efpia

European Federation of Pharmaceutical Industries and Associations

Review of 2012 and Outlook for 2013

Contents

04 Our Commitment

06 Learning from 2012, Looking forward to 2013

07 Facts and Figures

14 Health & Wealth: Time for Europe to look Forward

18 Innovative Medicines Initiative (IMI): Progress Through Partnership

22 Research regulation: New Pathways needed for new Medical Therapies

25 Stem Cell Research in the EU: At a Crossroads

27 Fighting Counterfeit Medicines, Protecting Patient Safety

30 Pharmacovigilance: Safeguarding Patient Safety

31 Intellectual Property: Protecting Innovation

32 Trade: Creating Opportunities by Leveling the Playing Field

34 HTA: European Collaboration can tackle Duplication

36 Pharmaceuticals in the Environment: Improving Standards, Protecting Public Health

38 Good Animal Welfare Holds the Key to Cures

40 Global Health in a Changing World

43 Annexes

43 Glossary of Terms

44 EFPIA Governance

Our Commitment

> The fact is, during tough economic times, the biopharmaceutical industry is one of the most resilient industries -- and that is a real strength for Europe.

One of Europe's top bankers has said that, after Lehman Brothers, the banks that did best, were the ones that stopped reading the papers. To reassure the conference moderator, he quickly added that he was still a loyal subscriber to FT - even if he did not read it. My point is that it is very easy to get carried away by the debate on Europe's future. It is important to keep an eye on the facts, and underlying trends.

It is true that my industry has taken heavy price cuts in the range of €8-9 billion. At this moment, we have more than 10 billion in outstanding debt - primarily hospitals running behind with their payments. My member companies have had to lay off some 20.000 people in Europe in the last three years.

But, many of these job losses have been driven more by companies adjusting to long-term trends as much as the immediate economic situation, namely: bringing medicines to market is increasingly difficult (both from a scientific and regulatory point of view); there is more aggressive competition after (and often before) patent expiry; and, most importantly, poor uptake of innovative medicines in Europe. It is these long-term trends that lie at the heart of my industry's vulnerability, rather than the normal economic cycle of booms and busts.

The fact is, during tough economic times, the biopharmaceutical industry is one of the most resilient industries – and that is a real strength for Europe. Indeed, we continue to spend an average of 15% on research and development, far more than any other sector. One of my member companies, Roche, invests €10 billion every year on R&D, more than the entire UK government research budget. My top three companies together spend as much as NIH, every year.

And the investments bear fruit. In the last year alone, we have seen a series of new generation medicines for multiple sclerosis. There are revolutionary medicines against drug-resistant tuberculosis and hepatitis C nearing the market. The huge investments in cancer research are paying off: cancer has become a chronic disease, in which patients don't need to be treated constantly – and increasingly survive.

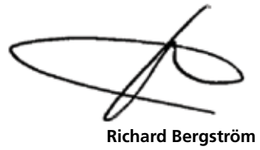
The biopharmaceutical industry directly employs a record 700,000 skilled people. Exports from Europe have gone from €22 billion to €80 billion in the last 12 years. Looking at the most "mobile" part of our investments, clinical research, industry investments keep going up (€30 billion per year), even if the number of clinical trials is flat.

Europe is holding its place. And there is cause for optimism. Even if markets around the world grow faster, the fundamentals in Europe are positive. Under the European welfare model, our citizens expect universal access to health care, including equity in access to medicines. The growth potential is significant. Health care (incl. pharmaceuticals) is the fastest growing part of the economy: 3-4% per year. I am aware that many ministries of finance see this only as an expense, but there also a growing realisation that Europe needs a healthy workforce that can stay productive longer: Active and healthy ageing is a good thing.

Tackling the inequalities in access to medicines, in an era of austerity, will be one of the biggest challenges going forward. There is a growing debate on "equalisation of access" as opposed to "equalisation of prices". There is no secret that I argue that companies, if they want, should be able to price differently, depending on ability to pay, to maximise volumes and access.

Europe is lagging behind in uptake of innovation. The experience with stability framework agreements with governments, that many of my national member associations have entered, is that new medicines can be introduced without "breaking the bank". This is a top priority for EFPIA in coming years: to get going again on new medicines.

I keep reading the papers, about doom and gloom, but I also keep an eye on the real world - and on what is in the scientific pipeline. And it makes me optimistic. Paraphrasing the motto of one of my member companies: we bring science to patients. That is our commitment.



Richard Bergström
Director General of EFPIA

Learning from 2012, Looking forward to 2013

Collaboration.

From big data to areas of unmet medical need – the challenges ahead call for a growing spirit of collaboration.

- ✱ *The Innovative Medicines Initiative: Progress Through Partnership* (p.18) shows what public-private partnerships can accomplish.
- ✱ Partnerships go beyond Europe: African and European scientists are sharing knowledge through EFPIA's understanding with EDCTP (p.41).
- ✱ The global health initiatives (p.40) bring together European political actors and healthcare stakeholders to debate common global health problems.
- ✱ **Our Goal:** Advance a collaborative spirit within the industry and with diverse stakeholders outside it, from policymakers to healthcare professionals.

Growth.

A programme of innovation-led growth is one way to ensure a competitive future for Europe.

- ✱ *Health and Wealth* (p.18) go hand in hand: Cooperation between the pharmaceutical industry and governments will pave the way.
- ✱ The pharmaceutical industry positively impacts European trade: What progress in promoting equitable trade can we look forward to in the year ahead? (p.32)
- ✱ A glance at the latest facts & figures (p.7) shows just how significant an impact the pharmaceutical industry can have on Europe's economies and societies.
- ✱ **Our Goal:** Tap into the pharmaceutical industry's potential to lead innovation-driven growth for Europe.

Patients.

The research-based pharmaceutical industry exists to bring new and improved medicines to patients – *all* patients.

- ✱ Inequalities persist and can worsen in tough economic times. Increased harmonisation, for instance of Health Technology Assessments (p.34) can help promote equitable patient access.
- ✱ The European Stakeholder Model is a tool that can help in *Fighting Counterfeit Medicines* (p.27).
- ✱ Supporting the efficient implementation of EU pharmacovigilance legislation (p.30) is one means of advancing public health.
- ✱ Pharmaceuticals in the Environment are a growing concern. The pharmaceutical industry is committed to illuminating the scientific facts on the topic (p.36).
- ✱ **Our Goal:** Push forward initiatives promoting patient safety in all possible forums, from ESM to the pharmacovigilance directive, and promoting patient knowledge through open dialogues.

Innovation.

An environment that fosters innovation will support the pharmaceutical industry in its efforts to develop and deliver better medicines to patients.

- ✱ Changes in science are allowing for improved means of medicines development: Now it's time for the regulatory framework to catch up (p.22).
- ✱ Innovation needs to be protected. *Intellectual property: Protecting innovation* (p.31) looks at how IP can safeguard innovation, not only in Europe but around the world.
- ✱ Stem cell research holds great promise for future medicines development – but is currently at a difficult crossroads in Europe and requires support (p.25).
- ✱ Scientific advances and improved research processes are decreasing animal testing and reducing impact of testing on animals (p.38).
- ✱ **Our Goal:** Work with relevant stakeholders to promote the necessary regulatory environment and push forward scientific advances that will foster innovation in Europe.

Facts and Figures

The innovative pharmaceutical industry is driven by, and drives, medical progress. Today the research-based pharmaceutical industry is entering an exciting new era in medicines development. Advances in science and technology are allowing for new research methods to evolve, offering new promise in the form of cutting-edge healthcare solutions, such as personalised medicines. The impact of the research-based pharmaceutical industry is already seen today, as European citizens can expect to live up to 30 years longer than they did a century ago. Investment in R&D also generates skilled labour, and contributes to a positive trade balance. The facts and figures portrayed here offer a glimpse of how the innovative pharmaceutical industry is impacting Europe and its citizens.

Employment

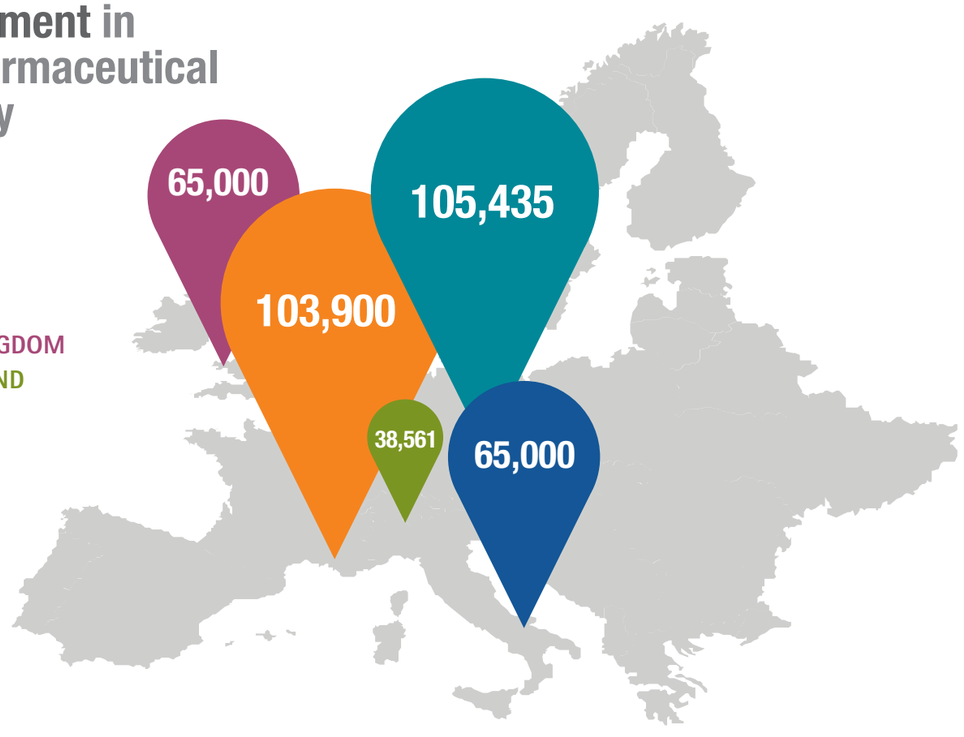
The pharmaceutical industry employs over

700,000

people in EU and directly generates 3 to 4 times more jobs downstream

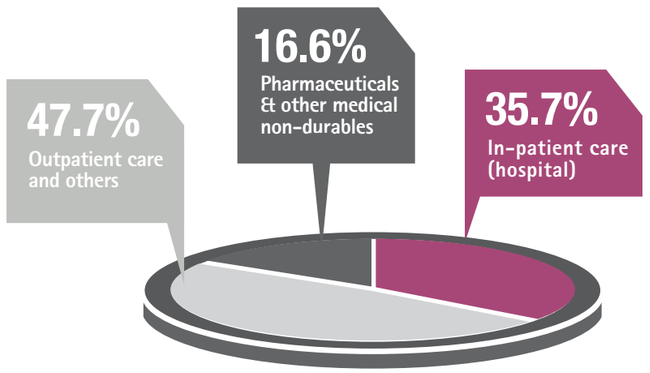
One in 6 are highly skilled R&D positions

