the future that we will be able to emerge properly from the current crisis.



“ We are concerned about short-term healthcare spending cuts, which decrease access to services, having a negative impact on morbidity and the health of the population. This leads to even greater costs in the future from the cumulative impact of unidentified and untreated conditions. Whilst in times of crisis there is a need to place more emphasis on efficiency, such short-term healthcare spending cuts are not efficient. Efficiency requires better use of pharmaceuticals, more transparency, and decisions which involve the patient. ”

Dr Josep Figueras

Director of the European Observatory on Health Systems and Policies
WHO European Centre on Health Policy

Short-term gain, long-term pain?

2011 was a year of continued economic crisis in Europe and indeed globally. As a result, health budgets have been coming under increasing strain. While overall spending curbs hit the headlines, hidden cuts were also being felt, with longer hospital waiting lists, reductions in services and increases in co-payment.

The pharmaceutical industry was not immune to these pressures and readily acknowledges the need for all parts of society to take their share of the pain in difficult times. Pharmaceutical companies contributed to over €7 billion in savings in 2010 and 2011 through price cuts and discounts in five European countries alone (Greece, Ireland, Italy, Portugal and Spain). Companies are also adapting to significant cost-containment programmes brought in as part of healthcare system reforms in other European countries such as Germany.

However, while focusing on short-term savings is a legitimate response to an economic crisis, simply failing to pay for services rendered is an altogether more problematic issue. By the end of 2011, Greece, Italy, Portugal and Spain collectively owed EFPIA members over €12.5 billion – with most debts lying with hospitals and local governments. In financial

terms, this amounts to almost half the total investment of the industry in R&D in Europe in 2011. In certain cases, non-payment of medicines bills became a crisis issue, to the point where supplies of medicines were put at risk.

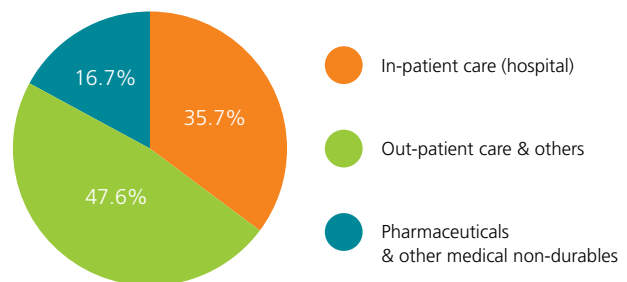
The industry has striven to address the issue of pricing and how this can be adapted to the varying stages of economic development and well-being across the EU. The goal is simple: to get medicines to patients in an economically sustainable way.

The challenge lies in ensuring that the need to balance budgets in the short-term does not lead to policies that will stifle innovation and economic growth in the medium-term. From the perspective of the pharmaceutical industry, this means avoiding measures such as international reference pricing to justify purchasing medicines at the lowest possible cost. It also means continuing to support policies that incentivise investment in innovation in healthcare, for the benefit of current and future generations of European citizens. Failing to do so would be short-sighted in the extreme, with potentially drastic long-term consequences for both the provision of healthcare services and the broader economic development of European countries.

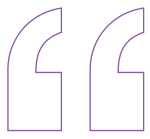
HOW MUCH DO MEDICINES COST COMPARED TO OTHER SERVICES?

In this climate of cost control or cutting, the relative cost of medicines should not be overestimated. Medicines only constitute one part of the total health package, with less than one fifth of total health expenditure in Europe being spent on pharmaceuticals and other medical non-durables. Even in costly diseases such as cancer and rheumatoid arthritis, medicines account for less than 10% of the total costs. This means that governments, which need to make savings in the healthcare sector, should be strategically spreading these savings across all elements of healthcare spending.

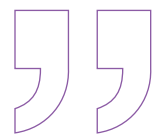
Breakdown of total health expenditure in Europe



Source: OECD Health Data 2011 - EFPIA calculations (non-weighted average for 24 EU & EFTA countries)



The problem for developed countries' health care systems is that there is about a 4% increase in annual demand for healthcare and a zero increase in resource. Given about 66% of the expenditure is on patients with long-term conditions, it is essential that over the next few years health services develop significantly better health care outcomes for the same resource. They will only achieve this if they realise the value that patients with long-term conditions can add to their own care.



Professor Paul Corrigan

former senior health policy adviser to United Kingdom Prime Minister, Tony Blair

GUIDING PRINCIPLES FOR NEGOTIATIONS WITH PUBLIC AUTHORITIES

As commercial entities supplying a public service with goods which are the result of long-term high-risk investment, the pharmaceutical industry attaches importance to certain guiding principles in their negotiations with governments:

- ✦ **Predictability** – business decisions are taken based on future expectations
- ✦ **Fairness** – equality of treatment between different actors
- ✦ **Patient focus** – a readiness to invest in support of improved patient outcomes
- ✦ **Reward for value** – we do not ask that everything that is new is automatically rewarded, but what is valuable to patients
- ✦ **Coherence** – an integrated approach to healthcare which is evidence-based

Especially in difficult economic times, the pharmaceutical industry's dealings with national authorities responsible for pricing and reimbursement should be based on clear principles of mutual respect and transparency. Differences in objectives should be acknowledged but should not stand in the way of dialogue and collaboration, and the legitimate viewpoints of all stakeholders should be acknowledged from the outset. Discussions should be guided by the key questions of availability, accessibility and affordability of medicines.

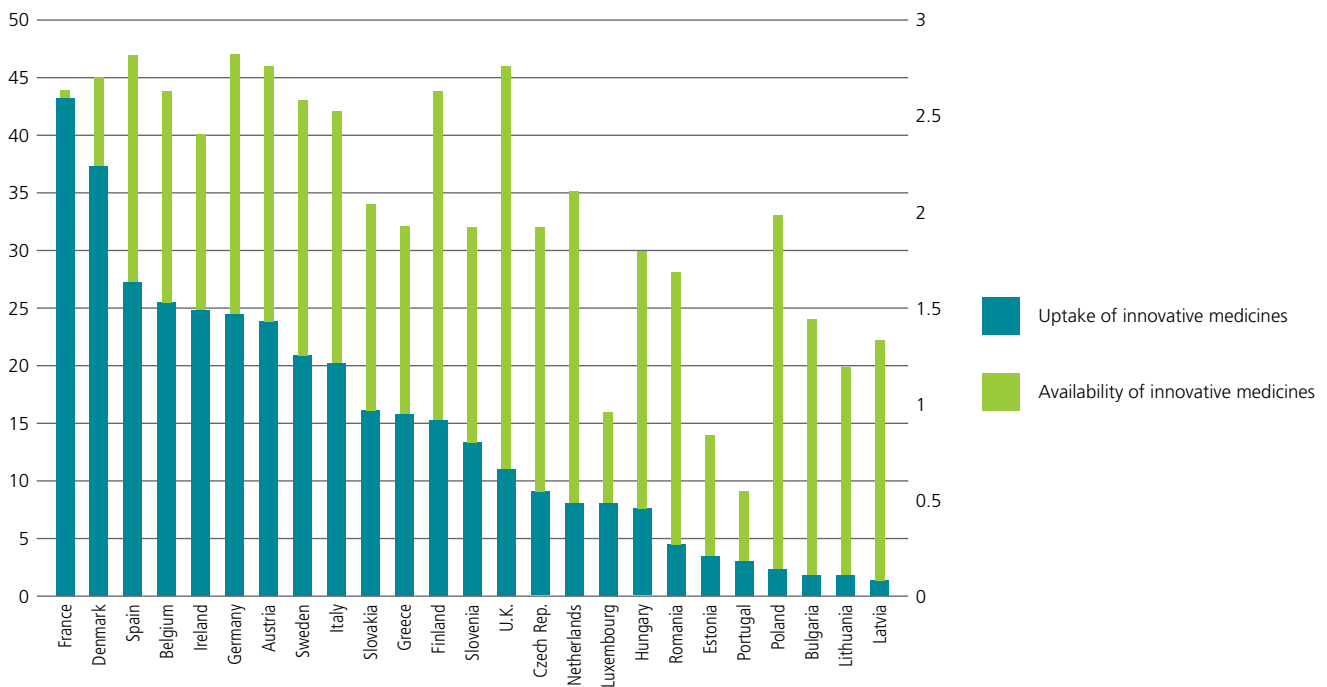
In the current period of economic crisis and widening disparities in access to healthcare, it also means that a certain amount of flexibility will be required. At present, there are huge differences in the uptake of innovative medicines from one EU Member State to another, as measured by sales. These variations appear to be more strongly linked to economic factors than the availability of the medicines on the markets in question. In this context, the industry believes that Member States should be ready to accept the need for a differentiation of prices according to affordability.

