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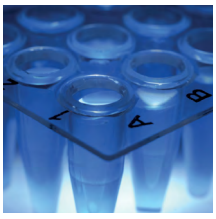
European Federation of Pharmaceutical Industries and Associations

Annual Report 2014

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CONTENTS

INTRODUCTION TO ANNUAL REPORT 2014

The Year When the Conversation Shifted

RICHARD BERGSTRÖM
Director General,
EFPIA

For many years, I have engaged in dialogue with stakeholders around the role and actions of my industry. Some people, particularly those that have to pay for patients to get access to new medicines, have complained about the quality of innovation. We have at times been accused of inventing new diseases, or of delivering only medicines that offer marginal improvement. This debate changed in 2014. The arrival of new cancer medicines (in immuno-oncology) and cures for Hepatitis C are without doubt fantastic news for patients. They do, however, represent a challenge to the system, and budget holders had not planned for these breakthrough innovations. I and others have been self-critical: next time around we need to have different mechanisms to plan and budget for rapid, yet managed, access to new medicines for patients. It will also be important to address the prevailing problem of inequalities in access between European countries, and between patient groups within countries.

The industry pipelines are full of innovative medicines for cancer, psoriasis, cystic fibrosis, heart failure, high cholesterol and other cardiovascular diseases. We also keep investing heavily in dementia and Alzheimer's. The debate in Europe places greater focus on patient access and new approaches for health systems to manage the entry of new therapies. This will include early use, while capturing real-world evidence to confirm clinical effectiveness in relation to existing therapies. There is great interest from both industry and health systems to pay for outcomes as opposed to by the pill or ampoule. My member companies have already agreed many managed entry agreements to assure early access for patients. This trend will continue.

One perfect example of collaboration is IMI, the Innovative Medicines Initiative the world's largest public-private partnership in life science. In IMI, my member companies and academics share their knowledge with other companies and academics to learn from successes and failures to speed up the development of new therapies. In 2014, IMI was extended to align with the new seven-year European Commission programme for research and innovation, Horizon 2020, with an additional budget of more than €3 billion. Sharing knowledge between companies and co-creating solutions with our stakeholders is the right thing to do if it helps patients get cures, and the relief for which they are waiting.

I am very happy that EFPIA, on behalf of its member companies and member associations, is engaged constructively with all stakeholders. After all, our business model is to deliver the new science to patients. That can only happen in partnership. The business model understandably will have to evolve with the times, and based on what society expects. As I look forward to 2015, we will be streamlining how EFPIA is governed, developing our economic and outcomes research capability, as well as building our communications function to ensure that your voice is heard in Brussels and across Europe.

FOREWORD

JOE JIMENEZ
EFPIA President
CEO Novartis

2014 saw a number of breakthrough medicines come to market. These can treat and even cure patients who previously had no alternative. But for our industry, success doesn't end here. We need to work together to ensure patients have fast and equal access to the medicines that are right for them. We must also continue to build trust in the way we conduct business and in the quality of the supply chain. Finally, we must transform health systems to achieve our vision of delivering the best possible outcomes for patients in a financially sustainable way.

The world is rapidly changing and the pace of innovation is accelerating. In response to these trends, we need to focus on three areas:

Accelerating innovation: In 2014, EFPIA's major milestone in accelerating development and expanding access was the launch of the Innovative Medicines Initiative 2. The objective of IMI-2 is to bring the right medicines to the right patients, for example by speeding the development of personalised medicines and designing regulatory approaches that more quickly bring new innovative drugs to the patients who need them. This included a € 280 million project to accelerate development of treatments for patients affected by the recent Ebola outbreak.

We will continue to adopt novel approaches that bring medicines to patients faster. We hope to target small patient populations with high unmet need. Then, as real-world evidence of the product's safety and efficacy increases, access will be gradually expanded to larger populations.

Setting high standards of business conduct and quality: Continuing to set high standards in the way we conduct business was another industry priority in 2014. We increased self-regulation by translating the EFPIA Disclosure Code into 29 country codes. This will increase transparency between our industry and healthcare professionals.

We also published principles for the sharing of clinical trial data, allowing researchers to access patient data, protocols, and clinical study reports. The framework opens up opportunities for scientific research, while protecting patient privacy and incentives to invest in research.

In the fight against counterfeit drugs, we joined forces with the generics industry, wholesalers, and pharmacists. We are currently rolling out a point-of-dispense techology to verify the authenticity of medicines and stop the entry of counterfeit drugs into the supply chain. This will better protect patients across Europe from illegal counterfeit products.

Collaborating as partners: Lastly, we're taking steps toward developing health systems that are focused on better outcomes for patients. Real-world outcomes data can help us improve treatment by identifying which interventions work best for which patients. It can also help patients choose the best providers and more actively manage their own health. A programme within IMI-2 called, "Big Data for Better Outcomes", aims to leverage big data to advance the way we deliver care, while protecting patient privacy.

EFPIA is also looking to enter into a structured dialogue with Member States on out-comes-driven healthcare. A successful dialogue could inspire national agreements to improve access in a financially-sustainable way, to the benefit of patients across Europe.

I look forward to working with all stakeholders on this journey. With a focus on those interventions that really work, an outcomes approach offers the right incentives for research, bringing investments and economic growth to Europe. Most importantly, it is the right thing to do for patients, and for the sustainability of our health systems.

ABOUT EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 39 leading pharmaceutical companies, EFPIA is the voice in Brussels of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

Our Vision

We support a vision of outcomes-driven, sustainable healthcare systems in Europe. We want systems that provide patients with equal and early access to the best and safest medicines; that support innovation while realistically balancing benefit and risk; that empowers citizens to make informed decisions about their health and ensure the highest security of the medicines supply chain. Such a vision will also assist policymakers in sustaining Europe's economic growth and competitiveness, by balancing healthcare budgets and helping to provide for a healthy and productive workforce. It also offers the most effective approach to deliver the innovative medicines needed to tackle current and potential health threats.

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Our Commitment

Improving patient outcomes, developing sustainable models of healthcare, reducing inequalities in health, accelerating patients' access to innovative medicines and improving patient safety – these are our primary commitments. By working in partnership with all healthcare stakeholders, we seek to develop practical solutions to make these goals a reality.

We believe that these commitments are in the best interest of Europe's citizens. We will engage with all partners in healthcare delivery to discuss, design and implement policies that help us achieve these goals, while improving public health, economic wealth, and enhancing Europe's industrial and science base.

1. Market Access

A challenging environment for our members

The research-based pharmaceutical industry can play an integral role in restoring Europe to growth and ensure future competitiveness in an advancing global economy. Employing some 707,000 people in 2014, it invested an estimated €30.5 billion in R&D in Europe.

However, increasing regulatory hurdles, escalating R&D costs and the impact of fiscal austerity measures are taking their toll. Wide variations exist in access to innovative medicines across Europe and the number of products and the speed with which they reach patients differ by country. The fragmented EU market has seen parallel trade flourish, depriving the industry of additional resources to fund R&D. It amounted to €5.4 billion (at ex-factory prices) in 2013.

Industry faces a number of challenges in ensuring patients across Europe get access to new, innovative medicines; given the complexity of health technology assessment (HTA), pricing and reimbursement processes.

Value assessment

EFPIA members are facing an increasingly complex and fragmented HTA landscape across Europe. National payers are challenging EMA decisions and clinical programmes agreed with EMA/FDA. Different approaches to clinical and value assessment lead to inconsistent access decisions for the same product. In addition, decisions that do not recognise innovation and deny patients access, are frequent, with many payers using contracting and tender agreements that focus on price and ignore value in a broader perspective.