Employment in the pharmaceutical industry
2012

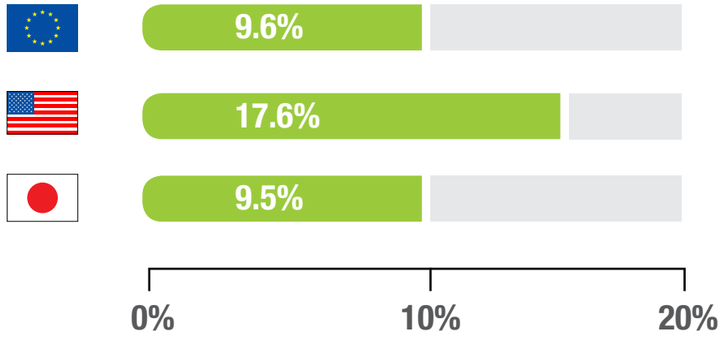


The Pharmaceutical Industry

Breakdown of total health expenditure in Europe 2020



Total spending (public and private) on healthcare
as a percentage of GDP at market prices



The production value of the European Pharmaceutical industry for 2012 is estimated at

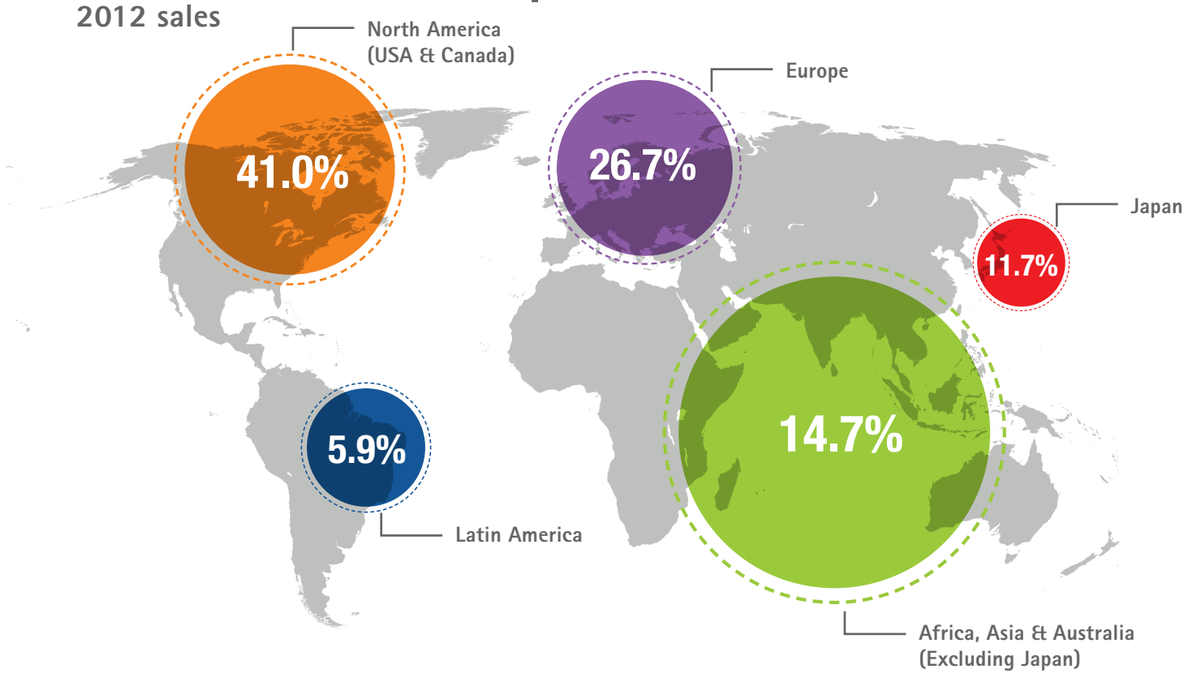
€210 BILLION

=

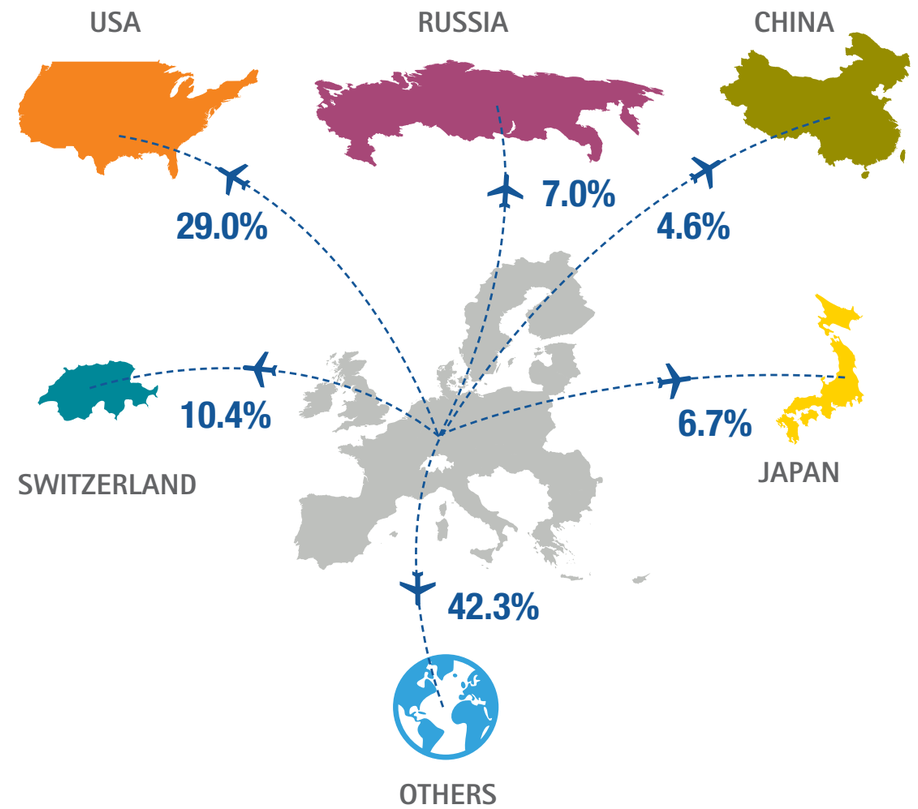
an amout roughly equivalent to the GDP of Finland.

Trade

Breakdown of the World pharmaceutical market
2012 sales



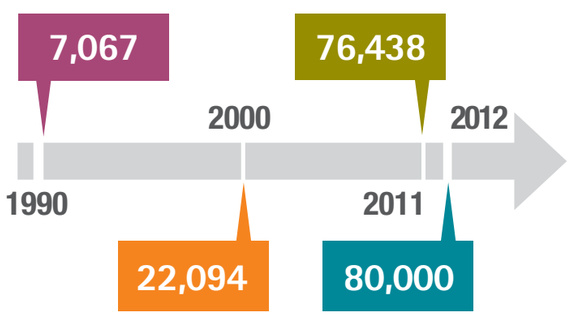
The European Union's top 5 pharmaceutical trading partners - EU Exports 2012



In 2012 Europe's pharmaceutical trade surplus was estimated at

€80 BILLION

European Pharmaceutical Industry Trade Balance



in million EURO

Top 5 net exporters of pharmaceuticals
in million EURO

SWITZERLAND: 28,438
IRELAND: 22,243
GERMANY: 13,791
BELGIUM: 8,767
UNITED KINGDOM: 7,139

R&D

Estimated cost of bringing a new chemical or biological entity to market

in USD million, Year 2011 USD

In 2012, close to

€30 BILLION

was invested in R&D

Ranking of Industrial Sectors by overall R&D intensity

R&D as percentage of net sales - 2011

- 15.1%: Pharmaceutical & Biotechnology
- 9.5%: Software & Computer Services
- 7.9%: Technology Hardware & Equipment
- 6.7%: Leisure Goods
- 5.9%: Healthcare Equipment & Services
- 3.1%: Chemicals

The cost of researching and developing a new chemical or biological entity was estimated

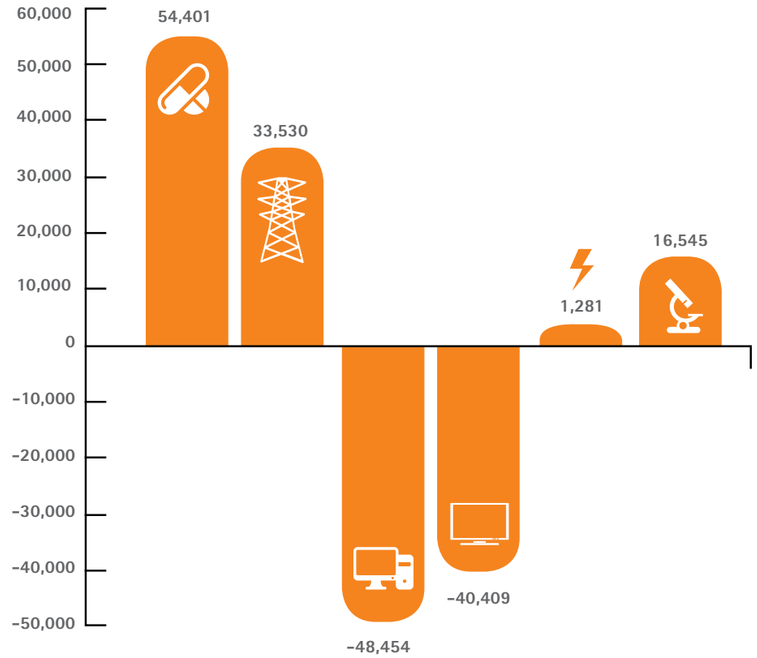
€1.2 BILLION

in 2012

EU-27 TRADE BALANCE - High Technology sectors

in million EURO, 2012

- Pharmaceutical products
- Power generating machinery and equipment
- Office machines and computers
- Telecommunication, sound, TV, video
- Electrical machinery
- Professional, scientific, controlling material



On average, only one to two of every 10,000 substances synthetised in laboratories will successfully pass all stages of development required to become a marketable medicine.