There is no easy one-size-fits-all solution to these challenges. However, what is clear is that unless they are addressed in a collaborative, forward-looking manner, the danger is that European citizens and patients will be the ones who suffer the most.



Is access to new medicines defined by availability or affordability?

2009 sales per 100.000 inhabitants vs. number of available innovative medicines



In September 2010, the Belgian Presidency of the EU published an analysis of 47 innovative medicines marketed in EU Member States from 2005-2009. The findings show big differences in the number of medicines that were available (green columns) and the uptake of innovative medicines (blue columns) from market to market. These variations in uptake of medicines

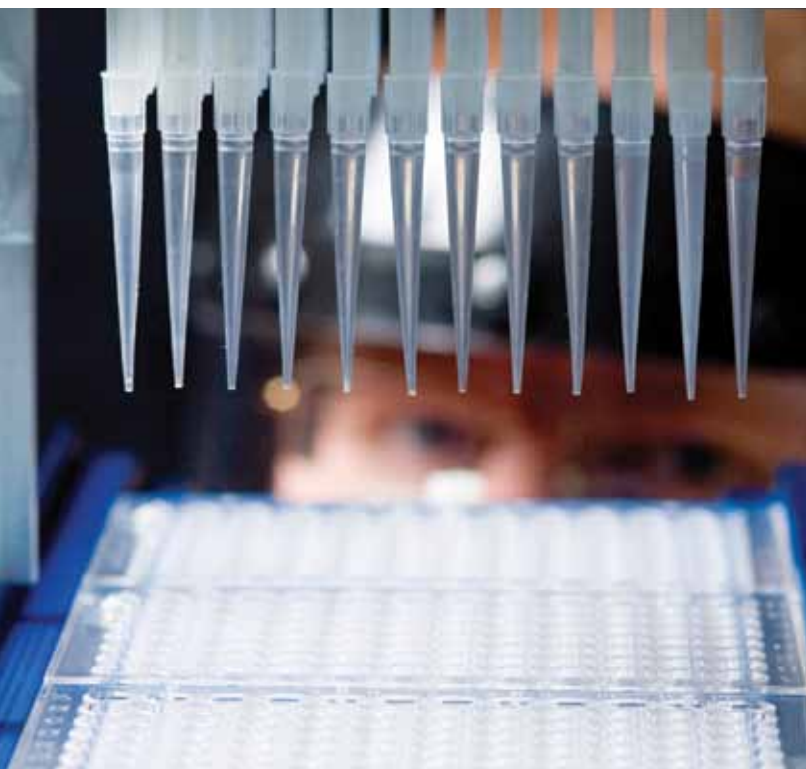
within Europe do not appear to be linked to differences in the availability of innovative medicines across markets but to differences in the average GDP per capita. For example, the amount per capita spent on these innovative medicines during this period was more than ten times higher in France and Denmark than in Portugal, Poland, Bulgaria, Lithuania and Latvia.

New models to research unmet needs

Europe has continued to grow in absolute terms as a location for investment in pharmaceutical R&D over the past decade. However, there has been a decline in our relative position. While a shift in investment towards emerging economies is expected, there is no doubt that Europe could do more to address the combination of rising R&D costs, burdensome regulatory requirements and slow uptake of innovation, that make Europe a challenging environment for healthcare innovation. If Europe is to continue to be the source of genuine medical breakthroughs with real societal and economic benefits, it must recognise, reward and use innovative medicines. Europe's ability to remain a leader in biomedical innovation also depends on regulators, industry and civil society developing new models of collaboration to research areas of unmet need.

“ Working together in drug discovery and development, partnerships between public and private organisations pave the way for a new generation of medicines. ”

Lambert van Nistelrooij
MEP (EPP, The Netherlands)



In this context, the European pharmaceutical industry is an enthusiastic supporter of European Commission's proposals for a new EU Framework for Research and Innovation – Horizon 2020. The programme is designed to create a knowledge-based economy in Europe capable of competing on a global scale over time. Key elements of the proposals launched in November 2011 are a dedicated science budget of €24.6 billion, as well as €31.7 billion, to address major concerns shared by all Europeans, including health, demographic change and well-being.

At the heart of the proposed programme is an emphasis on Public Private Partnerships (PPPs). The industry supports continuing public-private research collaborations that address scientific and technological bottlenecks in areas with grand societal challenges, such as neurodegenerative diseases and resistance to antibiotics.

The Innovative Medicines Initiative (IMI) has already begun to change the understanding of what PPPs can achieve in the life science arena. There is therefore a desire to build on the success and positive lessons from IMI to develop a new Partnership Framework with the European Commission focused on pharmaceutical R&D.

Supporting European competitiveness on a global scale

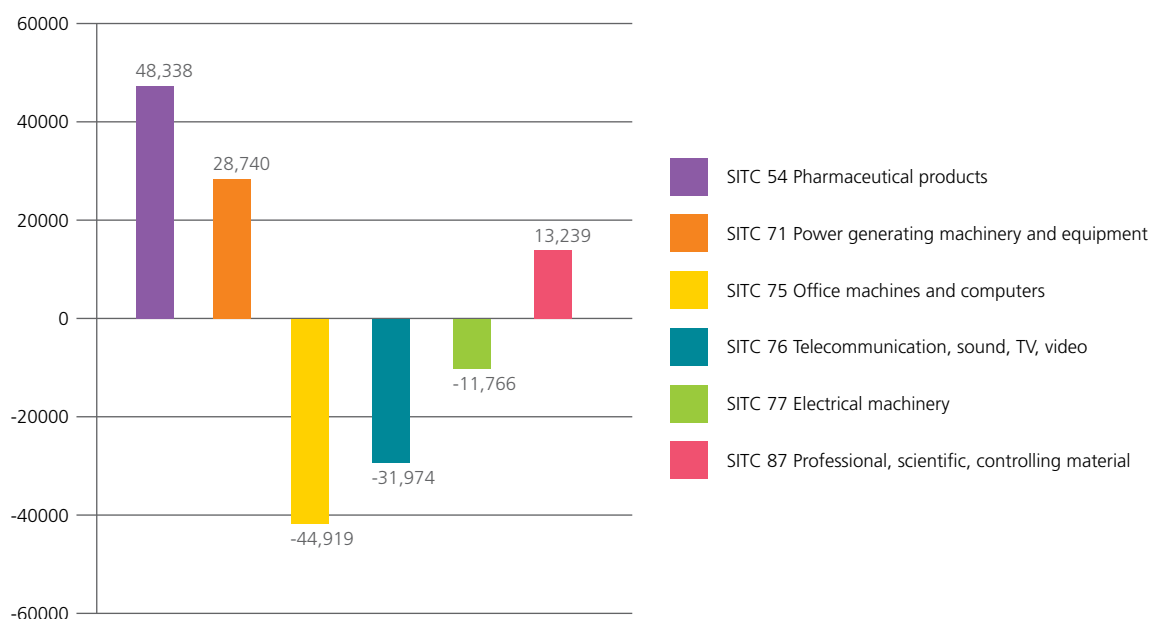
External Trade policy is one of the key tools to promote European growth and competitiveness, by ensuring a more predictable, sustainable and mutually attractive environment for engagement with our partners.