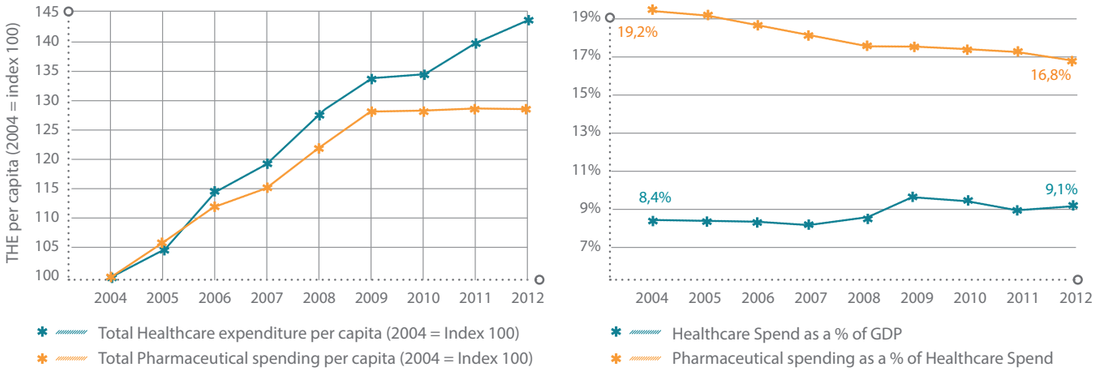
The HTA Network Strategy[1], endorsed in October 2014, saw Member States commit to collaborating on joint assessments and alignment of evidence requirements between regulators and HTA Bodies. Joint Action 3 (JA3) on HTA (2016-2019) will pave the way for a sustainable mechanism of joint work and reuse, to be established by 2019.

EFPIA believes that in order for European REA to improve market access it must be undertaken by a strong scientific body that assesses the relative clinical performance, while economic assessments must be local to account for diversity in health systems. It must be separate from the marketing authorisation process, but done concurrently to save time. Moreover, it must be integrated fully in national market access processes.

1. http://ec.europa.eu/health/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf

Across Europe growth of medicines expenditure is lagging behind growth in total healthcare expenditure

Total healthcare expenditure per capita and pharmaceutical expenditure per capita (2004 – 2012, 21 EU OECD Countries, population-weighted, current prices, PPP, $)



Note: Countries included: Austria, Belgium, Czech Re Austria Belgium Czech Republic Denmark Estonia Finland France Germany Hungary Ireland Italy Luxembourg Poland Slovak Republic Slovenia Spain Sweden United Kingdom

Source: OECD Health Statistics Database (accessed in April 2015).

JA3 will be critical to ensuring that only national assessors from within agencies involved in decision-making on access to pharmaceuticals are involved in European relative efficacy assessment (REA), and that MEMBER STATES commit to assessments they contributed to collaboratively at European level, by replacing the clinical part of their national processes. JA3 should also represent an opportunity to finalise the establishment of a sustainable mechanism for a joint scientific advice process involving regulators and HTA bodies at European level.

Broadening the pricing debate

Recent debates at European level indicate greater willingness by a majority of member states to discuss pricing issues. While member states guard their sovereignty in pricing and reimbursement of medicines, there is a growing appetite to work together on relative effectiveness and discuss the pricing of new medicines.

EFPIA continues to engage, on behalf of its members, in formal and informal discussions on pricing, considering it vital to maintain a dialogue with payers based on the long-term sustainability of systems.

The current policy debate offers scope for further analysing the broader societal, economic and health benefits of biomedical research and innovative medicines, calling for an in-depth review of existing inefficiencies across healthcare spending as a whole. We need to make some difficult choices, targeting high-value services to increase health gain and efficiency.

We must invest in the right infrastructure to ensure decision-makers are able to use better outcomes data and real world evidence. This requires upfront investment, but is likely to result in higher efficiencies in the long term. This includes strengthening health prevention policies, reorganising healthcare delivery, improving efficiency in secondary care, greater reliance on evidence to inform coverage decisions and service delivery, setting up interoperable e-health infrastructure and outcomes-based payment mechanisms.

Medicines budgets were under pressure during the crisis as governments looked for short-term savings. Introducing structural reforms while addressing waste in the health system must be the way forward. We don't want to promote spending on medicines at all costs, but budget decisions must be informed by an understanding of the trade-offs involved.

Procurement

One tool that has the potential to be used to pressure pharmaceutical costs, is tendering. EU rules provide for joint procurement of pharmaceuticals by public authorities in two or more Member States. Decision 1082/2013/EU aims to improve cooperation to deal with serious cross-border health threats, including through joint procurement. The new public procurement Directive 2014/24/EU promotes cooperation between contracting authorities and increased cross-border procurement.

Joint procurement must not jeopardise sustainability and supply of innovative medicines, nor distort competition by de facto limiting supplier numbers. It should be limited to circumstances where the need to use them is clearly identified against the original intents and where purchase and supply cannot be ensured by other means.

Joint procurement should address fundamental principles including a variety of quality selection criteria. Price should not be the only determinant; we need to ensure the autonomy of the physician, deliver a sufficiently broad choice of medicinal products and safeguard the continuation of treatment. Guaranteeing supply and fair competition between all potential suppliers, while ensuring confidentiality rules associated with local pricing and reimbursement negotiations are respected, is essential.

The promotion of off-label use for economic reasons is also a matter of serious concern for EFPIA. On 28 January 2015, EFPIA together with EUCOPE and EuropaBio filed a joint complaint against Italy's Law-Decree 36/2014 on Narcotic Drugs and Off-Label Use of Medicinal Products, which was converted into Law by the Italian Parliament on 14 May 2014.

The Law promotes off-label use by introducing more flexible reimbursement rules for unapproved indications, even where alternative on-label products are available. These off-label medicines have not been assessed to the same stringent standards for the off-label indication.

Despite existing EU case law, several Member States have adopted or are considering regulatory measures encouraging off-label use on cost grounds. Those promoting economic-driven off-label use when licensed alternatives exist, undermine the European regulatory framework, potentially compromise patient safety and create legal uncertainty. This may lead to "secondary national marketing authorisations", putting the European Commission's competence to authorise new medicines into question.

Economic off-label use will disincentivise pharmaceutical companies from investing in innovation and from undergoing costly and timeconsuming authorisation processes for new indications. This may result in fewer new medicines for patients and stifle innovation in Europe.

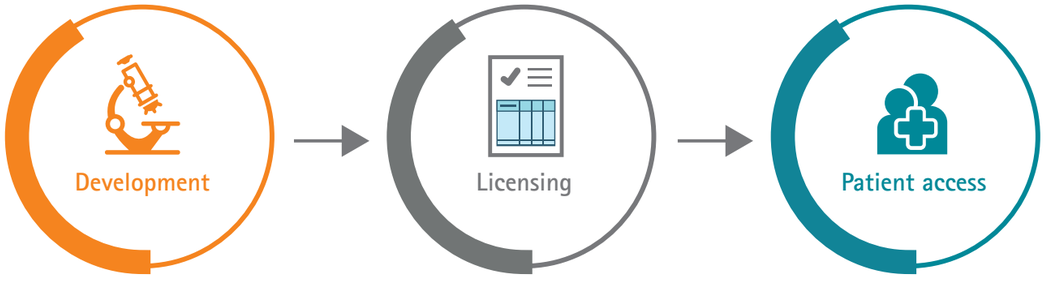
Looking forward, EFPIA will continue to ensure members' interests are represented across the price, affordability and value debates. We understand that the commercial environment presents numerous challenges and we will continue to strive to engage with stakeholders to find long-term, outcomes-driven, sustainable solutions.