TOP 5 investments in pharmaceutical research in Europe

in billion EURO

Health and Wealth: Time for Europe to look Forward

> We all know Europe is facing a demographic challenge. It threatens our economic equilibrium, and cutting the money available for pensions, health and care. We can't solve this challenge by thinking small, by cutting a few corners here and tinkering with a few budgets. We need a whole new way of operating, to turn this into an opportunity, to turn costs into investments.
>
> **Neelie Kroes**
> Vice-President of the European Commission
> responsible for the Digital Agenda for Europe

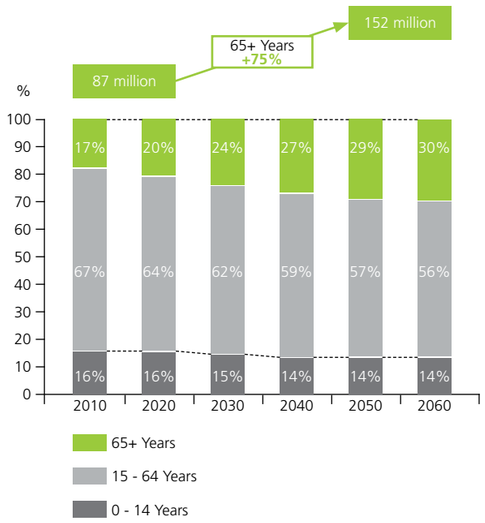
Europe is at a critical point in its history. While it remains one of the most advanced and prosperous economic regions of the world, over the last few years Europe has experienced the deepest depression since the 1930s. The Eurozone crisis has shaken the foundations of the European Project.

We now need to look forward. Europe must emerge from the crisis as a highly competitive economy with a productive and healthy workforce as well as a sustainable social model. There will be challenges in achieving this, but they can be overcome. The biopharmaceutical industry wants to play a strong role as a partner with European institutions and governments in making innovation-led growth happen. We believe that now is the right time to open a new dialogue with society on how best to do that so that we collectively move in the right direction.

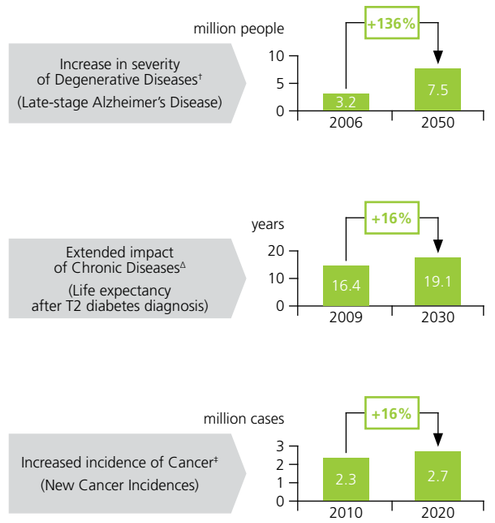
Health Outcomes

Over the last 60 years Europe has made huge strides in improving health outcomes. Medicines have played a key role in achieving extension of life expectancy in general and improved quality of life in later years by helping to address the challenges of infectious diseases, chronic conditions and, more recently, cancer. However, major inequalities in access to medicines persist across Europe. In addition to an ageing demographic, degenerative diseases are becoming the next major challenge for most healthcare systems across Europe. The number of Europeans over the age of 65 will increase by 75% over the next 50 years, and the incidence of dementia will more than double, see Figure 1. Continuing to improve the wellbeing and productivity of Europeans will be even more important in light of demographic change. Without new effective solutions, health and social expenditure will become unsustainable. Through its R&D activities and partnership initiatives, the pharmaceutical industry is committed to help in addressing these challenges.

Figure 1



Source: *European Commission (2012); † Hopkins University (2007); Δ UK Dept. of Health (2010), European Commission; ‡ WHO (2013)



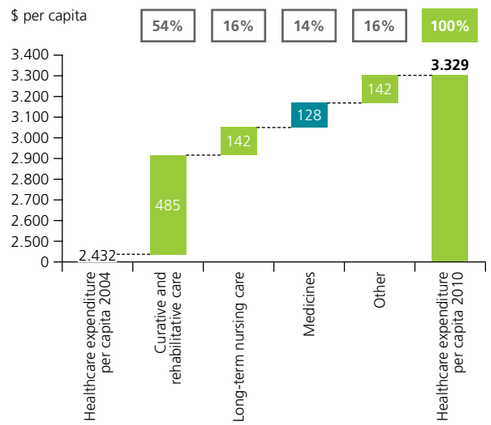
Source: *European Commission (2012); † Hopkins University (2007); Δ UK Dept. of Health (2010), European Commission; ‡ WHO (2013)

Sustainable Financing of Healthcare

Overall, medicines usage represents less than 15% of total healthcare costs, see Figure 2. Yet medicines are at the heart of many of the most effective pathways of any health system, such as respiratory complications, diabetes and cardiovascular disease. Early and appropriate use of medicines reduces the need for much more expensive healthcare interventions. For example, in the case of cardiovascular disease, early-stage intervention may result in a three-fold return on investment, releasing capacity in the acute and informal care sector and headroom to support patients at the end of life, see Figure 3.

Over the last decade, medicines expenditure in Europe has grown at a third of the rate of overall healthcare expenditure. The combination of cost controls and more competitive off-patent markets has led to an average decrease – albeit in absolute terms – in the unit costs of medicines, relative to a rise in the consumer price index in many markets of up to 20-30%, see Figure 4. Medicines expenditure tends to follow a sustainable life-cycle model and represents one of the best investments a health system can make and will continue to be so in the future.

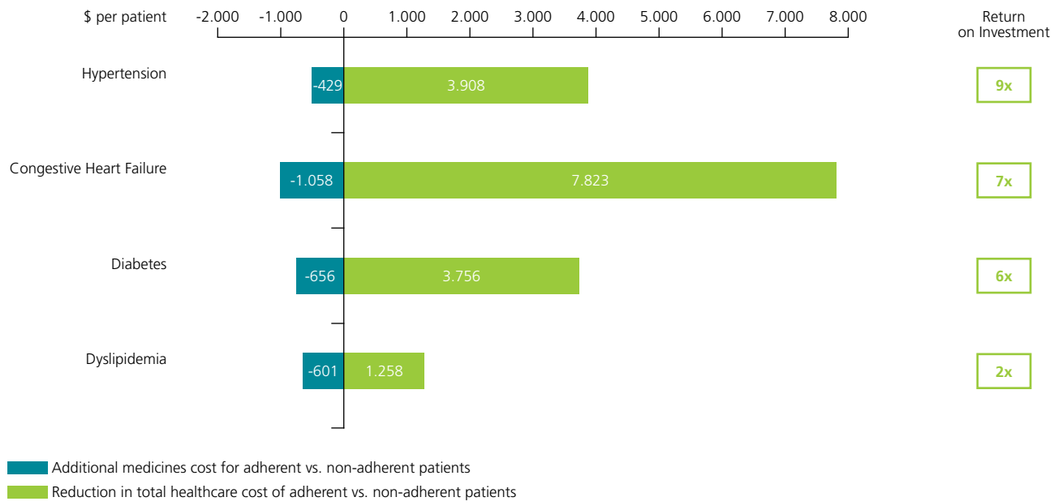
Figure 2



Note: Countries included: AT, BE, CZ, DK, EE, FI, FR, DE, HU, NL, PL, PT, SK, SI, ES, SE

Source: OECD Health Statistics Database (accessed 2013); Eurostat Database (accessed 2013)

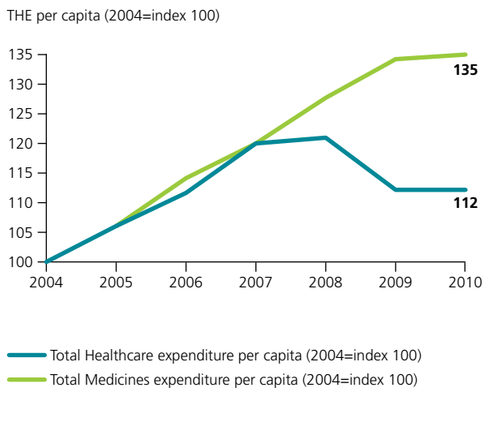
Figure 3



Note: Calculations are marginal effects from linear fixed-effects models of services cost. Main drivers for cost savings were inpatient hospital days and emergency department visits

Source: Roebuck et al: Increased Drug Spending Medication Adherence Leads To Lower Health Care Use And Costs Despite increased drug spending (2011)

Figure 4



Note: 2004 – 2010, 21 EU OECD Countries, population-weighted, current prices, PPP, $; Countries included: AT, BE, CZ, DK, EE, FI, FR, DE, EL, HU, IE, IT, LU, NL, PO, PT, SK, SI, ES, SE, UK

Source: OECD Health Statistics Database (accessed 2013); Eurostat Database (accessed 2013)

> Too often health is perceived as a cost, and not an asset for the future.

Commissioner for Health and Consumer Policy Tonio Borg
addresses the EU Health Policy Forum on "Investing in Health"

Growth and Competitiveness

Healthcare is one of Europe's most promising opportunities for growth. The healthcare industry itself is one of the most important employers. Biopharmaceutical companies, specifically, have the highest R&D intensity amongst comparable industrial sectors. Employment provided by the sector is of high quality, given the high proportion of jobs in R&D.

Beyond the healthcare industry, 'health' is a critical driver of growth in the economy more generally, a fact that is often neglected by policymakers. Reducing absenteeism in the workplace, keeping an ageing population healthier for longer (and in work rather than in expensive care homes or hospitals); and reducing government spend on sickness and disability are all factors that will only become more important in the coming decades. Given on-going inequalities in health outcomes across the EU, it is important to recognise the potential that exists in raising healthcare standards for all of Europe's citizens.

Europe has a strong foundation for leadership in life sciences. This can be built on for the future. Healthcare offers the potential for a unique 'triple win'. Smart and appropriate use of technology such as medicines can help not only improve the lives of patients, it can help address the fiscal challenges associated with growing public budgets as well as promote economic growth. This is an opportunity that should not be missed.

> Health is a value in itself but it is also an essential contributor to economic growth. Healthy citizens contribute to society, form a productive workforce and require less acute care and long-term care.

Paola Testori Coggi
Director-General for Health and Consumers at the European Commission

Innovative Medicines Initiative (IMI): Progress Through Partnership

The Innovative Medicines Initiative (IMI) sees the pharmaceutical industry working together with universities, hospitals, small and medium-sized enterprises (SMEs), patient organisations and public authorities. This unique PPP is jointly funded by the European Commission and the pharmaceutical industry. Current projects address a wide spectrum of challenges covering early to late stages of medicine development, and addressing a range of topics from chronic pain to anti-tuberculosis drug combinations.

IMI projects are fostering open innovation, with data being shared among pharmaceutical companies, academic teams and SMEs. The NEWMEDS consortium has generated the largest databases on trials of antidepressants and schizophrenia therapies. Meanwhile, the SAFE-T consortium has evaluated 153 potential translatable biomarker candidates for monitoring drug-induced injury of the kidney, liver and vascular system. The SUMMIT consortium, in collaboration with other initiatives, has generated one of the largest collections of data on diabetic damage to the kidney as well as on cardiovascular disease.