The pharmaceutical industry is one of the few major sectors to contribute positively to the EU's trade balance. Its trade surplus of €48.3 billion in 2011 was the highest among high-tech industries.

In parallel to dealing with domestic economic challenges, Europe is facing increasing competition for investment from fast-growing and rapidly changing emerging markets such as China, India, Brazil and Russia. The geographical balance of the pharmaceutical market – and ultimately its R&D base – is likely to be re-weighted towards emerging economies. This is a positive development if it is paralleled by a progressive alignment of trading conditions, enabling the EU to capitalise on its continuing advantage in the more advanced areas of technology. However, 2011 also saw a continuing trend of protectionism and lack of regulatory transparency across these markets, with many measures having a disproportionate impact on foreign companies. Examples of such measures include discriminatory tax incentives, lower standards applied to locally produced medicines and excessive import restrictions or requirements.



EU-27 Trade Balance - High technology sectors (€ million) - 2011



Creating a stable and predictable environment for investment in innovation and increasing access to healthcare are not a contradiction in terms, as is sometimes argued. On the contrary, they should go hand in hand for the benefit of future generations in Europe and around the world.



The support of the EU's external trade agenda is therefore key to ensuring market access for exports of innovative medicines by European companies and promoting a level playing field from a regulatory perspective vis-à-vis increasingly strong trade partners. To this end, bilateral negotiations between the EU and pharmaceutical growth markets should also be directed at ensuring that the intellectual property rights (IPRs) of innovative European industries are adequately protected in these countries.

Not only will this approach allow Europe's trade in innovative products to continue to grow, it will also enable major trading partners, particularly those from emerging economies, to implement appropriate policies to increase their own innovative capacity and boost their contribution to domestic and global health. Significant reforms of healthcare systems are underway around the world. The European pharmaceutical industry

is keen to work with governments to ensure that the end results include progress in access to innovative treatments for patients and expansion of healthcare coverage to lower-income populations.

However, this does not mean that trading partners such as India, with whom negotiations on a Free Trade Agreement continued throughout 2011, should adopt EU regulatory standards overnight. Changes to existing regimes are incremental and our industry recognises they should take into account the level of development.

Creating a stable and predictable environment for investment in innovation and increasing access to healthcare are not a contradiction in terms, as is sometimes argued. On the contrary, they should go hand in hand for the benefit of future generations in Europe and around the world.



BUILDING TIES WITH KEY PARTNERS

The European pharmaceutical industry supports the EU in seeking closer cooperation with key economic partners. Priority markets for the industry include:

- * High-growth emerging markets such as China, India, Brazil, Russia, Turkey
- * Other Latin American and Asian economies
- * Developed markets such as the USA, Japan, Canada, South Korea, Australia

The EU concluded an historic Free Trade Agreement (FTA) with South Korea in October 2010. Implementation of the agreement will begin in the second half of 2012. Other potentially significant FTAs are currently under negotiation with Canada, India, ASEAN countries and CIS countries. Meanwhile, the EU is also looking at ways to enhance bilateral relations with traditional partners such as the USA and Japan.

What needs to be done?

Investing in long-term solutions

Knowledge-based industries are essential to Europe's future, as reflected in the Europe 2020 strategy. As one such industry, the pharmaceutical sector is focused on the long-term. It has to be since it takes more than ten years to move from a molecule to new medicines on the shelf. Pharmaceutical R&D can transform healthcare and individual lives. Our ability to do that depends ultimately on a complex network of supporting conditions, which enable us to invest in producing medicines which contribute to affordable & high-quality healthcare.

Europe is at a tipping point. Historically, EU Member States have been successful in balancing the demands of affordability and reward for innovation in their health systems. Even in tough economic times, this philosophy needs to continue to be pursued with long-term impacts in mind. Decisions made today will have an impact on future generations of patients in the EU and elsewhere. As an industry that is based on long-term, high-risk investment, and seeks to continue to be Europe's flagship research-based industry, we urge the need for long-term thinking. This should not be limited to the industry, but should extend to regulators, legislators and the wider healthcare community and it should encompass both our domestic infrastructure and our place in the world innovation system.

Globalisation brings with it complex supply chains and significant differences in standards of regulation and enforcement from market to market. This leads to additional costs for industry and can act as an obstacle to greater investment in innovation to meet patient needs. EU policies and processes are highly relevant to global problems and Europe can play a role in leading the global debate on how best to address these complex issues. The EU's system for regulating medicines is highly respected. Based on this expertise, the EU can make an important contribution to aligning international regulatory approaches. Similar advanced thinking on more effective regulation can be seen in the ideas now being brought forward in discussions around the new Horizon 2020 research programme.

The EU could also lead the way in new thinking on how to balance access and affordability. This means first getting its own house in order, by recognising the need for differential pricing of medicines to ensure access to innovative medicines in less prosperous European countries. For its part, the European pharmaceutical industry is committed to improving global conditions for innovation, while recognising that innovation must be aligned with public health needs, and the specific requirements of developing markets in particular. The industry believes that a renewed dialogue on the global role of innovation-based European industries is overdue, and will seek to advance these discussions in 2012.

In parallel with globalisation, the second fundamental trend shaping the industry is the emergence of the "new science". This requires alignment of existing research structures and legal, regulatory and market conditions with the potential it offers. This involves a new way of thinking based on the recognition that innovation that directly benefits patients is not created in isolation in research laboratories. Rather it is fundamentally shaped by regulatory environments, and the capacity of health systems to absorb change.

We should not lose sight of the fact that innovation cannot happen in a vacuum. It requires incentives to justify the considerable investment and risk involved in turning exciting new ideas into everyday realities. The economic crisis coupled with the emergence of the "new science" has focused minds on the need for a new strategic approach to incentivising innovation in the post-blockbuster world of personalised medicines.



Especially in times of economic crisis, the focus of European countries on international therapeutic reference pricing measures hinders access to medicines. This situation could be improved if governments embraced differential pricing.



Richard Bergström
Director General of EFPIA



In the context of the European economic crisis, I still see a future in which truly innovative products are rewarded and where a highly competitive and evolving industry contributes to create a virtuous circle of growth, health and wealth. In this world, Europeans will enjoy the enhanced quality and quantity of life they deserve and be productive members of the European workforce. But unfortunately there is a second less positive scenario, where unbalanced cost containment measures damage what is probably Europe's leading source of knowledge-based jobs and exports. It will take leadership and collaboration to realize the first and avoid the second.

Eric Cornut

Head of Europe, Novartis and Chair of Executive Committee EFPIA



We cannot ignore the R&D process itself and in particular, how we draw on insights from research in the way we regulate and finance new medicines. To offer a few examples:

- * Regulatory assessment needs to be aligned with emerging knowledge about the classification of diseases, and there is still a need to create the right forum for such discussions to take place.
- * Biomarkers and diagnostics can be used to select patients more effectively for treatments and improve the efficiency of the clinical trials process, but they need to be endorsed by regulators and funded by health systems
- * Much of what we learn about the effectiveness of medicines lies in their everyday use by patients. The challenge is how to integrate this real life experience into assessments to complement the on-going reliance on traditional clinical trials. It is clear that existing systems are far from ready to deal with the increased role of patients in monitoring the effects of therapy that this would inevitably involve.
- * Finally, there is scope for much greater harmonisation of approaches among regulators in different regions assessing the same medicine.