2. Medicines Adaptive Pathways to Patients

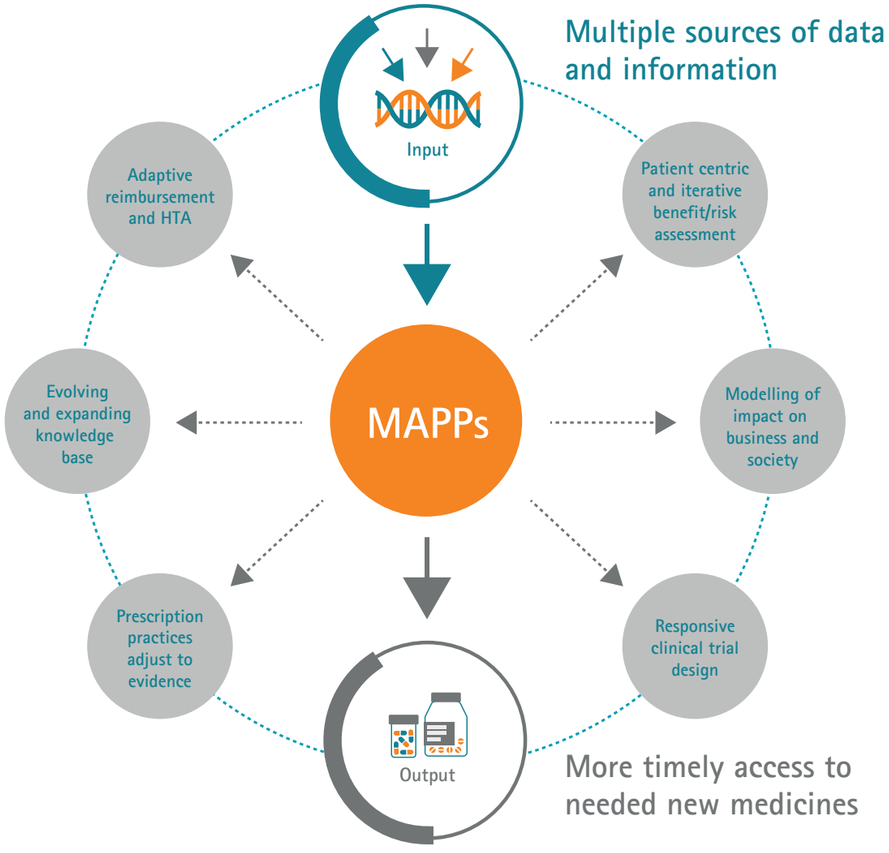
Current paradigms for bringing innovation to patients are being challenged by a broad spectrum of environmental and economic developments. Progress in life sciences and related technologies offer the potential to increase access in a more timely and sustainable way. However, conventional pathways of biopharmaceutical research and development have become a major hurdle to efficient drug development. Moreover, the regulatory environment struggles to keep pace with the latest scientific advances and uncertainties, impacting pricing and reimbursement.

EFPIA recognised the need for R&D and regulatory practice to evolve and so engaged in dialogue with key stakeholder groups to align approaches, and to identify gaps and potential barriers to changing the paradigm and generating missing evidence to enable early patient access to innovative healthcare solutions. IMI was recognised as offering a collaborative environment in which this evolution of research, regulatory, and access practice can begin to take shape.

Over the past year, we have witnessed the successful launch and progress of the EMA Adaptive Licensing Pilot in March (renamed Adaptive Pathways in December), and the launch of a call for an IMI2 Coordination and Support Action on MAPPs, to establish an enabling platform with relevant stakeholders. It creates a neutral forum to align the understanding of the impact of MAPPs, share experiences and actively promote MAPPs implementation. The Coordination and Support Action within IMI will address new ways of generating evidence (including real world evidence), design new research/regulatory/access pathways based on new evidence, and assess the impact on decision-making of these new pathways/evidence. It will also inform IMI as to whether new projects to deliver new/additional tools are necessary. We will continue engaging with all stakeholder and support processes set by the EU and other international bodies. Learning from the pilots launched by EMA and defining how to measure health outcomes will be equally instrumental.



The MAPPs "Ecosystem" Visualised



The recognition of a need for change is reflected in the increase in the number of related debates and initiatives seeking to explore new pathways of development and access. EFPIA communication activities and advocacy outreach have already contributed to this process and will continue to do so.

MAPPs enablers were also prioritised by the EFPIA Research Directors Group and are being considered and implemented in the context of various IMI strategic groups. Key milestones have included: industry alignment on the MAPPs brand; involvement of HTA bodies in the MAPPs discussion through HTAi Policy Forum in February; 29 applications to the EMA's Adaptive Pathways pilot; a NEWDIGS/EMA/EFPIA Workshop in April; MAPPs discussions at the DIA & HTAi Annual meetings in June; the CIRS Meeting: "Better Science, Better Health" Conference in October; EU Council Conclusions on adaptive pricing; the launch of IMI2 Coordination & Support Action for MAPPs; and progress on MAPPs principles, IMI portfolio & stakeholders engagement.

As a life-cycle approach, MAPPs will only materialise if a number of enablers can be developed and implemented, including new ways of collecting and evaluating data, and assessing risks and benefits.

3.
Regulatory Affairs

EFPIA sought to evaluate pharmaceutical legislation and guidelines, realise a vision for a new Research & Development model, optimise the implementation of the the Clinical Trials Regulation, and contribute to drug shortage deliberations. We also looked to push for enhanced EU-US regulatory alignment, achieve a balanced transparency policy and analyse the impact implementation of the EU pharmacovigilance legislation.

With the objective of evaluating pharmaceutical legislation in mind, our member companies contributed significantly to the Escher report on conditional marketing authorisation (CMA), pharmacovigilance, paediatrics and the decentralised procedure. Use of an independent, external scientific consultant, meant the European Commission and EMA paid greater attention to the results of the Escher report.

The results from the Escher study concluded: CMA is not used as thought but rather as a rescue option for challenging applications; companies' workloads after implementing the new pharmacovigilance legislation has increased significantly, despite the Commission impact analysis' claim that it would decrease; and many paediatric investigation plans are made in vain, because companies are forced to submit them too early.

During the course of 2014, and running into 2015, EFPIA has collaborated with the Commission to discuss how to implement and improve the use of regulatory tools. A similar collaborative effort was also instigated with the EMA. Going forward, in 2015, we will develop an EFPIA position on how to optimise the implementation and interpretation of the pharmaceutical legislation.

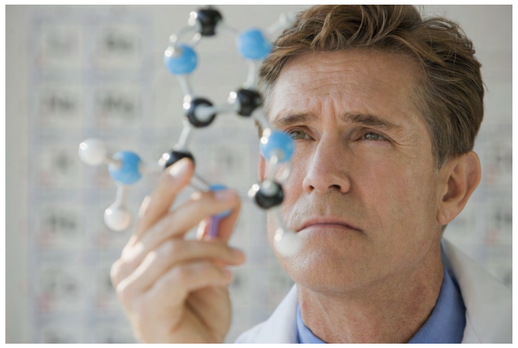
On the subject of realizing the vision for new R&D models, we have continued to focus on achieving regulatory excellence both in terms of the centralised and decentralised procedures and a series of telematics projects. During 2015, EFPIA will look at whether decision-making procedures at the Commission can be shortened. With regard to telematics, a pragmatic implementation of new IT-standards will be essential. Most of the other work-streams are now up and running as a result of various IMI projects.