IMI projects are already affecting research and development (R&D) productivity of pharmaceutical companies, through the effective prediction of adverse drug reactions, the pooling of data for further analysis, and the joint development of key standards for drug development. IMI projects are not only scientifically interesting, they are helping to change the way in which new drugs are discovered and developed – with the ultimate goal of improving medicines and patients' access to them.

In modernising the development process of medicines, IMI further seeks to:

- Drive the development of innovative medicines with a high level of safety and efficacy for millions of patients;
- Generate more and better quality jobs for scientists, reversing the European brain drain;
- Enhance European expertise and know-how in new technologies to attract pharmaceutical R&D investment to Europe;
- Create a stronger competitive advantage for smaller companies (SMEs, spin-offs and start-ups) and public organisations by collaborating with a multitude of stakeholders, enhancing Europe's competitiveness.

These are big goals, requiring an ability to look at the big picture. Investment in IMI and similar initiatives is an investment in the future of European competitiveness, and the health of European citizens. It is essential that Europe's decision-makers support European research and innovation by maintaining funding for initiatives like IMI. Sadly, Horizon 2020 – the funding mechanism supporting IMI and a number of other PPPs fostering innovation – is already under threat: A number of Member States want a significant reduction to the initial €80 billion proposed by the European Commission for Horizon 2020.

Finally, it is essential to note that the problems addressed by IMI projects go far beyond European borders. IMI's investment in global issues like antimicrobial resistance can benefit patients around the world, and are a step towards maintaining European competitiveness and leadership in pharmaceutical development, healthcare, and innovation. The key to success is the collaboration among the many stakeholders involved in IMI projects. Looking forward, IMI will continue to champion such cooperation, and to show how PPPs can create winning solutions.

Investing in Europe's Future: Healthy Minds, Healthy Brains

Education

In order to achieve sustainable solutions to emerging healthcare problems, it is essential to invest in the education and training (E&T) of research professionals. IMI has established five projects targeting E&T needs.

- **European Medicines Research Training Network (EMTRAIN)** aims to set up a pan-European platform encompassing the full lifecycle of medicines research.
- **SafeSciMET** is a pan-European network set up to establish modular E&R programmes for medicines regarding safety sciences.
- The **European programme in Pharmacovigilance and Pharmacoepidemiology (Eu2P)** focuses on improving understanding of medicines risks and benefits in large groups.
- **PharmaTrain** is the project that gave birth to the Cooperative European Medicines Development Course (CEMDC), a postgraduate qualification in medicines development created with the collaboration of 12 universities.
- The **European Patients' Academy on Therapeutic Innovation (EUPATI)** on Therapeutic Innovation (EUPATI) is a patient-led initiative developing training courses, educational material and an online library to educate patients about R&D.

Brain-Related Illnesses

Brain-related research is another necessary investment for a positive future for Europe. The brain and central nervous system are difficult to study, and many areas of unmet need remain. IMI projects are addressing such gaps.

- The **Pharma-Cog** project is developing new tools to test candidate drugs for the treatment of Alzheimer's – an increasingly important area of research as Europe grapples with an ageing population.
- **EU-AIMS**, a project funded by the Innovative Medicines Initiative, which is set to kick off the two largest ever clinical studies of ASD (Autism Spectrum Disorders) in 2014.
- IMI's **EUROPAIN** project is looking to deepen our understanding of chronic pain, a condition that impacts one in five Europeans.
- The **NEWMEDS** project has created the largest known database of studies on schizophrenia. NEWMEDS research has already indicated that not only schizophrenia, but also intellectual disability and autism, may be impacted by copy number variation (CNV; when the number of copies of a particular gene varies between different people).

‘New drugs for bad bugs’

IMI’s many diverse projects have a common goal: To improve medicines development, support EU innovation, and ultimately ensure a healthy population. Many projects require a lengthy development timeframe, and may not see conclusive results for several years. However, IMI projects are already proving the unique abilities of PPPs to tackle pressing healthcare problems. The quick reaction of IMI’s New Drugs for Bad Bugs (ND4BB) initiative is one example.

The ND4BB programme has already launched 2 projects, COMBACTE (Combatting Bacterial Resistance in Europe) and TRANSLOCATION (Molecular basis of the bacterial cell wall permeability), to target the growing threat of antimicrobial resistance (AMR). Aside from their timeliness, these projects are noteworthy for their collaborative framework: As a PPP, COMBACTE is breaking the mould when it comes to traditional relationships between academia and the industry, by pushing aside the fee-for-service model.

The launch of these two projects is timely and essential: In November 2012, the European Parliament passed a resolution calling for immediate action to tackle antimicrobial resistance. Already, there are over 25,000 AMR-related deaths in the EU every year, costing the European economy more than 1.5 billion euro annually. The research provided by COMBACTE and TRANSLOCATION will be invaluable. By further nurturing similarly collaborative projects, IMI projects can continue to deliver results that will benefit patients in the EU and around the world.

IMI: Past, Present and Future

In 2012, the IMI made big steps forward in terms of both project achievement and stakeholder engagement. IMI launched 4 new calls for project proposals, conducted 14 interim reviews of ongoing projects, and initiated 13 new projects. 2012 also saw IMI hold 16 events engaging with policymakers and influential industry leaders, while additional events promoted IMI to potential project applicants. Further, there were 366 publications from IMI projects.

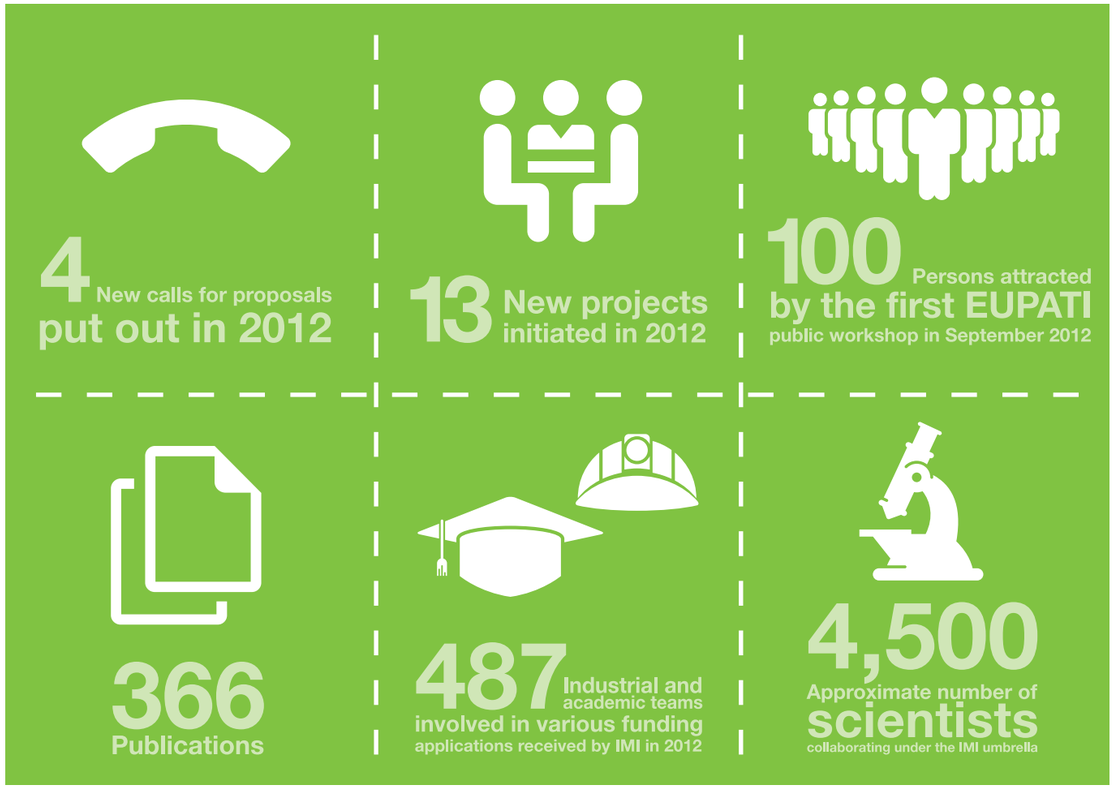
Looking to 2013, IMI is moving forward with the European Medical Information Framework (EMIF). This project will develop a common framework to share patient-level data, which can be linked to various medical and research data sources in order to open up new research avenues. Obesity and Alzheimer’s disease will be major points of focus.

In the years ahead, IMI will continue to nurture collaborative projects and educational initiatives. Towards this end, IMI is embracing a number of “think big” projects that will address long-term needs; these include the New Drugs for Bad Bugs (ND4BB) programme on anti-microbial resistance, and the European Lead Factory (ELF), which aims to boost drug discovery in Europe. Investment in these areas offers the opportunity to find solutions for long-term healthcare problems.

www.imi.europa.eu

> This is a historic opportunity for Europe to overcome a public health problem which threatens millions of lives worldwide. For researchers in universities, hospitals and small and medium-sized enterprises it is also a unique opportunity to speed up their research in the area of antimicrobial resistance, as the collaboration will give them access to the knowledge and expertise of the pharmaceutical industry.
>
> **Michel Goldman**
> IMI’s Executive Director, commenting on the IMI call to tackle anti-microbial resistance

IMI in Numbers



Research Regulation: New Pathways needed for New Medical Therapies

Continued innovations in biomarkers, gene therapy, and diagnostic technologies will require improved regulatory pathways to ensure that the best treatments are available to patients when they need them. However, to succeed, this new system should be balanced with the reality that investing in breakthrough R&D technologies must be cost-effective for all stakeholders.

For targeted medicines, the current processes of regulatory evaluation, decision frameworks and delivery systems are limiting the implementation of new, better therapies. A healthcare ecosystem designed to enable innovation must also consider that investing in breakthrough R&D must be cost effective for all stakeholders. EBE and EFPIA hope that, beyond taking stock of what has been achieved to date, the –omics report will chart a path to be explored by different Commission services; facilitating the promise that innovative medicines can effectively deliver the right prevention and treatment to the right patient at the right time.

There is much room for optimism regarding the next generation of medical therapies. From the discovery of HER2 over-expression in the personalised treatment of breast cancer twenty years ago, therapeutic innovation is continuing to drive advances in the understanding of the genetic mechanisms of diseases. A recent study published in *Nature* and funded by Cancer Research UK has identified the existence of 10 distinct types of breast cancer, each with its own unique molecular structure, thus providing ever greater possibilities for the discovery and advancement of cures.[1]

These innovative breakthroughs are not limited to oncology. Improved understanding of the genetic causes of, for example, neuro-degenerative diseases, respiratory diseases, and cardio-vascular diseases, will help to identify patients that will better respond to a given medicine. These advances will also ultimately result in new prevention and treatment pathways. Are the current regulatory and healthcare frameworks ready for this scientific evolution?