The European pharmaceutical industry will continue to promote stronger and more effective collaboration with regulators and civil society on all these issues in 2012. The next phase of the Innovative Medicines Initiative (IMI) and the EU's flagship Horizon 2020 programme can act as launch pads for exciting new discoveries that can benefit future generations of patients in Europe and around the world. Meanwhile, the raft of pharmaceutical legislation going through the EU decision-making process offers an important opportunity to bring about a step change in the regulatory processes for bringing the fruits of this research to the patient.



“ The pneumonia vaccines are a symbol of one of the most exciting trends in global health – the drive toward equity in creating and delivering innovations. In the past, drug companies developed vaccines for rich countries... But that is changing. The newest pneumonia vaccines were available in developing countries just a few years [after they were made available] in developed countries. The same is true of a new rotavirus vaccine. Now it is up to the GAVI Alliance and global health leaders to ensure that these vaccines reach the children who need them. ”

Bill Gates
Co-Chair of the Bill and Melinda Gates Foundation
and GAVI funder

Building Trust – A Responsible Pharmaceutical Industry

Lessons.

What did 2011 teach the pharmaceutical industry?

- * **Trust in the industry.** It is critically important that decision-makers listen to the industry and take advice on matters affecting innovation and access to medicines. This will only happen if there is trust.
- * **Striking a balance.** Our experiences in 2011 reconfirmed that the industry can only be sustainable if we can find a way of working with public authorities in a mutually respectful way to the benefit of patients.
- * **Working in partnerships pays dividends.** The industry has proved the effectiveness of working with others to help patients in a range of issues, such as tackling neglected tropical diseases or combatting antimicrobial resistance.
- * **Pro-active engagement on environmental impact needed.** The industry needs to heed concerns about the impact of the medicines on the environment and to engage actively with health and environmental regulators to ensure that the health benefits of these products are not lost to the patient.

Beliefs.

What values have shaped the way the pharmaceutical industry has addressed issues in 2011?

- * **Doing good is good for business.** Sustainable business depends on doing more to make a difference for society. A successful business must take a long-term view.
- * **People's health matters.** The industry is a private sector entrusted with a key role in people's health and needs to act responsibly towards the authorities and taxpayers who are its ultimate customers.
- * **Being open about what we do will build trust.** We need to have frank and open discussions, if myths and suspicions about the industry's motives are to be dispelled, and its full contribution to society properly realised.
- * **The industry's contribution adds value** beyond its unique contribution of creating new medicines and vaccines. Our engagement with others in seeking solutions to health challenges is substantive and for the long-term.

Actions.

What did the pharmaceutical industry do in 2011?

- * **Working towards corporate responsibility policy and guiding principles for ethical conduct.** This will be launched with partners in 2012.
- * **Opening up clinical trials information for the benefit of patients.** The industry is actively supporting an EU clinical trials register and has had its own clinical trials portal for many years.
- * **Fighting Neglected Tropical Diseases (NTDs) together.** Thirteen pharmaceutical companies committed 1.4 billion treatments for each of the next ten years towards fighting NTDs.
- * **Working towards an environmental strategy.** The industry will actively engage on a new approach to environmental issues, including working with legislators in seeking to address the potential impacts of discharge of products into the environment, and highlighting environmental best practice among its companies.

Impact.

What did the pharmaceutical industry achieve in 2011?

- * **Entered agreements with many governments** on difficult issues such as pricing and unpaid bills and most importantly, on how to deliver cost efficiencies without jeopardising patient outcomes.
- * **Building trust.** This is a long-term process but the EFPIA code of practice and the clinical trials register demonstrate the industry's will to be transparent.
- * **Practical measures to build openness.** EFPIA took the initiative to limit the giving of medical samples, in keeping with the EU legislation. EFPIA has developed the e4ethics platform, which provides for pre-assessment of multinational events in Europe.
- * **On-the-ground solutions that help the patient.** Working with others to find practical solutions that help patients in Europe and in developing countries through partnership programmes aimed at improving the performance of health systems.

The pharmaceutical industry and corporate responsibility – more than a “nice to have”

Corporate Social Responsibility (CSR) is part and parcel of any 21st century business’ licence to operate. The European Commission has defined CSR as “the responsibility of enterprises for their impact on society”.

Societal expectations of the private sector are not fixed in stone. Over the past twenty years, trust in business, in general, has eroded and the pharmaceutical industry has not been spared. Like many industries, the pharmaceutical industry has sought to adapt to changing expectations. Sometimes changes are not as fast as stakeholders would want, and sometimes stakeholders themselves do not recognise the changes that have taken place. Added to this, the events surrounding the withdrawal of the diabetes medicine, Mediator, have negative ramifications which affect the whole industry and diminish public trust. The reaction to such events often extends beyond the immediate issues at stake.

The pharmaceutical industry’s reputation has come under fire concerning the lack of transparency around its relationships with governments and the health community, its pricing strategies, its impact on the environment and its actions in developing countries around access to medicines. The industry recognises that it needs to address these critical issues and build trust if it is to be sustainable in the long term. In particular, the industry is entrusted with a key role in the most sensitive area of our lives – our health - and has an obligation to understand and communicate the effects of its products. In addition, the industry is engaged in transforming the breakthroughs taking place in the life sciences into social benefit. Many of these raise challenging ethical and scientific questions. The industry has a responsibility to deliver value for money to health systems, which are often heavily funded by taxpayers, and vary enormously in their ability to make healthcare affordable for their citizens.

While acknowledging the need to change behaviour, EFPIA also recognises that the pharmaceutical industry needs to improve its ability to understand how its business activities are perceived by the individuals with whom it works – from staff to patients, customers, suppliers and shareholders – and to better align themselves with their values as people.

Working with governments as customer and regulator

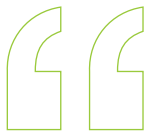
The pharmaceutical industry’s business model is unique. Like other sectors, pharmaceutical companies need to serve the interests of shareholders and to bring a return on the huge investments needed

to produce innovative medicines and vaccines. A differentiator is the industry’s clients. These are largely governments and therefore, at the end of the day, the European taxpayer. And it is these same governments, who set the regulatory framework for the industry, define society’s needs for its products and decide how they should be paid for. The growing voice of patients and that of healthcare professionals provides an additional dimension to these relationships, which are, of necessity, long-term, complex and highly interactive.

Checks and balances already exist to ensure that the roles of these different groups are not undermined. The industry believes that these safeguards are effective but that they should be kept under review. Where suspicions of conflict of interest arise, we should ensure that these are not made worse by a perceived lack of openness about the governance of the industry’s relationships with governments, as both our regulator and customer.

Addressing unmet need

At first glance, it seems hardly necessary to attempt to define unmet need. Yet the industry has found that there are situations where finding ways of addressing unmet need involves more than science. Industry engagement in addressing neglected diseases, where there is an absence of ability to pay, is one example. For three years, the industry has also been involved in trying to find a solution to the long-term decline in investment in antibiotics. These are life-saving treatments whose efficacy is eroded by use - the more they are used, the more resistance emerges. They also offer lower commercial returns than other therapeutic areas, and very challenging regulatory requirements. With other stakeholders, we are developing a new business model based on public-private partnership which will deliver better alignment between the private and public sector in pursuit of the preservation of antibiotic effectiveness. We will continue to work with partners in the public sector to make progress on science in those areas where needs are not being met, simply because the science is too challenging for a single company to take on.