During 2014, EFPIA worked intensively to make sure that the implementation of the Clinical Trials Legislation ran in accordance with the legislation, but also in a way that was both pragmatic and cost-effective. A practical example of this is a draft layperson summary of clinical trial results that we prepared to aid companies in their own preparation of summaries. A further illustration is the fact that we encouraged the Commission to delete the requirement to have the expiry date applied to the inner packages of clinical trials materials. Should this requirement become a reality, the cost of clinical trials will increase, especially during the early phases, when little stability data is available.

In its contribution to deliberations on drug shortages, EFPIA has, together with other industry associations, developed communications principles for supply disruptions. This work was recently publicly recognised by the EMA. In 2015, we will also work with other stakeholders to see if it is possible to achieve a similar result for wholesalers and pharmacists, among others.

In its efforts to move towards global regulatory convergence, EFPIA secured support from the Commission and the EMA within the framework of the framework of the Translatlantic Trade and Investment Partnership (TTIP), to respond to the objections from the Food and Drug Administration (FDA) on the mutual recognition agreement as regards inspections. PhRMA and EFPIA will submit a comprehensive response to the FDA's objections. Long-term work aimed at getting authorities from emerging markets to become members of ICH will hopefully be achieved by 2016.

For the year ahead, EFPIA will continue to focus on evaluating pharmaceutical legislation and guidelines, realising the vision for a new R&D model, optimising the implementation of clinical trials regulation, analysing the impact of the implementation of the pharmacovigilance legislation and contributing to drug shortage deliberations. Additionally, we will be looking at achieving a balanced transparency policy, and ensuring that patient access to medicines is not endangered by the inclusion of environmental risk assessment in the benefit/risk evaluation process. Finally, we will contribute to deliberations on pharmaceuticals in the environment, ensure global convergence around rigorous regulation and engage with EU telematics processes to progress the EFPIA Operational Excellence Project.

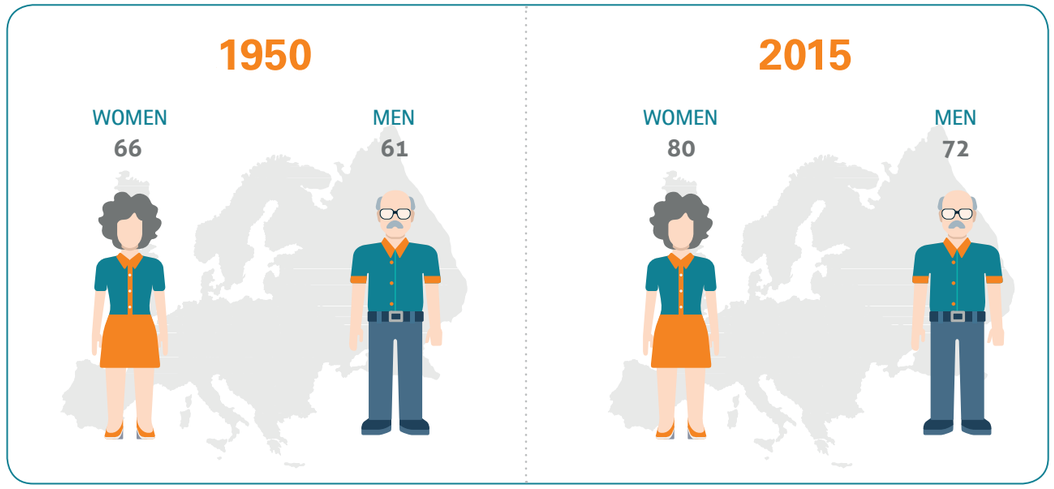


4. Health & Growth

Over the last 60 years, Europe has made significant progress in improving health outcomes for its citizens. Life expectancy has increased by nearly a decade, and effective treatments have become available for many of the most common infectious and chronic diseases. As well as playing a key role in this progress, the industry continues to drive growth as one of the largest investors in research and development in Europe.

Almost a decade of difference in life expectancy across Europe

Changes in life expectancy 2005-2015 (predicted)

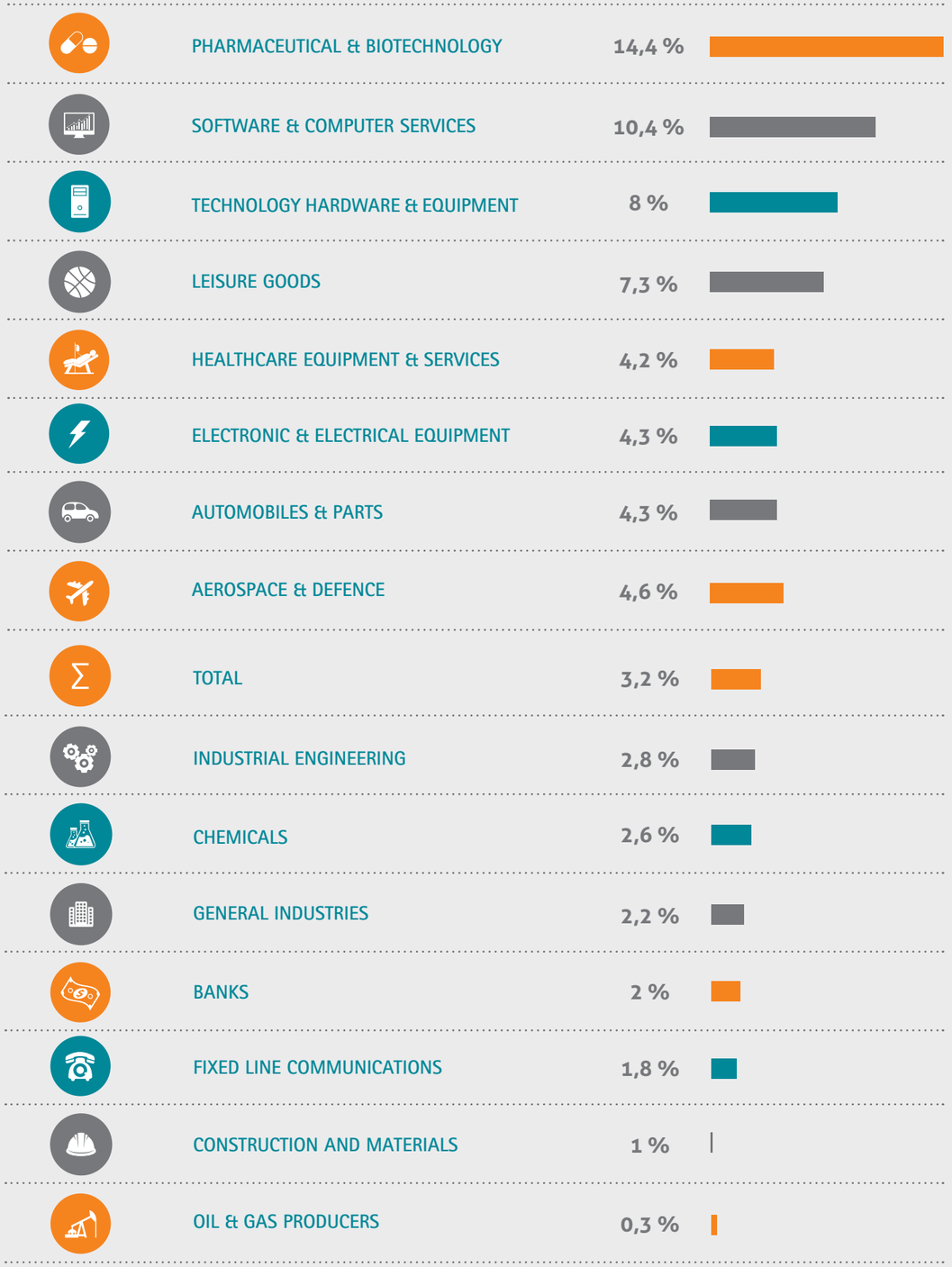


What is Health & Growth?