Prof. Sumitran-Holgersson, a member of the research team at Gothenburg University that developed a stem-cell technique that reduces the risk of rejection in vein transplantation, posed some crucial questions in a recent interview: "*Could the EU help me get this therapy to the rest of the world? How can I build the infrastructure and get the therapy out there?*"[2] The answers to Prof. Sumitran-Holgersson's questions are vital to the future success and development of innovative therapies in Europe.

In February of 2012, Forbes Magazine ran an article calculating that the full cost to a pharmaceutical company of launching a new therapy was $4 billion USD[3]. The cost of launching a new therapy is partially driven by a regulatory system that does not respond well to the segmented and smaller populations of current science-led medical innovations, ultimately stopping many new ground-breaking medicines from reaching the patients who need them.

> We are losing a lot of research from Europe because of red tape... Personalised medicine promises a wealth of new possibilities for European patients, by making healthcare delivery as tailored to the individual as their fingerprint.
>
> **Irish Health Minister James Reilly**
> speaking at the European Alliance for Personalised Medicine (EAPM) conference on Innovation and Patient Access to Personalised Medicines

A case in point is the first stem-cell therapy approved for sale by the European Medicines Agency (EMA) in 2009. This innovative treatment substitutes common invasive knee replacement surgery with a procedure which uses the patient's stem cells to re-grow a patch of their own cartilage. The subsequent rejection of an FDA application, without the funding of an additional US-based phase III trial, led to an 85% decline in the company's share price and a struggle for survival.[4] Even though the therapy is approved by the EMA, gaining reimbursement in Europe moves slowly.

Another example is that of a novel lung cancer drug for a well-defined small patient population presenting with a specific gene mutation. Studies showed 60% of patients in late metastatic stages of the disease surviving nearly a year after starting treatment.[5] While approved together with the companion diagnostic by EMA and FDA, the treatment has had a very difficult time gaining reimbursement and patient access in Europe.

These two examples illustrate a much larger issue – new innovative drugs and therapies that are needed by patients face enormous barriers to implementation and adaption. They also outline why an alternative must be found that enables the earlier availability of safe and effective medicines in a framework that is financially viable for all stakeholders, as the current healthcare system's existence is being challenged.

[1]C. Curtis, et al, "The genomic and transcriptomic architecture of 2,000 breast tumours reveals novel subgroups", Nature; 486, 346–352 (21 June 2012)
[2]N. Moran, "Experts debate the future of stem cells"; Science|Business, Pg. 20, January 2013, http://www.sciencebusiness.net/OurReports/ReportDetail.aspx?ReportId=39
[3]M. Herper, "The Truly Staggering Cost Of Inventing New Drugs", Forbes, February 10, 2012; http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/

[4]FlandersBio, "Tigenix reports on regulatory path for ChondroCelect in the US"; http://flandersbio.be/news/tigenix-reports-on-regulatory-path-for-chondrocelect-in-the-us/; accessed May 12, 2013
[5]FDA Approval for Crizotinib, National Cancer Institute, NIH; http://www.cancer.gov/cancertopics/druginfo/fda-crizotinib; accessed May 13, 2013

> Everybody recognises that there are many unmet needs for most patients with life-threatening diseases. Patients know their needs best but rarely have the broad know-how on how the highly regulated and complex R&D process works. Our Patients' Academy aims to address this by educating patients about the medicines development processes. We know it can be done.

Nicola Bedlington
Executive Director of the European Patients' Forum
and project coordinator of EUPATI (IMI project)

The European Medicines Agency has highlighted their willingness to seek new regulatory pathways. It states, in a recent press release: "Medicines regulation today is characterised by the increasing complexity of applications for new medicines, such as nanomedicines or personalised medicines, and the drug-development environment as a whole… An innovative evaluation framework involving iterative phases of data gathering and regulatory evaluation is needed in order to align regulatory approval more closely with patients' needs for timely access to innovative medicines. This also includes the ability to integrate in the decision-making process multiple data sources – not only industry studies but also data from real-world use, as well as the views of patients on the level of risk acceptable for a given medical benefit."[6]

The above changes are vital to address the current deficiencies of the healthcare system and their impact on EU stakeholders.

For patients and healthcare professionals, a regulatory environment should be created that supports the patient's need for timely access to effective innovative medicines. For industry members, improved pathways would support innovation, increase effectiveness, and reduce R&D costs promoting investment by the European pharmaceutical sector.

For payers, recent peer-reviewed research shows that analysing the cost of treatment alone may overlook the gains in efficiency that a new targeted therapy can provide in other parts of the healthcare value chain.[7] In order for payers to be aware of such efficiencies, new pathways will require payers to be part of the evaluation process.

Ultimately, a revised regulatory framework to promote innovation in healthcare would support the translation of scientific breakthroughs from the lab to patients, increasing innovation in the life sciences and creating benefits to society. Without improvement, the barriers to providing the rapid deployment of new therapies will continue to mount, eventually putting the entire healthcare ecosystem at risk for all European stakeholders.

[6]Press release, "Euroepan Medicines Agency's Management Board welcomes new civil-society members" http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/03/news_detail_001749.jsp&mid=WC0b01ac058004d5c1; accessed May 12, 2013
[7]W. Van Dyck , et al," Unlocking the value of personalised healthcare in Europe—breast cancer stratification http://www.healthpolicyandtechnology.org/article/S2211-8837(12)00044-5/fulltext; accessed May 12, 2013

Stem Cell Research in the EU: At a Crossroads

We are currently at a crossroads regarding investment in stem cell research in Europe. The EU has set itself ambitious goals in the interests of innovation, investment, and growth – and yet a desire for financial cuts is threatening the funding required to promote essential innovative processes, including stem cell research.

As the representative of the research-based pharmaceutical industry in Europe, EFPIA believes that it is vital for the EU to keep funding this research, which holds huge promise in helping patients suffering from a variety of diseases.

Demystifying stem cells

The debate on stem cells is a complicated one where ideology has at times gotten in the way of good science. Stem cells have two fundamental properties of particular interest in medicine: They can divide indefinitely and produce identical copies of themselves, and they can divide and produce more specialised cell types. Depending on their derivation, they vary in the number and types of cells they can produce.

In terms of research, there are three main types of stem cells that are of interest: tissue (adult) stem cells, embryonic stem cells and induced pluripotent stem (iPS) cells.

Tissue stem cells are derived from or reside in a foetal or adult tissue. They are multipotent with potency limited to cells of a particular tissue e.g. skin stem cells or haematopoietic (blood) stem cells.

Induced pluripotent stem cells (iPS) are genetically engineered through the manipulation of the expression of certain genes. This type of cell is not yet fully understood, and therefore not ready for clinical use.

Embryonic stem cells are found in very early embryos. They are pluripotent and can form all the different types of cells in the body, including germ cells.

> The discoveries have shown that specialized cells can turn back the developmental clock under certain circumstances. These discoveries have also provided new tools for scientists around the world and led to remarkable progress in many areas of medicine.
>
> **Prize committee at Stockholm's Karolinska Institute, upon awarding the 2012 Nobel Prize of medicine**
> to Sir John Gurdon and Shinya Yamanaka
> for their work on the reprogramming of adult cells back into embryo-like cells that can be used as replacement tissue for damaged brain/heart cells

Why stem cells are vital to healthcare research

Embryonic cells are the most controversial issue in the debate where researchers have been accused of killing babies. This misrepresents the science of stem cells. Embryonic stem cells are isolated from an embryo four or five days after fertilisation. At this stage, the embryo is a blastocyst, a ball of around 100 cells with the potential to develop into each of the different cell types that make up the human body.

Most scientists agree that research should continue on all types of stem cells, but no other type of stem cells can currently entirely replace embryonic stem cells. Their unique ability to differentiate into all types of cells gives scientists access to cells that would be difficult or impossible to obtain otherwise. Once tamed, stem cells could help people with Parkinson's disease, type I diabetes, arthritis, severe burns, and cardiovascular diseases – to name but a few.

What can the EU do?

The ruling by the European Court of Justice regarding patents for stem cell research further confused the debate. Those opposed to the field claim that the ruling means embryonic stem cell research has no viable future in Europe. We at EFPIA welcome the recent clarification by German Courts as we believe that the case was on the patentability of certain types of cell and not on stem cell research.

The European Parliament must also send a clear signal recognising the importance of embryonic stem cell research. To close down such a vital avenue of research would be a massive blow to European science and innovation. There must be continued funding from the EU in its Horizon 2020 framework to show European citizens that it is looking to cure diseases that will affect increasing numbers of people as our populations get older.

In the case of stem cells, we are no longer talking about nebulous promises for the future, but about therapies within tangible reach. Relocation of this research will not make it disappear; it will just slow access for European patients to the fruits of this research. What's more, maintaining such sensitive research in Europe means that it will be subject to appropriate scrutiny and regulation. An issue such as stem cells, that has the potential to save so many lives, deserves a rational and well-informed debate, involving those whose lives and wellbeing depend on today's research.

> Stem cell therapies have the potential to do for chronic diseases what antibiotics did for infectious diseases.
>
> **Joseph Martin**
> Former Dean of the Faculty of Medicine at Harvard University

Fighting Counterfeit Medicines

EFPIA, in partnership with key supply chain stakeholders, is working towards a harmonised pan-European medicines verification system to combat counterfeiting. Since 2010, EFPIA, EAPC, GIRP and PGEU – respectively representing the research-based pharmaceutical industry, parallel distributors, pharmaceutical full-line wholesalers and pharmacists at EU level – have joined forces to promote greater patient safety. The result is the European Stakeholder Model (ESM). The ESM is in line with the EU Falsified Medicines Directive adopted in 2011 (DIR 2011/62/EU), a welcome step in helping to ensure that European countries and actors move together as they push forward in the fight against counterfeiting.

The adoption on July 1, 2011 of the EU "Falsified Medicines Directive" (FMD) constitutes an important step in better protecting patients from counterfeit medicines.
The FMD introduces mandatory, harmonised pan-European safety features to fight counterfeiting. These will include tamper-evident packaging and a "unique identifier" in the form of a serial number that will be applied to prescription medicines and enable identification of individual packs. The European Commission will define the mechanics of this system, including the technical specifications of the unique identifier, in Delegated Acts that are to be adopted by 2014.

EFPIA supports this legislation and is pleased to work with stakeholder groups and the EC in establishing this system to promote patient safety. Together with EAEPC, GIRP and PGEU –EFPIA has developed the European Stakeholder Model (ESM), a concrete proposal for a harmonised system for the verification of pharmaceutical products in Europe. ESM is designed and governed by the stakeholders who will use it on a day-to-day basis, and meets the requirements of the FMD.