We must stand in front of the mirror and ask ourselves – what's the most we can do to make a positive difference, to do better, be responsible, to keep challenging and demanding better? One person can make a difference by accepting the responsibility of doing the best they can do, for the business and wider society.

Sir Andrew Witty
CEO of GSK and President of EFPIA



Towards a new policy on ethics and transparency

The industry recognises the need to put its collaborations with other stakeholders on a new basis. These relationships underpin progress in healthcare. At the same time the industry is actively engaged in addressing the issues of perceived conflict of interest and a lack of transparency. As part of the work led by Commissioner Tajani in charge of Industry and Entrepreneurship, a new charter is being developed setting out the key principles which should guide the industry when dealing with healthcare actors such as doctors, nurses and patient groups.

We already do a lot, in October 2011, the European Commission published a Communication on a new policy on corporate social responsibility. It states that to fully meet their social responsibility, enterprises "should have in place a process to integrate social, environmental, ethical and human rights concerns into their business operations and core strategy in close collaboration with their stakeholders". Building on the work led by Commissioner Tajani, the pharmaceutical industry has taken up the challenge and is seeking to be the first sector to come up with a corporate responsibility plan.

The industry believes that prohibiting contacts between the key stakeholders will undermine progress in healthcare, which depends on scientific exchange and dialogue. At the same time, these relationships and the contribution that make must be visible and transparent. Both the purpose of these relationships and the means by which they are regulated must be more open to public scrutiny. Collaboration with physicians is a crucial part of the innovation process and must be protected by excluding unnecessary non-scientific activities.

Detailed rules for the promotion of medicines and interactions with healthcare professionals, as well as patient organisations, are laid down in codes of conduct that are binding for EFPIA members. These codes address medicines promotion and relationships with patient organisations. The codes were amended on 14 June 2011, and came into force in their revised form as of 1 January 2012. Practical measures that demonstrate the industry's commitment to ethical conduct and transparency, include the industry's initiative of specifying that medicinal

samples should be limited to four per healthcare professional per year over a two-year period. During 2011, EFPIA member associations have integrated this new standard into their national codes of conduct. In addition, scientific conferences and meetings play an important role in the continuing training of healthcare professionals. The industry has long recognised the need to ensure that the content of any such meetings sponsored by the industry should be purely scientific and that the hospitality offered should be appropriate. The required standards are reflected in article 9 of the EFPIA Healthcare Professional code of conduct. In order to give additional guidance to members, the industry has developed the e4ethics platform which provides for pre-assessment of multinational events in Europe. Following a trial period, the platform was launched at the end of 2011.

Sharing clinical information – helping patients access new treatments more quickly, while safeguarding sensitive commercial data

In 2011, more than 4000 clinical trials were performed in Europe (EU/EEA) involving about 400,000 patients. Roughly 25% of EU clinical trials are performed in more than one EU Member State. An important service provided by the pharmaceutical industry is the worldwide clinical trials portal (clinicaltrials.ifpma.org), where the pharmaceutical industry posts information on clinical trials for all to consult. Part of building trust, is being as open as possible with data. Our industry therefore supports the 2011 launch of the EU clinical trials register. This gives all EU citizens access to information on the thousands of authorised pharmaceutical clinical trials that are underway in the EU. The industry welcomes all moves to remove perceived secrecy, as long as legitimate trade secrets are protected. In 2011, the industry contributed to the European Medicines Agency (EMA) consultation on increased transparency and access to information included in companies' applications for marketing authorisation. Industry and regulators must work with patient groups to make sure that data is provided in a way that is helpful for patients and relatives.

Improving our environmental record

The pharmaceutical industry is one of the most heavily regulated industries across all of its activities. Strict regulations apply to the manufacture and release of medicines. Environmental risk assessments are also required for the marketing approval of any medicine.



ENVIRONMENTALLY SMART SOLUTIONS

- ✦ **Lundbeck** installed new equipment in its chemical production plant in Lumsas in Denmark in 2011 which allows it to purify solvents 50 times more effectively than before and to reuse them in all processes.
- ✦ **GSK** built one of North America's largest solar array rooftop in Pennsylvania, as part of their strategy to reduce electricity usage by 45% by 2015.
- ✦ **Novartis** invested €5.3 million in solar panels for their California plant, which contribute to 20% of the site energy's requirement.
- ✦ **AstraZeneca** is developing and applying Environmental Reference Concentrations (ERC) to 30 of its active pharmaceutical ingredients. The ERC approach effectively allows standards to be set for controlling manufacturing discharges, in that concentrations in the receiving environment should not exceed certain values. This approach is based on established environmental quality standard concepts currently used in much national and international legislation.

The World Health Organization (WHO) has recently stated, "Although current published risk assessments indicate that trace concentrations of pharmaceuticals in drinking-water are very unlikely to pose risks to human health, knowledge gaps exist in terms of assessing risks associated with long-term exposure to low concentrations of pharmaceuticals and the combined effects of mixtures of pharmaceuticals." The pharmaceutical industry supports greater efforts in understanding the long-term environmental impact of man-made substances, including medicines, and in minimising their release into the environment. At the same time, any debate about the impact of pharmaceuticals in the environment, and decisions made, need to be based on sound scientific evidence. This is, after all, a prerequisite for a knowledge-based economy. This evidence should clearly address and differentiate between the potential for an impact on human health from pharmaceuticals in the environment, and the potential impact on the environment. It should also take into account the effect of any measures on the availability of medicines.

Quick solutions are not easy to identify. However, the industry is committed to improving the environmental impacts of its products and processes, and is actively developing proposals for a coherent response to societal concerns, which balances environmental concerns with the needs of patients.

Going the extra mile – the pharmaceutical industry's contribution to global health

The pharmaceutical industry has taken considerable measures to improve health in the developing world through funding R&D, donation and health awareness programmes, and training for healthcare professionals. Still, more progress is needed to address today's health challenges, especially in relation to diseases of the developing world, and the increasing burden of non-communicable diseases in developing countries.

Global health partnerships – a track record of R&D discovery, funding, donations and training

As part of its commitment to global health, the pharmaceutical industry is contributing to tackling unmet medical need in various ways. One approach, which is increasingly employed, is Public Development Partnerships (PDPs) in order to tackle communicable diseases in the developing world. Since many of the diseases in question will never generate commercial revenues, joint approaches are often seen as the best way of making an impact in developing countries. In this way, pharmaceutical companies can join with others with complementary expertise. Non-profit medicine research and development organisations such as the Drugs for Neglected Diseases Initiative (DNDi) is one such PDP with pharmaceutical companies as partners contributing funds and collaborating in R&D projects to find new cures for Leishmaniasis, Sleeping Sickness, Chagas disease. In 2011, DNDi, started projects in the areas of Paediatric HIV and Helminth infections.

The Global Funding of Innovation for Neglected Diseases (G-FINDER) survey finds that in 2010 \$3.2 billion (€2.6 billion) was allocated for research relating to neglected diseases – a stark increase from a decade or two before. Pharmaceutical industry investment represents 16.4% of this. Important cuts in public and philanthropic funding, combined with increased pharmaceutical industry investment, has resulted in the pharmaceutical industry becoming the second largest funder of R&D for diseases of the developing world.

In 2011, the pharmaceutical industry had 93 on-going R&D projects for diseases of the neglected world, with 48 medicines in the pipeline for malaria and 81 medicines in development for HIV/AIDS. Aggregated pharmaceutical industry R&D funding investment for 2010 reached \$503 million (over €406 million), with the industry in top funding positions for a wide number of diseases. The pharmaceutical industry contributes 75% of R&D funding for tuberculosis, malaria and dengue. It was also the biggest funder for bacterial pneumonia and meningitis, and rheumatic fever.