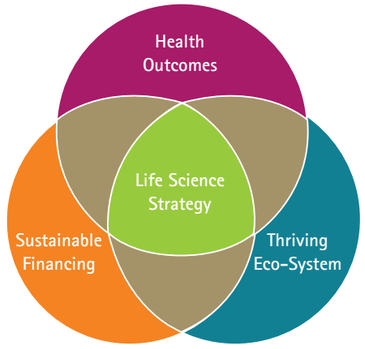
Health and Growth was our attempt at EFPIA to articulate a vision for the pharmaceutical industry's role in Europe over the coming decades. We chose the title 'Health and Growth' because we feel it sums up what is a unique dual contribution that the pharmaceutical industry makes in Europe. On the one hand, our products are dedicated to addressing patients' health problems. On the other hand, we are a significant contributor to economic growth, directly through our €30bn plus investment in European research and development and high quality jobs and, indirectly, by helping keep millions of Europeans healthy enough to work.

The bio-pharmaceutical sector is a key growth driver

R&D expenditure as percentage of net sales (2012)



European Life Science Strategy



Improving HEALTH OUTCOMES and removing inequalities in Europe

Supporting SUSTAINABLE FINANCING approaches to funding healthcare and medicines

Building a THRIVING ECOSYSTEM for healthcare innovation in Europe

Europe had just started to emerge from perhaps its most difficult period of economic and social challenge since the Second World War. Five years of Eurozone crisis had cut growth, increased unemployment and, in many countries, led to significant cut-backs in public services, including health, as governments tried to stay within the public expenditure limits set by the European treaties.

A new generation of political leaders were about begin their tenure in Brussels following the European parliamentary elections, coinciding with the establishment of a new European Commission. Several leaders saw the need to move Europe's political narrative away from austerity towards a more optimistic view of the future. New ideas were sought that could help bring prosperity back to a region that needed to put economic crisis behind it.

In Health and Growth we call for a new generation of public-private partnerships that can unlock the great potential our industry has to drive both health and economic goals. We believe that by working with health systems, research partners, universities and other parts of the life science eco-system we can help create the sort of innovation that Europe needs. Knowing that the financial sustainability of health systems is a critical priority for their ability to function effectively, though, our explicit focus in Health and Growth is to seek solutions that not only enhance health outcomes but also help to ensure the efficient use of public money. Our strategy laid out a number of specific policy priorities, many of which are now advancing well.

What were the key facts?

At EFPIA we are firm supporters of the idea of evidence-based policy and, throughout the development of our Health and Growth strategy,
we were keen to make sure that we had access to the best available evidence on three key themes:

1) What drives positive health outcomes for patients?
2) What is the role of pharmaceuticals in the debate on the financial sustainability of health systems, and where are the most likely sources of solutions to financial challenges?
3) What is the state of play with Europe's life science eco-system? What are its strengths and weaknesses and what does Europe need to do to ensure future success?

You can access Health & Growth resources and evidence at www.efpia.eu.

How did we use it?

There is no doubt that EFPIA's focus on evidence has been highly appreciated by the stakeholders with which we interact. This ranges from politicians to public officials, patients and other groups that are interested in debating the future of healthcare.

The evidence we collected – all of which is available on EFPIA's website – has been presented in a wide range of public fora: conferences; stakeholder meetings, such as the European Health Forum at Gastein; and in detailed policy discussions, both in Brussels with groups including the Commission, as well as in Member States by our national member associations.

We have used the evidence to try and ensure a fact-based, honest conversation about what Europe's challenges are and where solutions might be found. Working with evidence allows us all to challenge assumptions and assertions (including our own) and promote better policymaking.

What were the outcomes from using the evidence base?

Our Health and Growth Strategy - including the evidence-based discussions that have accompanied it - has already lead to progress on policy in a number of areas:

- We are developing a new IMI programme on health outcomes and big data that will create a unique platform for collaboration between health systems, the research community and industry. The end goal here is to support outcomes-based health reform throughout Europe. If we can develop a good understanding of health outcomes in each disease area we can – with the aid of new IT technology – measure and understand better what is likely to lead to the best care for patients.

There is a broad consensus among the best health systems in the world that such data-driven, outcomes-based approaches can both improve the quality of care and reduce cost to health systems. This is exactly what Health and Growth is all about, so we are excited that IMI offers a platform for real progress.

- We have signed a number of framework agreements with European governments on the management of the medicines bill, as well as on the competitiveness of the life sciences sector. The agreement signed in Lithuania is well into its implementation phase now and a number of similar agreements are in development.
- The new European Commission has identified clearly the pharmaceutical industry as a strategic sector for Europe's future. The Commission is currently developing its own strategy for our industry that we hope will lay the foundation for more collaboration in Europe.

Where will it go next?

EFPIA is committed both to pursuing the goals set out in our Health and Growth strategy and to continuing to invest in evidence to support high quality policy discussions. Having developed our strategy, we now need to implement it. We cannot do that alone, so EFPIA will continue to pursue an open and collaborative approach to improving Europe's health and economic growth in future.

5. Innovative Medicines Initiative

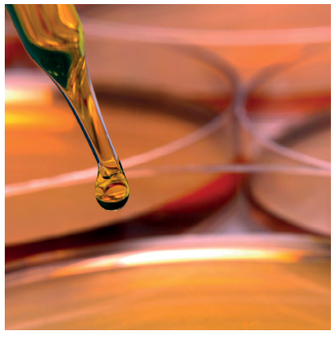
The challenges facing healthcare systems and the scientific community cannot be addressed by one stakeholder group alone: we must look to translate new scientific and technological opportunities into integrated healthcare solutions.

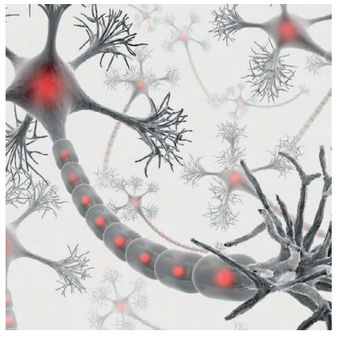
EFPIA believes that the Innovative Medicines Initiative (IMI) provides an effective vehicle to test the boundaries of open collaboration and to integrate different perspectives to reduce attrition, speed up patient access to innovative healthcare solutions and to improve outcomes.

To achieve these aims, last year, we focused on issuing calls in IMI1 and continued evolving the scheme so that it remains at the forefront of open collaboration. We launched IMI2, adopted a scientific framework that combines societal and industrial priorities and secured both a legal framework and flexible set-up, suitable for a public-private partnership. We aimed to develop an ambitious portfolio of projects to be launched in IMI2 and integrate other life-science sectors.