Our overriding objective is to develop a cost-effective system that provides a high level of security for patients and that can be effectively integrated into existing structures in the pharmaceutical supply chain. The members of this European coalition stand ready to work in partnership with national regulators and governments to ensure optimum implementation of the ESM at the national level.

> With no country, no drug, no medical product immune from counterfeiting, a global effort is needed to combat this threat which puts the lives of millions of people at risk every single day.
>
> **Ronald K. Noble**
> INTERPOL Secretary General

2012: Year of Progress for the ESM

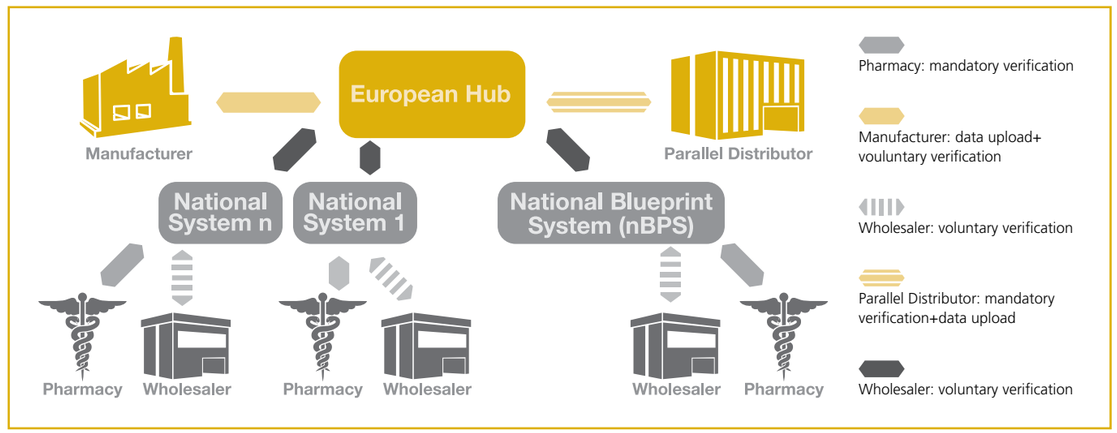
With a reputation as one of the most credible players in the coding sphere in Europe, the ESM has already seen great success. In March 2012, EFPIA, GIRP and PGEU received the "2011 Best Pharmacy Initiative of the Year" from Correo Farmaceutico.

2012 also saw the coalition expand, with EAEPC joining. In June, the four organisations officially launched a Memorandum of Understanding (MoU) outlining the key features of the system and its governance. The coalition was further solidified with its joint submission to the European Commission's public consultation on the Delegated Acts regarding the FMD provisions on safety features.

To further the initiative, EFPIA launched a public tender to select an IT supplier for the future ESM system in April 2012. While taking concrete steps to drive the ESM forward politically and technically, ESM stakeholders were also engaging with additional potential supply chain partners. Through informal sessions, the dialogue between EGA, AESGP, EAHP, HOPE, EUCOPE and CPME has progressed substantially. Outreach at the national level has also advanced, through stakeholder-organised workshops aimed at informing and exchanging best practices.

What's next? The ESM in 2013…

In 2013, tender negotiations will be concluded and the construction of the system will start. The system will be implemented in phases, first at the European Hub (see graphic), and then the national Blueprint template (nBPS). Legal experts within the coalition will work to establish the not-for-profit organisation that will govern the system, the European Medicines Verification Organisation (EMVO). Activities targeting stakeholders at the national level, including public authorities and patient organisations, will be strengthened as well.



Protecting Patient Safety

Recent cases concerning the seizure of counterfeit medicines in both Europe and the US confirm the need for stringent measures to tackle the global problem of counterfeiting. For EFPIA and its members, patient safety always comes first. This is why we are engaging with our international sister organisations and all relevant stakeholders, in Europe and beyond, to make sure that anti-counterfeiting remains an industry priority and that action is taken – now.

Internet Sales and Access to Safe Medicines

As more patients look to the Internet for the supply of medicines, EFPIA is strongly committed to protecting their safety. Many people are unaware that a large number of online pharmacies are not regulated and that when purchasing medicines online, there is a high risk of buying counterfeit products. A report by the European Alliance for Access to Safe Medicines (EAASM) found that 62% of medicines bought online were either substandard or counterfeit.[1] Meanwhile, the World Health Organization (WHO) suggests that over 50% of medicines purchased from online sites concealing their location may be counterfeit.

Efpia is devoted to promoting access to safe and effective medicines, advocating for patient education and awareness, and combating unsafe medicines, including those sold by illegitimate online pharmacies.

To this end, we support the Alliance for Safe Online Pharmacy, ASOP EU[2], launched in December 2012. The Alliance aims at creating an environment that enables patients to buy medicines online safely (where permitted by law).

The Council of Europe MEDICRIME Convention

The Council of Europe's MEDICRIME Convention was launched in 2010 and now has 21 signatories. The Convention aims to protect patients globally, especially in developing countries, by criminalising the manufacture and supply of counterfeits.

EFPIA supports the Convention and encourages more states to sign up and ratify it. The rules are not binding at this time, but the symbolism is strong and will only be made stronger as more countries become involved.

The Importance of International Cooperation

The threat of counterfeit medicines is not confined to a specific region of the world. It is a global issue and efforts to tackle it must be so too.

The ASOP EU initiative supported by EFPIA is closely linked to ASOP US and the Center for Safe Internet Pharmacies (CSIP) both of which were launched under the auspices of White House Intellectual Property Enforcement Coordinator Victoria Espinel in July 2012.

Overall, EFPIA works closely with its sister organisations (including IFPMA, PhRMA and JPMA) to share information and best practices, as well as to enact global initiatives and drive industry efforts for greater patient safety.

> In the case of drug counterfeiting, it can mean the difference between life and death for a patient. It is estimated that 10 per cent of medicines are fake and these figures can go up to 50 per cent, particularly in some poorer countries.
>
> **Christopher Viehbacher**
> EFPIA President and CEO of Sanofi

[1]PEAASM report "The Counterfeiting Superhighway", EAASM, http://www.eaasm.eu/home
[2]For more information, please visit the ASOP EU website: http://asop.eu/home

Pharmacovigilance: Safeguarding Patient Safety

Pharmacovigilance is the process by which the safety of medicines is monitored in order to reduce risks and increase benefits. EFPIA considers the EU Pharmacovigilance Directive and Regulation to be essential elements of the framework for public health protection and to ensuring that patients get the highest quality of medicines possible. It will make it easier for patients and doctors to identify medicines which are subject to additional monitoring and it encourages reporting of adverse events through national reporting systems.

In 2010 the European institutions adopted a new Directive and Regulation dedicated to pharmacovigilance, amending the community code for pharmaceutical products, which became applicable from July 2012 onwards. The subsequent Implementing Measures Regulation published in 2012 provides the basis for making the legislation operational.

The change to the legislation is mainly seen in the implementation of new processes and procedures, bringing about system changes, particularly regarding IT infrastructure. For aspects of the legislation which relate to products on the market (such as Periodic Safety Update Reports and Risk Management Plans), greater understanding of how these aspects will be implemented is required in several areas. The industry will therefore need time to fully adapt to the new requirements. The main challenge for industry is the complexity of the changes as well as availability of the details of implementation.

The legislation as a whole will enhance protection of public health, with industry, regulators and the public all playing their part. Appropriate transitional arrangements are needed to give sufficient time for implementation. The principle of increased transparency is an important theme of the new legislation which will enable healthcare professionals and patients to be better informed about medicines.

EFPIA strongly supports the legislation and we are working with the regulators to implement a system that is effective in promoting and protecting public health. There will be high implementation costs, particularly in the initial stages, which will not only affect companies but also Member States. There will also need to be consistent application of the new directive across Member States to ensure increased patient safety throughout the EU.

Intellectual Property: Protecting Innovation

The EU has a world-class system of intellectual property (IP) protection, which encompasses patents, trade marks, designs, copyright and related rights as well as regulatory data protection and other regulatory exclusivities. There are few sectors of the EU economy which do not depend on intellectual property in some form. The IP system is a key enabling factor of pharmaceutical innovation, as it provides necessary incentives to research and develop new medicines, thereby addressing global health needs.

2012 saw some important developments in this field. Regulations were agreed which will see the creation of a unitary patent, and an agreement was reached to create a unified patent court which, after a transitional period, will have exclusive jurisdiction throughout most, and perhaps eventually all, of the EU for European and unitary patents. The aim of these initiatives is to reduce the cost of obtaining patents in the EU and facilitate resolution of patent disputes. It is hoped that SMEs, in particular, will benefit. EFPIA has contributed and will continue to contribute positively in the interest of ensuring that the new EU regime provides high-quality decisions. In parallel with these developments, EFPIA remains committed to seeking improvement in the efficiency and fairness of existing enforcement processes.

Global trends in applications for IP rights clearly demonstrate that innovative capacity is increasingly diffused across the globe. The EU cannot afford to be complacent about its relative attractiveness as a research and development location and that is why initiatives such as Horizon 2020 are so important. Through flexible IP rules, and building on past experience, the EU is breaking new ground in how to structure collaboration between the public and private sectors in ways that are effective for both. Without intelligent application of IP proactively addressing new areas of research, and new ways of doing research, it can be difficult to bridge these two worlds. Europe is leading the way.

Just as the EU needs to maintain its own competiveness, it also needs its trading partners to incorporate robust but balanced intellectual property rules into their domestic legal regimes and for these to be respected in practice. There are many significant markets for EU exports where intellectual property protections fall short at least of harmonised norms if not international legal obligations.

Investing resources in implementing robust IP protections may not be a priority for the world's Least Developed Countries (LDC) which is why EFPIA supports the extension of TRIPS implementation deadlines for LDCs. Yet for some other EU trading partners, it is time to move forward. EFPIA hopes that 2013 will bring a more constructive approach to discussions of IP both internationally and with civil society in the EU.

> "As documented in nearly 250 pages of facts, explanations, and practical examples, the policy spheres of public health, intellectual property, and trade share much common ground and many social values. All of these policy spheres should operate in the public interest. As we all know, medical products differ in significant ways from other consumer goods. For this reason, the international systems that govern intellectual property rights and trade have health-specific provisions."
>
> **Dr. Margaret Chan**
> Director General of the World Health Organisation

Trade: Creating Opportunities by Leveling the Playing Field

Against the backdrop of the financial crisis and cost-containment measures across Europe, increased access to third markets is more necessary than ever. EFPIA supports an open trading system that creates new opportunities for trade and investment, and promotes competitiveness and innovation on a level playing field. The EU's external trade agenda is key to achieving these objectives, both at multilateral and bilateral level. EFPIA contributes to shaping this agenda and is actively engaging with various EU institutions in order to ensure that the European pharmaceutical industry has greater access to global markets through predictable and non-discriminatory trade and investment conditions.