“ The NCD Alliance believes that addressing the NCD epidemic requires a multi-stakeholder approach. We recognise that working with the private sector will be important to operationalise the multi-sectoral and whole-of-society approaches that lie at the heart of the 2011 UN Summit Political Declaration on NCDs. ”

Ann Keeling
Chair of the NCD Alliance

WIPO Re:Search - a sharing platform for R&D

Recognising the need for more progress in neglected disease research, WIPO Re:Search was formed in 2011 through the efforts of several of the world's leading pharmaceutical companies, the World Intellectual Property Organization (WIPO) and BIO Ventures for Global Health (BVGH). WIPO Re:Search provides access to intellectual property for pharmaceutical compounds, technologies, and – most importantly – expertise and data available for research and development for neglected tropical diseases, tuberculosis and malaria. By providing a searchable public database of available intellectual property assets and resources, WIPO Re:Search facilitates new partnerships to support organisations that conduct research on treatments for neglected tropical diseases, ultimately improving the lives of those most in need.



Beyond these investments, the pharmaceutical industry has engaged in creative approaches to finding new collaborative ways to increase medicine innovation for diseases of the developing world. Pharmaceutical companies are providing access to proprietary research tools and databases, sharing compound libraries with the World Health Organization and researchers, foregoing licences or providing royalty-free licences on co-developed products.

Other in-kind contributions to the R&D effort made by the pharmaceutical industry include technology transfer, provision of expertise, and teaching and training as well as regulatory assistance.

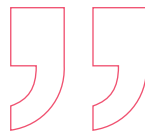
Complementing this considerable effort to improve the innovation pipeline for diseases of the developing world, pharmaceutical companies are involved in large-scale medicine distribution and prevention initiatives. In 2011, the pharmaceutical industry had over 200 global partnerships underway across the world, in particular in developing and emerging markets. Each partnership is unique, but often involves healthcare system capacity building, educational programmes, and mechanisms to facilitate access to high-quality pharmaceuticals. Over the past decade global health partnerships (GHPs), as a form of Public Private Partnerships (PPPs), have emerged with surprising force and speed as an innovative system to address global health challenges.

The research-based pharmaceutical industry has also spearheaded a variety of donation programmes. Some of these programmes have existed for many years and involve significant financial commitments.

Since 2000, the scale of industry's donations has greatly increased. From 2000 to 2009, the research-based pharmaceutical industry has donated to developing countries more than 2.4 billion treatments. In addition, as part of the London Declaration, the industry has pledged to donate 14 billion treatments for neglected tropical diseases (NTDs) from 2011 to 2020. A sustainable healthcare system will not be built solely on donations, but they can play their part, alongside more broad-based efforts to strengthen health systems.



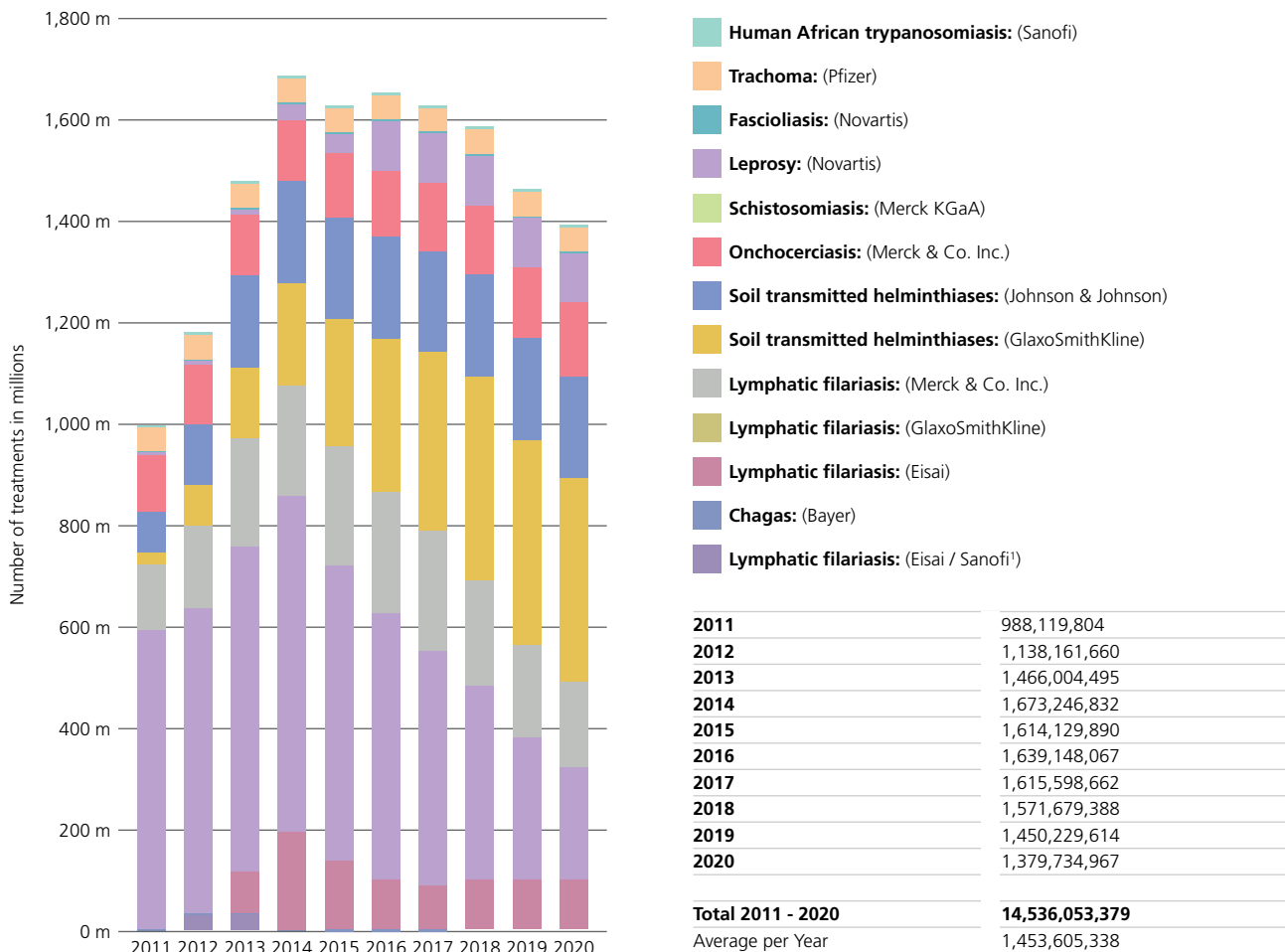
Support for these neglected tropical diseases has increased exponentially, measured most especially in massive drug donations from both traditional and newly supportive pharmaceutical companies.



Dr Margaret Chan
Director-General of the World Health Organization

14 billion treatments to be donated between 2011 and 2012

Pharmaceutical companies sign the "London Declaration" in support of eliminating and controlling neglected tropical diseases between 2011 and 2012 through landmark donations



IFPMA, Research-Based Pharmaceutical Industry Pledges 14 Billion Treatments to Help End Nine Neglected Tropical Diseases, News Release (Geneva, January 30, 2012), http://www.ifpma.org/fileadmin/content/News/2012/IFPMA_Ending_neglected_tropical_diseases_January2012.pdf.

¹The Bill and Melinda Gates foundation is also contributing.

Pharmaceutical industry partnership with GAVI

In the area of vaccines for children, the industry is an active partner in the Global Alliance for Vaccine and Immunisation (GAVI). GAVI is boosting immunisation rates and reducing the gap in vaccine access among children in developing countries. Cooperation with GAVI has included



participating in innovative financing mechanisms, such as the Advance Market Commitment (AMC), that provides a platform for investing in the development of a sustainable supply of breakthrough vaccines. This enables developing countries to receive vaccines more quickly than would have been possible if left to normal market mechanisms and at prices far lower than those paid in developed countries.