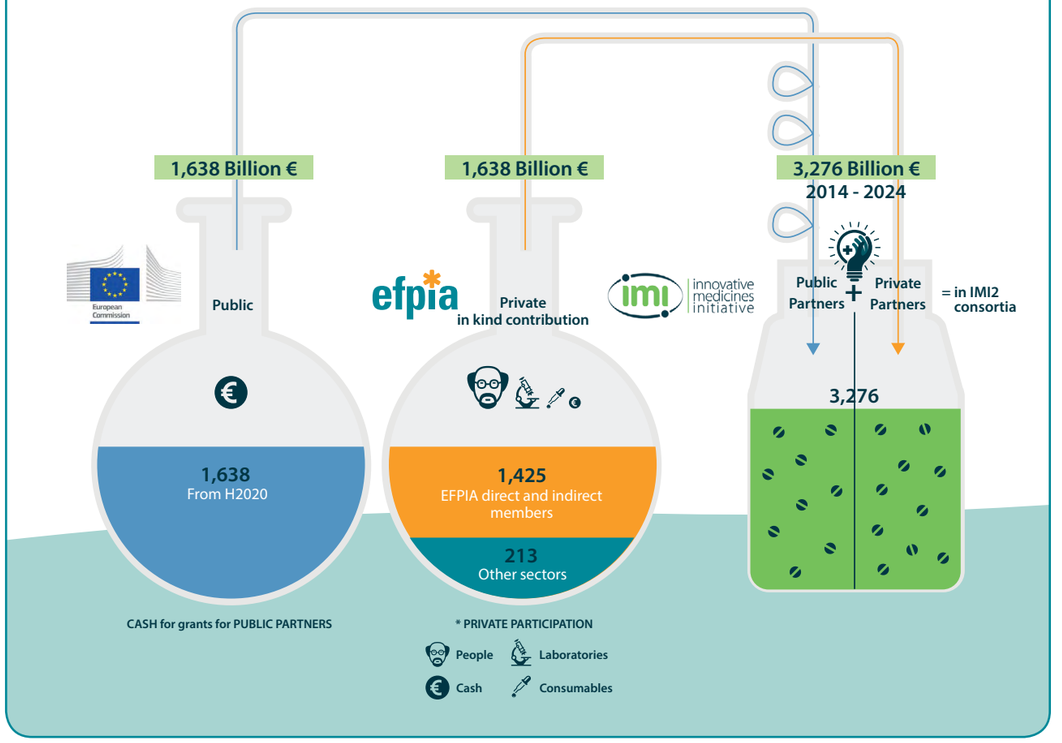
For IMI, we aligned with the Commission on a Strategic Research Agenda and with clear priorities. The EU supported the IMI concept through the adoption of the IMI2 Regulation, which sets the objectives, and the Delegated Act, which established the specific IP framework, something that proved to be instrumental to the success of IMI. We also successfully issued the first four IMI2 calls, which involved a commitment of €220 million for projects that are transformative, integrate non-pharmaceutical sectors and address public health priorities.

We created Partners in Research to support the evolution of the life science sector and act upon policies that serve to integrate other technologies and sciences that are needed to address unmet medical needs and exploit the vast health potential offered by science.





EU-Industry Contribution to IMI2



Special attention was also paid to the Ebola+ call, which included new fast-track processes, proving that the EU and industry could react quickly and flexibly. Beyond IMI, which addressed vaccines and diagnostics, EFPIA also effectively supported a global industry call for new antiviral molecules active against Ebola.

Amongst the challenges faced by our innovative medicines strategy, are the Commission's objective to harmonise all instruments in Horizon 2020, which is often non-compatible with the spirit of public-private partnerships. We also acknowledge that IMI is no longer the only health and pharma research initiative - these are mushrooming and companies have to make difficult decisions on where to place their investments. Scrutiny of the funding, transparency, types of investments and return on investment for the society from IMI is increasing and we need to continue to engage, communicating the industry perspective.

Going forward, EFPIA will continue simplifying and evolving IMI together with our partners to ensure it remains competitive. We will harmonise processes, where necessary, to reduce the bureaucratic burden and differentiate, where appropriate, to secure competitiveness.

We will also strive to establish collaborations with other initiatives, defining complementary programmes and transformative and ambitious projects to optimise R&D, secure early patient access and address areas of unmet medical need.

6.
Animals in Research

Replacement, Reduction, Refinement

The use of animals in research is a complex and emotive subject. However, currently, it is only through the restricted use of animals in research in combination with other research tools, that the pharmaceutical industry is able to advance medical science for the benefit of patients and society as a whole. Through its Directive 2010/63, Europe offers the best protection of laboratory animals where these are to be used.

We therefore sought during the course of the last year to defend Directive 2010/63 on the protection of animals used for scientific purposes against the European Citizens' Initiative "stop vivisection" . We supported the implementation of the Directive across Europe, as well as, the development and implementation of the 3Rs (Replacement, Reduction and Refinement) principles, including through IMI and other collaborative initiatives.

Recently, the Commission announced that the EU Directive was finally transposed into national legislation in all Member States. EFPIA collaboration with a number of Laboratory Animal Science Organisations supported this implementation process, in addition to dialogue with competent authorities locally and in Brussels. EFPIA was also invited to join Commission working groups to develop guidance on education and training, animal welfare bodies, ethics committees and statistical reporting. This guidance is now finalised and available on the Commission website. EFPIA also hosted a workshop to assess the implementation and identify areas where the research community can support best possible implementation at national level.

EFPIA joined forces with other scientific organisations to support the Directive. The strength of mobilisation amongst the scientific community to both defend the EU legal framework and to identify research areas that can further the 3Rs and improve the research toolbox is reaching unprecedented levels.

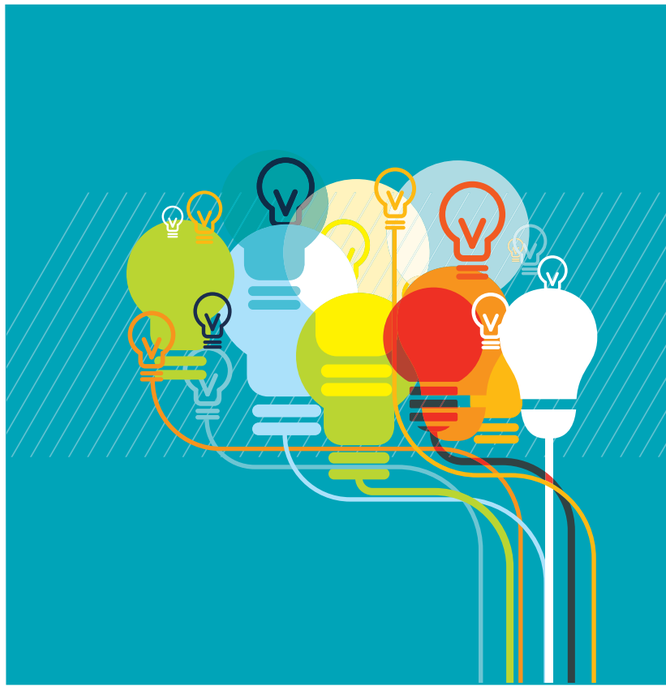
EFPIA has also sought to address the continuity of supply, noting that activists have focused on the supply chain. We are actively supporting countries and organisations that continue supplying high quality animals – in particular dogs and primates – and encouraging transportation via the shortest routes.

In terms of communication and the dissemination of information, among other things, we published in the Journal of the American Association for Laboratory Animal Science the following article: "Global 3Rs efforts – Making progress and gaining momentum: how the European pharmaceutical industry is contributing."