In recent years, the EU has engaged in an ambitious trade policy agenda, encompassing the negotiations of Free Trade Agreements (FTAs) with key, fast-growing trading partners, as well as conducting high-level dialogues in various fields, such as regulatory and intellectual property (IP). In 2012, EFPIA continued its active advocacy on trade issues and succeeded in leveraging the interests of the European pharmaceutical industry through its active involvement in relevant trade initiatives. As regards FTAs, EFPIA continued to support the negotiation of high-quality, comprehensive FTAs that substantially cover both tariff and non-tariff barriers, promote investment, address the protection and enforcement of intellectual property rights, and enhance transparency.

EFPIA firmly supported the launch of FTA negotiations with Japan, being one of the strongest advocates of this trade agreement. Furthermore, EFPIA actively participated in the scoping exercise prior to the launch of this agreement by providing substantive information concerning the priorities of the pharmaceutical industry, which was duly taken into consideration during 2012. FTA negotiations were to be formally launched in 2013, and EFPIA will play a key role in ensuring that the key barriers faced by our Industry in Japan are duly addressed by these negotiations.

As regards the negotiations of the EU-Canada FTA, we have been working hand-in-hand with our sister association in Canada, Rx&D, to keep our priority issues high on the agenda of the EU's negotiators.

In 2012, we conducted several successful advocacy outreach activities to key opinion leaders, notably advocating for the establishment of a level playing field in the domain of intellectual property protection. In 2013, we will continue our outreach to key stakeholders and decision-makers in full coordination with Rx&D ahead of the imminent conclusion of negotiations.

EFPIA has also been providing input to the EU's High-Level Dialogues with most relevant trading partners, such as China and Russia, in the areas of intellectual property, public health and regulatory matters. As regards China, we have successfully kept our key priorities high on the EU's Trade and Health agendas while strengthening our cooperation with the Chinese Industry. EFPIA Director General (DG) Richard Bergström paid his first visit to China in July 2012 in the framework of the EU-China High-Level Regulatory Dialogue. During this visit, successful meetings with key opinion leaders were held and EFPIA strengthened ties with the Chinese Industry Association (CPIA), which were formalised in May 2013 by the signature of the Memorandum of Understanding between EFPIA and CPIA.

EFPIA has also stepped up efforts in building a closer collaboration with the EU in its engagement with Russia. In 2012, we continued our advocacy towards the mutual recognition of clinical trials, which is expected to bear fruit in 2013, and we upheld our engagement in the EU-Russia IP dialogue, which resulted in meaningful commitments from the Russian government regarding data protection. We will continue to voice our industry's concerns over Russia's protectionist public procurement measures.

The Russia Association of International Pharmaceutical Manufacturers (AIPM) became a member of EFPIA in 2012, which will further increase our impact in addressing trade barriers in Russia. In this regard, the EFPIA DG's visit to Moscow in early 2013 will strengthen cooperation between both associations.

Likewise, EFPIA has strengthened its ties with the Ukrainian Association of Pharmaceutical Research and Development (APRaD), which joined EFPIA in 2012. The EFPIA DG already visited Ukraine in 2012 and is planning his second coordination trip in the autumn of 2013. Furthermore, the Association of Research-Based Pharmaceutical Companies (AIFD) also joined EFPIA in 2012, with whom we have worked closely in solving longstanding barriers faced by our Industry in Turkey. EFPIA DG will conduct his first visit to Turkey to interact with key decision-makers in 2013.

We have also closely monitored developments regarding the EU's FTA negotiations with India. Relevant outreach to a wide array of stakeholders took place in 2012, which will be continued during 2013.

EFPIA has been closely involved in EU negotiations with other fast-growing economies, such as the ASEAN countries. The FTA negotiations with Singapore were finalised in December 2012, where EFPIA played a key role in transmitting the interests of the industry and optimising access to pharmaceutical products in Singapore. With respect to the EU's negotiations with Vietnam, EFPIA furnished EU negotiators with a substantial submission reflecting the pharmaceutical industry's priorities in 2012. In 2013, we will actively engage with relevant EU institutions to ensure that these matters are duly addressed in the agreement. Furthermore, EFPIA participated in 2012 in the scoping exercise prior to the launch of EU-Thailand FTA negotiations, and has duly submitted detailed comments regarding the key areas where this FTA could serve the interests of the pharmaceutical industry.

In addition to this large number of trade initiatives, the trade agenda in the year ahead will be marked by the launch of negotiations on the EU-US Transatlantic Trade and Investment Partnership in summer 2013. Substantial preparatory work was already undertaken during 2012, which will be significantly strengthened throughout 2013 in order to maximise this great opportunity to reinforce the transatlantic pharmaceutical marketplace. This FTA will represent one of the key priorities in our trade agenda, and EFPIA will ensure that the industry's interests are fully incorporated in the negotiations. To this end we will work in close cooperation with our sister association, PhRMA.

HTA: European Collaboration can tackle Duplication

> EPF sees in the Cross-border Healthcare Directive the potential to reduce health inequalities for patients in access to healthcare. We believe that many aspects of the Directive can be built upon to achieve better quality care for all patients - such as stronger European cooperation in the crucial areas of quality and safety, HTA, eHealth and rare diseases.
>
> **European Patients Forum's position on the Cross-border Healthcare Directive**

Health Technology Assessment (HTA) is a general concept that reflects a wide range of methods used by policymakers to support their health policy decisions. HTA is used to measure the medical, economic, social and ethical implications of the use of all health technologies, e.g. medicines, as well as diagnostic and treatment methods, medical equipment, rehabilitation and prevention methods, and organisational and support systems used to deliver healthcare. The overall goal of HTA is to support decision-making that is patient-focussed and achieves optimal value. Unfortunately, this is not the case in many countries. HTA is often used as a way to contain cost without taking into account the broader benefits outside the health care budget – such as whether people can stay in the work force longer or stay in nursing homes, costs often carried by society.

In Europe, national decision-makers are increasingly making use of HTAs to support decisions on the allocation of healthcare resources, including expenditure on medicines. National budget holders are interested in understanding the added value of new medicines compared to existing treatments. The evidence required to prove this added value needs to be generated by the developers of medicines during drug development, and comes in addition to the requirements from regulatory agencies for regulatory approval. Over the past few years, regulatory and HTA agencies[1] have been increasingly willing to jointly discuss appropriate evidence requirements along the life cycle of products. Industry welcomes regulatory and HTA advice on companies' development plans in order to ensure targeted drug development and the delivery of the appropriate evidence at the appropriate time, in the interest of improved access to innovative medicines for patients.

HTA in EU Member States has been established with a variety of objectives and methodologies, resulting in different HTA evidence requirements for industry across Member States. This has led to inconsistencies in findings on the added value of the same innovative medicines from one country to the next. A study conducted for the Belgian EU Presidency in 2010[2], for example, found that because of differences in assessments, France and Belgium had a different understanding of 'added value responding to unmet medical need', leading to differences in access for patients in these two countries.
In the interest of a more streamlined process, and more equal access to innovative medicines for European patients, the European Commission is supporting EU-wide collaboration between HTA agencies. A pilot project (EUnetHTA) has been working on raising and streamlining methodological standards, and a permanent European network, expected to be set up by October 2013, is going to continue this endeavour. Industry supports European collaboration on HTA as a way to tackle unnecessary duplication and to enable greater clarity, higher methodological standards in HTA, and improved predictability, along with better and more timely access to medicines. In particular, industry calls on the European collaboration on HTA to recognise the role that HTA plays in fostering innovation in Europe. In some countries, HTA has evolved contrary to its objective of supporting patient-focussed decision-making and has been misused as a rationing tool. In particular, models focusing only on binary decisions based on fixed cost-effectiveness thresholds fail to recognise innovation and do not give sufficient considerations to patient-relevant outcomes. Industry considers that HTA should primarily build on assessment of medical added value of health technologies taking into account health outcomes relevant to patients. Where economic evaluation is used, it should be one of the information elements of HTA but should not mandate decisions.

Moving forward, HTA and the assessment of medicines more generally will need to adapt to the new science. Advances in science and technology have allowed us to refine the way we develop medicines. For instance, personalised medicines for cancer offer targeted treatments based on a specific cancer subgroup's unique molecular makeup. Because cancer cells are heterogenous and genetically unstable, the cancer subgroup may develop resistance to a pharmaceutical agent during treatment. This has encouraged a move away from traditional trial models, towards adaptive methodologies. Such shifts represent significant changes in the sphere of medicines research and development, and need to be considered when reviewing HTA systems. The regulatory environment surrounding medicines research and development – including HTA – must acknowledge and reflect these changes.

The aim is an HTA process that is comprehensive, transparent, robust and systematic. An HTA system based on these principles can help healthcare decision-makers in effectively reaching decisions and determining allocation of resources, and can also facilitate informed updates and diffusion of health technology. As elements of HTA in the EU come under review, it is essential that all relevant stakeholders – including patients, healthcare professionals and industry – are active in the conversation.

[1]Pilot projects of HTA-regulatory dialogue took place in individual Member States (such as the UK or Sweden), at the EMA, at the level of EUnetHTA, as well as in multi-stakeholder platforms such as the Tapestry networks
[2]Slide 4, http://www.health.belgium.be/internet2Prd/groups/public/@public/@mixednews/documents/ie2divers/19064375.pdf

Pharmaceuticals in the Environment: Improving Standards, Protecting Public Health

The issue of Pharmaceuticals in the Environment (PIE) is attracting increasing attention, sparking concerns about the impact drug traces could have not only on the environment but also on human health. The pharmaceutical industry is committed to addressing these concerns, by illuminating the scientific facts of the issue, as well as the regulations that govern the industry in regards to environmental impact.

Medicines, like many foods or nutritional supplements, are sometimes not completely absorbed or broken down by the human body. As a result, residue of the pharmaceutical or its breakdown products may be excreted and end up in rivers, streams or lakes. To a much lesser extent, pharmaceutical products may also enter the environment through inappropriate disposal of unused products or via pharmaceutical manufacturing discharges. It is important to remember that pharmaceuticals represent only one of many sources of chemicals and substances present in the environment and should therefore not be addressed alone.

Strict regulations apply to the manufacture and use of medicines, as well as to their disposal. As part of the drug approval process, companies filing for a drug registration have to produce an environmental risk assessment (ERA). This helps highlight any potential impacts of new medicines on the environment. The impact of PIE on human health is thought to be minimal: In the wider field, a WHO report updated in 2012 concludes that pharmaceuticals in drinking water pose a negligible risk to human health.

Overall, the industry is constantly striving for new ways to improve our environmental sustainability, from purifying solvents to installing solar panels and controlling manufacturing discharges of active pharmaceutical ingredients. However, there are aspects of the environmental impact of pharmaceuticals about which more could be learned and we are committed to supporting that process as part of our environmental strategy. As a result of a review carried out in 2012, we are looking in more detail at two areas. The first is to examine whether we should strengthen the existing ERA process. Second, we believe that a pragmatic and scientifically-robust process should be put in place to address the areas where we do not have enough data (this is a particular concern in relation to older compounds).