Each year, pneumococcal disease takes the lives of half a million children under five years of age, making it the leading vaccine-preventable cause of death among young children. The most effective way to prevent these deaths is to ensure access to effective, safe and affordable vaccines. Pneumococcal vaccines are new, complex vaccines that would normally reach low-income countries 10-15 years after their introduction in industrialised countries.

Thanks to the roll out of the Pneumococcal AMC in 2010-2011, children in Benin, Cameroon, the Central African Republic, the Democratic Republic of Congo, Guyana, Honduras, Kenya, Mali, Nicaragua and Yemen are all being immunised against the main cause of pneumonia today.

2010, saw the world's first large-scale clinical trial of a malaria vaccine completed enrolment, 15,640 babies and young children in several African countries received the so-called RTS,S or Mosquirix, an experimental vaccine for malaria vaccine developed in a public-private partnership with the Path Malaria Vaccine Initiative (MVI) and GSK.

“ Vaccination is one of the most effective public health interventions, contributing to health and welfare worldwide. By protecting individuals, whole communities can benefit from the dramatic reduction and even elimination of certain vaccine-preventable diseases. Therefore, the challenge of achieving the Decade of Vaccine's objectives requires a country-led, broad-based, collective approach involving players from public, non-governmental, and private sectors. This is necessary to ensure sustained production, access to, and use of high quality and innovative vaccines for both developed and developing countries. ”

Patrick Florent
President of the European Vaccine Manufacturers (EVM)

What needs to be done?

Working with others to do better

In 2012, the industry will be moving into the active implementation of a number of key initiatives, all of which will help demonstrate our commitment to patients and innovation.

The legislative review of the clinical trials directive will provide opportunities to open up more information on trials to patients. At the same time, the industry needs to defend sensitive commercial information (regulatory data protection) if incentives for future innovation, and with it, new medicines for patients, are to be safeguarded.

The industry will actively engage with the European institutions and other stakeholders on an industry environmental strategy. These initiatives will underline the industry's commitment to improved partnership and dialogue with both health and environmental regulators, lessening the impact of its products on the environment, whilst safeguarding patients' access to medicines.

Pharmaceutical companies will continue in their engagement in initiatives such as the London Declaration, the Decade of Vaccines, the follow-up to the 2011 UN meeting on non-communicable diseases and GAVI.

Last, but not least, under the leadership of Commissioner Antonio Tajani in charge of Industry and Entrepreneurship, and in collaboration with other health community representative organisations, the industry has been developing guiding principles to define the basic principles governing relationships with key partners, such as the medical profession and patient representatives, as well as governments. We hope to make this public in the course of 2012. Particularly important is for the industry to promote understanding and dialogue about its relationships with healthcare professionals and regulators. These are important relationships, which influence the type of research the industry carries out, and the uptake of new medicines. Most importantly, the industry must find ways to secure that patients have access to new medicines – despite financial austerity. Maybe the financial crisis presents an opportunity for industry and payers to re-engineer the way medicines are introduced and paid for.

“Many companies and organisations have worked for decades to fight these horrific diseases. But no one company or organisation can do it alone. Today, we pledge to work hand-in-hand to revolutionize the way we fight these diseases now and in the future.”

Sir Andrew Witty
CEO of GSK and President of EFPIA





Annexes

Glossary of Terms

Clinical trials	Set of procedures in medical research and medicine development that are conducted in humans intended to discover or verify the effects of one or more investigational health interventions (e.g., medicines, diagnostics, devices, therapy protocols).	Human Genome	The entirety of a human's hereditary information.
Differential Pricing	Adapting medicine prices to the purchasing power of consumers and epidemiological conditions in different geographical or socio-economic segments.	International Reference Pricing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country. In some countries, the referencing pricing system is applied rigidly, while in other countries, it is simply one of many elements of information used to inform the pricing decision. The basket of countries chosen varies, based on a range of criteria used to justify the selection of countries.
Epigenetics	Variations in the way genetic material is packaged and read can influence gene activity without altering the sequence of DNA. These patterns of modifications in identical twins are different despite their having the same DNA.	Neurodegenerative diseases	An umbrella term for diseases, which result in the progressive loss of structure or function of neurons, including Parkinson's, Alzheimer's, and Huntington's.
E-health	The application of Information and Communication Technologies (ICT) across a range of functions in the healthcare sector with a view to enhancing continuity of care and ensuring access to safe and high-quality healthcare.	New Science	A general term used for, biotechnological advances in the pharmaceutical industry, including personalised medicines, epigenetics, diagnostic tools such as biomarkers and nanotechnology.
Falsified Medicines	A falsified medicine gives a false representation of its identity and/or source and/or record keeping for traceability; pretends to have been assessed and approved by the competent regulatory authority, pretending to be a genuine quality product; has an intention to deceive by a fraudulent activity; is falsified for profit motives, disregarding public health and safety; and that disputes concerning patents or trademarks must not be confused with falsification of medicines.	Non-durables	Consumable medical supplies are non-durable medical supplies that are usually disposable in nature, cannot withstand repeated use and are primarily and customarily used to serve a medical purpose.
Free Trade Agreement	An agreement between partner countries which aims to eliminate tariffs, import quotas, and preferences on most (if not all) goods and services traded between them, whilst ensuring market access (e.g. through transparency, IPR protection and enforcement, regulatory harmonisation).	Off-Patent Pharmaceuticals	A medicine that has come to the end of its patent term and is open to generic competition.
Generic medicines	A medicine which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicine, and whose bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies.	Omics	A short-hand term used to refer to a field of study in biology. For example, genomics is the study of genomes.
Genome	A genome contains all of the information needed to build and maintain that organism, it contains the entirety of an organism's hereditary information.	Patient adherence	The degree to which patients adhere to medical advice and take medicines as directed.
Health Technology Assessment	is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.	Personalised medicines	Tailored treatment to patient subgroups based on their biological characteristics.
		Therapeutic Reference Pricing	A method of comparing the prices for a range of different medicines, which are deemed by the founder to be similar in as much as they are part of the same therapeutic area and in some circumstances, are interchangeable. However, they are not the same medicine.

Credits

EFPIA would like to thank its members for their valuable contributions to this Annual Review.

Commissioned by EFPIA. The Annual Review was researched and written by Acumen Public Affairs, edited by Gary Finnegan and designed by Morris & Chapman.

EFPIA Governance

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 32 national associations and 35 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 quality of life around the world.

The EFPIA General Assembly comprises all full members and meets once a year to define the Association's general policy. The Board comprises representatives from 23 corporate members (full member companies only); the Executive Committee is composed of delegates from member companies and associations, elected for a period of two years. The Board/Executive Committee carries out the tasks and duties determined by the General Assembly, and ensures that these are implemented by the General Management.

EFPIA Board

The Board sets EFPIA's strategy priorities, approval of EFPIA policy positions, key objectives and deliverables for draft EU legislation, ensuring good governance and policy alignment for EFPIA in a global context.