Dispelling the myths and misconceptions about the roles of animals in testing continues to be a major challenge. The discussion surrounding the European Citizens' Initiative remains of particular concern going forward and we continue to register problems involving activists targeting the supply chain, including animal breeders and transport systems such as airlines. This is an ongoing problem that was underscored in last year's report.

We are moving the message forward through increased and intensified collaboration with the scientific community on the animal testing issue. We are also focusing on heightened transparency surrounding our activities in this field and EFPIA strongly recognises the need for continued and improved communication on the subject of animals in research to reassure the public and other stakeholders that we are firmly committed to the 3Rs.

7. The protection of intellectual property rights



2013 was something of a watershed for IP rights in Europe with the European Observatory quantifying the significance of IP for the EU economy for the first time.

As a result, in 2014, the Commission published two Communications, denoting that a reappraisal of IP is underway, including looking at how to improve public understanding. There is much to do here, particularly to address the misapprehension that patents set prices and to respond to external demands for transparency without undermining innovation. These challenges will be part of the picture in 2015 as well, and will be part of a balanced industry agenda addressing IP and access to medicines. For the longer term, we will need to reflect on the continuing adaptation of the IP system to the industry's changing business model and emerging societal needs.

During what continues to be a difficult period of austerity in Europe, EFPIA embarked upon 2014 with a view to securing an effective protection ecosystem for pharmaceutical innovation. We also sought to safeguard Europe's position as a global champion of IPR, projecting a clear and convincing voice in favour of strong, yet wholly appropriate, IP standards worldwide.

Important milestones this year included the following:

We submitted a concrete proposal for an Early Resolution Mechanism ("ERM") to address patent disputes sufficiently in advance of generic launch to increase legal certainty for all stakeholders.

We welcomed the EU Communication providing an Action Plan aimed at renewing the consensus on the enforcement of intellectual property rights in the EU. More particularly, we worked to support political agreement on transit control within the EU Trademark Package.

Among other achievements for EFPIA in 2014, were interventions on the supplementary protection certificate (SPC) term, novelty issues and data protection for fixed dose combinations.

We continue to play a leading role in mobilising cross-sectoral engagement to protect natural products research in Europe and initiated a continuing dialogue with the European Patent Office.

Successful as EFPIA's activities have been in 2014, some important challenges lie ahead. We will focus intently on progressing transparency while ensuring that commercial information is adequately protected. One major example of what this would entail, is contained within the framework of the Trade Secrets Directive, where we have argued against the extension of the scope to include institutional transparency policies and supported a focus on the need to harmonise protection against unlawful acquisition, use or disclosure of these secrets.

On the international stage, EFPIA welcomed the Communication on "Trade, Growth and IP", which gives the EU a new strategy for the protection and enforcement of intellectual property rights (IPR) in third countries. It contains a balanced approach to access to medicines, which provides a good basis for further policy development.

We were able to secure the inclusion of industry issues in the 2015 dialogue with China and the addition of new IP commitments to the Comprehensive Economic and Trade Agreement (CETA). This last understanding, with Canada, is the first free trade agreement with any G8 country. In an increasingly complex international environment for IP, we hope that TTIP will provide a platform for the EU and US to further their collaboration while respecting the differences between our IP systems.

The election of a new government in India has sparked some hopes of a revitalisation of trade relations and there is clearly a readiness on the part of the government to strengthen India's capacity for innovation. However, at the same time, 2014 saw more limited progress elsewhere in relation to patentability standards and none in relation to availability of regulatory data protection.

What is fundamentally important for the research-based pharmaceutical industry in Europe is that, while EFPIA champions the IP agenda, it is simultaneously recognised as a partner in improving the availability of medicines to the patients that need them. We remain confident that, although it must continue to adapt, and requires the right policies in areas such as healthcare financing, the IP system is the right way to balance society's long-term need for investment in innovation with the need to ensure early patient access.

8. Building relationships; driving transparency

Collaboration between industry, health professionals and the research community benefits patients. It is a relationship that has delivered numerous innovative medicines and changed the way many diseases impact on our lives.

To support future collaboration, building on our members' commitment to transparency has been a cornerstone of EFPIA's work in 2014. Two key areas of focus have been the implementation of the EFPIA Disclosure Code and the publication and subsequent implementation of the EFPIA/PhRMA *Principles for Responsible Clinical Trial Data Sharing*.

Working with member associations and companies, the EFPIA Disclosure Code has been transposed into 29 national Codes, leaving four countries - Denmark, France, Portugal and the Netherlands - where local legislation or existing transparency self-regulation has been approved by the Board as an alternative arrangement. EFPIA staff, in association with members of the Compliance Committee, have provided support and additional guidance to enable harmonisation of the implementation across Europe.

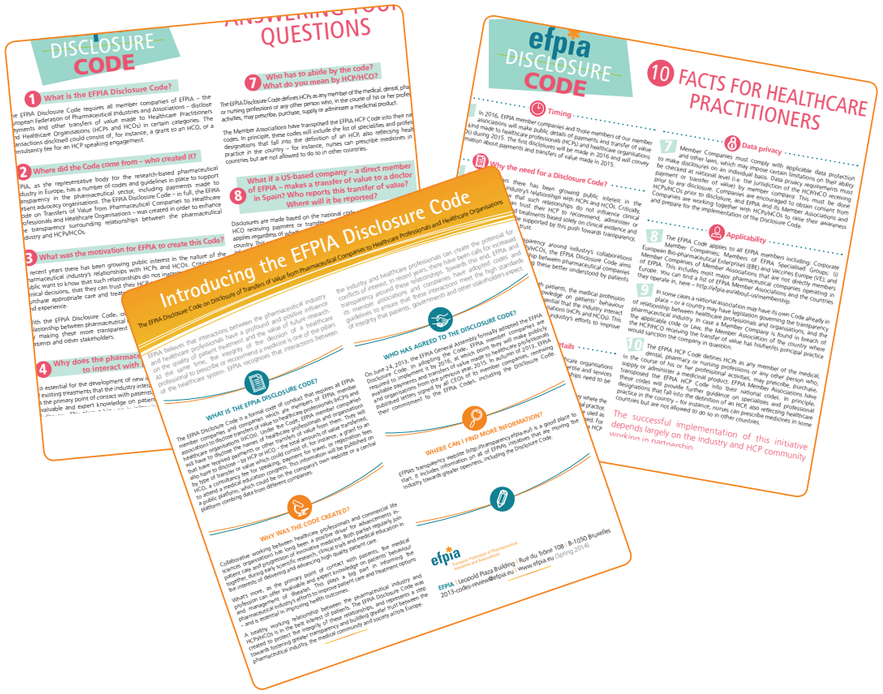
There remain a number of challenges ahead. EFPIA is working with national associations to assess the impact of national law and regulations on the implementation of the Disclosure Code. Engagement with the health professional community to communicate the process, rationale and benefits of greater transparency is of paramount importance. The requirement for health professionals to give consent to disclose transfers of value, makes it critical that we generate support in the healthcare community for disclosure.

As we look forward, EFPIA's priority will be to support member companies and associations to engage with stakeholders on the issue, sharing the importance of transparency and developing partnerships to drive up the rates of consent. We will continue to produce communications materials to support the project and engage at a pan-European level with key healthcare organisations.

January 2014, marked the implementation of the EFPIA/PhRMA Principles for Responsible Clinical Trial Data Sharing. The principles underlined the commitment of the pharmaceutical industry to disclosing clinical trial data. EFPIA members have made significant progress in developing processes for clinical trial data access schemes, translating principles into practice.

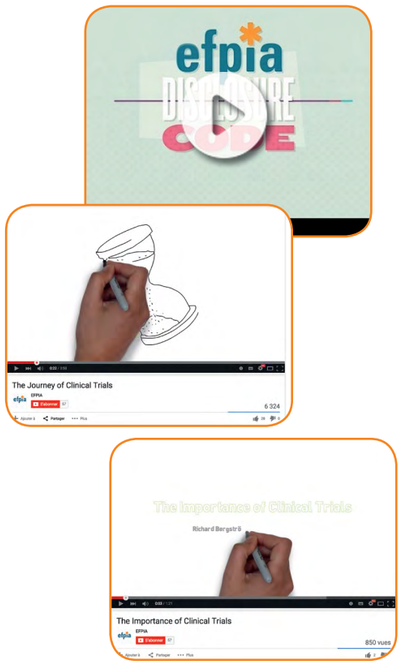
In addition to these industry-led developments, EFPIA and its member companies have continued to engage with stakeholders on the EU clinical trial regulation and the EMA's Transparency Policy. We continue to support the aim of striking a balance between responsible reporting of trial data for public health benefit and safeguarding patient confidentiality, respecting the integrity of the regulatory systems worldwide, and maintaining incentives for investments in biomedical research.

As we move forward, we will continue to drive implementation of the EFPIA/PhRMA principles, working with members to develop best practice, for example, via publication of layperson summaries of all clinical trials. We also recognise that, in the future, clinical trial data will be enhanced by the availability of real world data from patient registries, hospitals and general practitioners. We will continue to work with European partners in research to develop systems to maximise the potential of big data while protecting confidentiality of patient data, to further biomedical research.



Principles for Responsible Clinical Trial Data Sharing

1. ENHANCING DATA SHARING WITH RESEARCHERS
2. ENHANCING PUBLIC ACCESS TO CLINICAL STUDY INFORMATION
3. SHARING RESULTS WITH PATIENTS WHO PARTICIPATE IN CLINICAL TRIALS
4. CERTIFYING PROCEDURES FOR SHARING CLINICAL TRIAL INFORMATION
5. REAFFIRMING COMMITMENTS TO PUBLISH CLINICAL TRIAL RESULTS



- http://transparency.efpia.eu/the-efpia-code-2
- https://www.youtube.com/watch?v=u-2mkxhpm54
- https://www.youtube.com/watch?v=15hknL5m5W0

9.
Your voice in Europe

Last year, EFPIA set out to become pro-actively more visible in Brussels. As a result EFPIA has been able to anticipate and contribute more effectively and constructively to important debates, prior to any potential, legislative action being taken.

The election year for the European Parliament and the new Commission saw EFPIA emphasising the need for a life sciences strategy before the new Commission embarked upon its duties. The aim was to overcome silo mentalities and to elicit from the European Commission a comprehensive strategic agenda for the pharmaceutical industry in Europe. We believe an integrated approach to life sciences within the European Commission would support this important goal.

The Brussels Advocacy Steering Committee (BASC), a group of Heads of Public Affairs in Europe from member companies and associations, has been operational for one year and has established itself as an effective horizon scanner of EU policy.

We remain convinced that the new European Commission's clear focus on European competences means that the development of new legislation over the next five years is a relatively unlikely prospect. This point is given more credence, as it has fallen to Commissioner Timmermans to coordinate the work on better regulation within the Commission and thereby to ensure that every proposal respects the principles of subsidiarity and proportionality – these aspects being at the very heart of the Commission's work.

This renders it imperative that we as an industry must look for other ways to enter into and shape dialogue with Member States and the European Parliament.

We are witnessing increased activity from European parliamentarians in the field of health. This represents an opportunity for EFPIA to engage with these policy-makers on the need for a life sciences strategy, and to discuss the role of the European Semester for healthcare systems. BASC has already embarked upon this effort in cooperation with the European Generics Association (EGA).

Establishing BASC and adopting a more pro-active advocacy line, focused on the three Brussels institutions, are amongst some of our important achievements this year. This was supplemented by an equally pro-active drive to engage with our membership about developments at both European and national level.

EFPIA has also sought to intensify dissemination of the Health and Growth initiative. We have increased significantly stakeholder engagement, as evidenced by EFPIA's involvement in the Patient Access Partnership and the follow up to the Vilnius Conference and Declaration – together with the European Patients' Forum, European Public Health Alliance, EGA – as well as others specific cooperative efforts and projects with the EGA.

We have prepared effectively for future Presidencies of the Council of Health Ministers, and organised, where possible, conferences under the umbrella of these Presidencies in order to engage with Member States.

The introduction of new policy-makers brings with it dual challenges of establishing common ground and inspiring their interest in health policy. Overcoming the twin hurdles of health being predomi- nantly a national competence, and Member States being hesitant to discuss health at EU level, is often difficult.

Where no legislation is foreseen from the European Commission, EFPIA persistently aims to drive home its key priorities – including market access, life sciences strategy, adaptive pathways, and Pharmaceuticals in the environment. In fact, the tenor of the on-going, lively access/pricing debate in Brussels is being forced down a narrow path. EFPIA has chosen to respond to it in a sensitive way, which has proved challenging.

Building on the outcomes of health and growth, we are now looking to ensure that the idea of a life sciences strategy really takes root in all institutions, starting with DG GROW but moving to other DG's as well, including SANTE, RESEARCH and ECFIN.

EFPIA is also seeking an opportunity to enter into a structured dialogue between industry and Member States, hosted and catalysed by DG SANTE, on outcomes-driven, sustainable healthcare. A successful dialogue could inspire agreements, at national level, to improve access, while helping to manage medicines budgets.

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EFPIA CORPORATE MEMBERS

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ALCEDIAG
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Illumina
Intersystems
PMB Alcen
Siemens
Zeiss
Zoetis

EFPIA MEMBER ASSOCIATIONS

Member Associations

AUSTRIA
Fachverband der Chemischen Industrie Österreichs (FCIO)

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

DENMARK
Laegemiddelindustriforeningen
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)

RUSSIA
Association of International Pharmaceutical Manufacturers (AIPM)

SPAIN
Asociación Nacional Empresarial de la Industria Farmacéutica (Farmaindustria)

SWEDEN
Läkemedelsindustriföreningen / The Swedish Association of the Pharmaceutical Industry (LIF/Sweden)

SWITZERLAND
scienceindustries

TURKEY
Turkey Arastirmaci Ilac Firmalari Dernegi (AIFD)

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

Affiliate Member

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

CROATIA
Innovative Pharmaceutical Initiative

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
Malta Maltese Pharmaceutical Association (PRIMA)

ROMANIA
Association of International Medicines Manufacturers (ARPIM)

SERBIA
Innovative Drug Manufacturers' Association (INOVIA)

SLOVAKIA
Slovak Association of Innovative Pharmaceutical Industry (AIFP)

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

UKRAINE
Association of Pharmaceutical Research and Development (APRaD)

EFPIA GOVERNANCE

BOARD MANDATES 2013-2015

Approved by the General Assembly of 6 June 2014, including changes approved by the Board since 6 June 2014

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completing Chris VIEHBACHER's mandate as President

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Marc DE GARIDEL (Ipsen)
completing Ulf WIINBERG's mandate as Vice-President

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EFPIA represents the pharmaceutical industry in Europe. Through its direct membership of 33 national associations and 39 leading pharmaceutical companies, EFPIA provides the voice of 1,900 companies committed to researching, developing and bringing new medicines to improve health and quality of life around the world.




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