Board members (2010/2012)



President
Sir Andrew Witty
GlaxoSmithKline
(United Kingdom)



Vice-President
Chris Viehbacher
Sanofi
(France)

Corporate Members

Carlos Alban, Abbott (USA)
Lucia Aleotti, Menarini (Italy)
Andreas Barner, Boehringer Ingelheim (Germany)
Béatrice Cazala, BMS (USA)
Alberto Chiesi, Chiesi (Italy)
Roch Doliveux, UCB (Belgium)
Antoni Esteve, Esteve (Spain)
Andreas Fibig, Bayer HealthCare (Germany)
Ken Frazier, MSD (USA)
Jorge Gallardo, Almirall (Spain)
Tony Hooper, Amgen (USA)

Carlo Incerti, Genzyme (USA)
Joe Jimenez, Novartis (Switzerland)
Tony Kingsley, Biogen Idec (USA)
Simon Lowth, AstraZeneca (UK)*
Stefan Oschmann, Merck Serono (Germany)
Jaak Peeters, Johnson & Johnson (USA)
Ian Read, Pfizer (USA)
David Ricks, Eli Lilly (USA)
Lars Rebien Sorensen, Novo Nordisk (Denmark)
Pascal Soriot, Roche (Switzerland)
Harald Stock, Grünenthal (Germany)
Ulf Wiinberg, H. Lundbeck (Denmark)

Ex Officio (EFPIA Board)

Eric Cornut, Executive Committee Chair, Novartis (Switzerland)
Thomas Cueni, Executive Committee Vice-Chair, Interpharma (Switzerland)
Jane Griffiths, Executive Committee, Vice-Chair, Johnson & Johnson
Philippe Lamoureux, Member Association Representative, LEEM (France)
Marc De Garidel, President EBE, Ipsen (France)

*CEO ad interim

EFPIA Executive Committee

The role of the Executive Committee is the implementation and operation of the priorities set by the Board to which it is accountable. The corporate heads of European operations of the member companies and heads of national associations sit on the Executive Board which agrees on the steps necessary to implement strategy and priorities set by the Board and oversight of the implementation.



Eric Cornut
Chair, Novartis
(Switzerland)



Jane Griffiths
Vice-Chair, Johnson & Johnson
(USA)



Thomas Cueni
Vice-Chair, Interpharma
(Switzerland)

EFPIA Policy Committees

For each main field – scientific, regulatory & manufacturing; economic and social policy; intellectual property; trade & external market; research and trust, reputation and compliance – a policy committee to develop the public policy line to be taken.

Policy committees may set up Committees or working groups (WGs) in order to tackle specific issues or areas.

There are six main EFPIA Policy Committees:

Economic and Social Policy Committee (ESPC) Chair - **Thomas Cueni**, Interpharma
Vice-Chair - **Chris Strutt**, GlaxoSmithKline

External Trade Policy Committee (ETPC) Chair - **Stephen Cobham**, Sanofi
Vice-Chair - **Gisela Payeras**, GlaxoSmithKline

Intellectual Property Policy Committee (IPPC) Chair - **David Rosenberg**, GlaxoSmithKline
Vice-Chairs - **Stephane Drouin**, Pfizer; **Allen Norris**, UCB

Research Directors Group (RDG) Chair - **Peter Høngaard Andersen**, H.Lundbeck

Scientific, Regulatory and Manufacturing Policy Committee (SRMPC) Chair - **Sue Forda**, Eli Lilly

Trust, Reputation and Compliance Policy Committee (TRCPC) Chair - **Richard Bergström**, EFPIA

EFPIA Executive Team

The Director General heads up the EFPIA team and is appointed by the Board to manage EFPIA.



Richard Bergström
Director General



Marie-Claire Pickaert
Deputy Director General

EFPIA Members: National Associations and Companies

EFPIA include: research-based pharmaceutical companies, developing and manufacturing medicines in Europe for human use – called *corporate members*; and those organisations representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies – called *member associations*.

EFPIA Member Associations

Austria

Fachverband der Chemischen Industrie Österreichs (FCIO)

Belgium

Association Générale de l'Industrie du Médicament (AGIM-pharma.be)

Denmark

Lægemiddelindustriforeningen The Danish Association of the Pharmaceutical Industry (LIF)

Finland

Lääketeollisuus ry Pharma Industry Finland (PIF)

France

Les Entreprises du Médicament (LEEM)

Germany

Verband Forschender Arzneimittelhersteller (VfA)

Greece

Hellenic Association of Pharmaceutical Companies (SfEE)

Ireland

Irish Pharmaceutical Healthcare Association (IPHA)

Italy

Associazione delle imprese del farmaco (Farmindustria)

Netherlands

Vereniging Innovatieve Geneesmiddelen Nederland (Nefarma)

Norway

Legemiddelindustriforeningen Norwegian Association of Pharmaceutical Manufacturers (LMI)

Poland

Employers Union of Innovative Pharmaceutical Companies (Infarma)

Portugal

Associação Portuguesa da Indústria Farmacêutica (Apifarma)

Spain

Asociación Nacional Empresarial de la Industria Farmacéutica (Farmindustria)

Sweden

Läkemedelsindustriforeningen The Swedish Association of the Pharmaceutical Industry (LIF)

Switzerland

scienceindustries

Turkey

Araştırmacı İlaç Firmaları Derneği (AİFD)

United Kingdom

The Association of the British Pharmaceutical Industry (ABPI)

EFPIA Affiliate Member Associations

Bulgaria

Association of Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM)

Croatia

Croatian Association of Research-based Pharmaceutical Companies (CARC)

Cyprus

Cyprus Association of Pharmaceutical Companies (KEFEA)

Czech Republic

Association of Innovative Pharmaceutical Industry (AIFP)

Estonia

Association of Pharmaceutical Manufacturers in Estonia (APME)

Hungary

Association of Innovative Pharmaceutical Manufacturers (AIPM)

Latvia

Association of International Research-based Pharmaceutical Manufacturers (AFA)

Lithuania

The Innovative Pharmaceutical Industry Association (IFPA)

Malta

Maltese Pharmaceutical Association (PRIMA)

Romania

Association of International Medicines Manufacturers (ARPIM)

Serbia

Innovative Drug Manufacturers' Fund (INOVIA)

Slovakia

Slovak Association of Research Based Pharmaceutical Companies (SAFS)

Slovenia

Forum of International Research and Development Pharmaceutical Industries (EIG)

Ukraine

Association of Pharmaceutical Research and Development (APRaD)

EFPIA Corporate Members

Abbott

Almirall

Amgen

Astellas

AstraZeneca

Baxter

Bayer HealthCare

Biogen Idec

Boehringer Ingelheim

Bristol Myers Squibb

Chiesi Farmaceutici

Daiichi-Sankyo

Eisai

Eli Lilly

Laboratorios Dr Esteve

Genzyme

GlaxoSmithKline

Grünenthal

Ipsen

Johnson & Johnson

H. Lundbeck

Menarini

Merck

Merck Sharp & Dohme

Novartis

Novo Nordisk

Orion Pharma

Pfizer

Roche

Sanofi

Servier

Takeda

UCB

EFPIA Affiliate Corporate Members

Bial

Vifor Pharma

European Vaccine Manufacturers (EVM)

The European Vaccine Manufacturers (EVM) is a specialised group within EFPIA. Established with the goal of supporting improved public health through immunisation at all stages of life, EVM represents the vaccine research and manufacturing industry operating in Europe. The EVM members are committed to investing in R&D of innovative vaccines for both developed and developing countries.

President: **John Glasspool** (Novartis Vaccines)

European Biopharmaceutical Enterprises (EBE)

The European Biopharmaceutical Enterprises (EBE) is the European trade association representing the needs and interests of biopharmaceutical companies of all sizes operating in Europe. EBE is a specialised group within EFPIA, providing targeted and results-oriented support for its members, embracing policy advocacy, regulatory intelligence, strategic communication, business development, networking, education and training.

President: **Marc De Garidel**

(Chairman and Chief Executive Officer, Ipsen Group)

Vice-President: **Carlo Incerti**

(Senior Vice-President, Global Market Access, Genzyme)



European Federation of Pharmaceutical
Industries and Associations