We also recognise that these concerns extend beyond European borders, particularly in regards to manufacturing. Most major companies in the industry have established programmes to ensure that suppliers are adhering to local regulations, or have implemented voluntary global company standards in line with, or exceeding, local legislation. Progress has been made and the industry supports further improvements through continued with third-party programmes.

The industry supports greater efforts in understanding the long-term environmental impact of manufactured 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 needs to be based on sound scientific evidence, especially since knowledge gaps currently still exist in terms of assessing the risks associated with long-term exposure to low concentrations of pharmaceuticals and the combined effects of mixtures of pharmaceuticals.

Ultimately, any framework for action arising from the debate on PIE must ensure that environmental issues are appropriately managed without undermining patient needs, public health or medical research.

Good Animal Welfare Holds the Key to Cures

The study of animals is one of many essential steps in medicines development, both in terms of experimental research and in checking for the safety and efficacy of new medicines. The biological similarities between humans and animals allow researchers to predict most potential effects of medicines – both good and bad – thereby safeguarding the wellbeing of patients. Without this, the medical treatments we have today would not exist. Although pharmaceutical companies cannot avoid the use of laboratory animals, it is in the interest of science to meet high standards of animal welfare. To put animal welfare principles into action, we systematically replace animals with alternative methods where possible, reduce and refine the use of laboratory animals (3Rs), and improve standards of care throughout the supply chain and during research.

animaltestingperspectives.org

Use of animals in testing and research is regulated at both EU and Member State levels. The latest legislation passed at EU level in September 2010 came into force on 1 January 2013 and is based on the 3R principles (Directive 2010/63). The research-based pharmaceutical industry not only complies fully with the letter of the law, it goes beyond compliance, and leads by example. Our report published in 2012 tracks these activities. It shows how applying advances in science and continued commitment to improving research processes, through initiatives such as the Innovative Medicines Initiative (IMI), drives animal welfare.

Research involving animals poses dilemmas. The current consensus is that research with animals is justified where there are clear benefits for our health and when the 3Rs are applied. Advances in science, and consistent efforts to improve research processes, are leading to fewer tests and experiments on animals, and to new ways of reducing the impact on animals. This is why dialogue and transparency about the use of animals for medical research and developments in science need to be debated by everyone involved.
Our blog, www.animaltestingperspectives.org, serves as a hub for this conversation.

International Collaboration

Steps taken by the medical research community, indirectly through changing research pathways or directly through efforts to minimise animal testing, have had an impact already. The total number of animals used in medicine research is now less than half what it was 20 years ago. The pharmaceutical industry is committed to working with regulators to ensure that alternative approaches to animal testing are implemented as quickly as possible.

This also requires collaboration at a global level. EFPIA is actively involved in a range of initiatives which facilitate international dialogue and regulatory acceptance, such as the European Partnership for Alternative Approaches to Animal Testing (EPAA), International Conference of Harmonisation (ICH) and the Innovative Medicines Initiative (IMI), a public-private partnership between the European Commission and EFPIA.

IMI funds a number of projects focussed on developing omics, imaging, and in *silico* and *in vitro* methods, which can potentially minise the use of animal testing. One example is StemBANCC, which aims to generate and characterise high quality human pluripotentent stem (iPs) cells that can then be used to study diseases and for drug testing. Recognising the value of such initiatives, ATLA – *Alternatives to Laboratory Animals* – provides progress reports on such IMI projects.

Despite such efforts, it is important to stress that there is no viable replacement for animal research and testing that could be comprehensively implemented in the foreseeable future: the human body is simply too complex to permit modelling or test tube methods to effectively replace animal testing of compounds. At this point, animals are simply an irreplaceable resource in the testing of medicines and their safety for humans and therefore continued supply and transport of animals in conditions which secure maximum welfare remains a priority for researchers.

Global Health in a Changing World

The global economic landscape is changing. Previously-underdeveloped and newly-industrialised countries are gaining strength and influence in the global market. EU companies operating internationally now consider emerging markets as an integral part of their strategy.

At the same time, global health issues have changed. Although tropical diseases remain a significant burden on the population in the poorest countries, the global burden of disease looks increasingly similar across countries. Yet the levels of access to healthcare that Europe achieves remain out of reach for many populations. EU policy has to adapt. Rather than simply provide countries in need with charity, new relationships are needed with these newly-influential political and economic actors. In Europe, the public policy debate focusses on sustainable solutions and capacity-building.

EFPIA believes that trade, health and development are policy areas that can reinforce one another, and that collaboration between industry, governments and other stakeholders can advance shared objectives. Following this belief, EFPIA members have formed the Global Health Initiative (GHI). The GHI working group aims to encourage collaboration among European political actors to create unique solutions for shared problems in global health.

To this end, it was decided that public debates bringing together all relevant stakeholders in the European Parliament would be the most productive means of delivering tangible conclusions. Each GHI debate is sponsored and hosted by an MEP in a room of the European Parliament.

Debates feature experts from different fields (institutions, NGOs and industry), who are invited by GHI to present on a concrete topic. As a Q&A session is a significant part of each debate, the inclusion of such experts gives participants the opportunity to expand their own knowledge and adds depth to the conversation. These events make a point of seeking the opinions of all involved actors ensuring that inclusive conclusions are made.

A series of events took place from early 2012 and were to run until May 2013. Participants discussed whether research is addressing the needs of the developing world; the ethics of clinical trials in third countries; and how to transfer technologies to developing nations in a sustainable way. All debates highlighted the need for political involvement that will create an industry-friendly environment and enable third countries to benefit. The results of those debates which have already occurred will be published in late June 2013. In September, a new series of debates will kick off, as GHI further seeks to find collaborative solutions to today's global health problems.

Useful links

- IFPMA page on Global health
- DG Development
- DG Trade Access to Medicines
- EFPIA direct page to the reports of all debates

> "Development and health practitioners share the same goals of tackling inequality and improving the well-being of individuals and communities, yet they often lack the common language or approaches to find solutions together. This gap is artificial, to be bridged through dialogue and inter-institutional partnerships."

Helen Clark
UN Development Programme (UNDP) Administrator
Speaking at the Harvard School of Public Health

> "It is critical that more African researchers are sufficiently trained and equipped with skills and expertise in clinical trials research in the fight against diseases that severely impact the social and economic development of sub-Saharan Africa."

Professor Charles Mgone
EDCTP Executive Director

EDCTP

EFPIA recognises that the best way to tackle global health problems is to collaborate across borders. In this spirit, EFPIA signed a Memorandum of Understanding (MoU) with the European & Developing Countries Clinical Trials Partnership (EDCTP) to establish a fellowship scheme for clinical researchers in Sub-Saharan Africa and Europe. The initiative will allow African researchers to take up placements in a European-based pharmaceutical company to work on clinical trials research for a period of up to two years. The European Commission's Directorate-General for Research and Innovation is also collaborating in this initiative.

Research will focus on development of new or improved drugs, vaccines, microbicides, and diagnostic tools for three primary poverty-related diseases – HIV/AIDS, tuberculoses and malaria. "This is a great opportunity for all parties involved," noted Richard Bergström, the Director General of EFPIA, upon the MoU's signing: "EFPIA's members will benefit from interaction with African scientists from diverse backgrounds beneficial to the development of new or improved treatments in poverty-related diseases. We hope to help them acquire skills relevant to achieving their research and professional goals." The first call for applications is expected to launch in the second half of 2013.

More information about EDCTP is available www.edctp.org

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).

Differential Pricing Adapting medicine prices to the purchasing power of consumers and epidemiological conditions in different geographical or socio-economic segments.

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.

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.

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.

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).

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.

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.

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.

Human Genome The entirety of a human's hereditary information.

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.

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.

New Science A general term used for, biotechnological advances in the pharmaceutical industry, including personalised medicines, epigenetics, diagnostic tools such as biomarkers and nanotechnology.

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.

Off-Patent Pharmaceuticals A medicine that has come to the end of its patent term and is open to generic competition.

Omics A short-hand term used to refer to a field of study in biology. For example, genomics is the study of genomes.

Patient adherence The degree to which patients adhere to medical advice and take medicines as directed.

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 EFPIA staff, 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 34 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and 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 25 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 & Executive Committee

The role of the Board is decision making on strategy setting, priorities and governance. The role of the Executive Committee is the implementation and operation of the priorities set by the Board to which it is accountable.

Board members

President
Chris Viehbacher
Sanofi
(France)

Vice-President
Roch Doliveux
UCB
(Belgium)

Vice-President
Joe Jimenez
Novartis
(Switzerland)

Corporate Members
Carlos Alban (AbbVie)
Lucia Aleotti (Menarini)
Béatrice Cazala (BMS)
Alberto Chiesi (Chiesi)
Marc De Garidel (Ipsen)
Ruud Dobber (AstraZeneca)
David Ebsworth (Vifor Pharma)
Antoni Esteve (Esteve)
Andreas Fibig (BayerHealthCare)
Jorge Gallardo (Almirall)
Allan Hillgrove (Boehringer Ingelheim)
Anthony Hooper (Amgen)
Robert Hugin (Celgene)
Carlo Incerti (Genzyme)
Lise Kingo (NovoNordisk)
Tony Kingsley (Biogen Idec)
Daniel O'Day (Roche)
Stefan Oschmann (Merck)
Eric-Paul Paques (Grünenthal)
Joaquin Duato (Johnson & Johnson)
David Ricks (Eli Lilly)
Adam Schechter (MSD)
Mike Warmuth (Abbott)
Andrew Witty (GSK)
Ulf Wiinberg (Lundbeck)
John Young (Pfizer)

Ex Officio (EFPIA Board)
Jane Griffiths, ExCom Chair, (Johnson & Johnson)

Luc Debruyne, ExCom Vice-Chair, (GSK)

Pascale Richetta, ExCom Vice-Chair, (AbbVie)

Humberto Arnes, (Farmaindustria)

Birgit Fischer, (VfA)

Roberto Gradnik, EBE President, (Stallergènes)

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.

Chair
Jane Griffiths, Johnson & Johnson

Vice-Chair
Luc Debruyne, GSK
Pascale Richetta, Abbvie

Vice-Chair Member Associations (MA)
Humberto Arnes, (Farmaindustria)

Second MA Delegate ex-officio
Birgit Fischer, (VfA)

Corporate Members
David Allsop, (Biogen Idec)
Khoso Baluch, (UCB)
Ole Chrintz, (Lundbeck)
Ron Cooper, (BMS)
Ugo Di Francesco, (Chiesi)
Reinhard Franzen, (Bayer)
William Gaussens, (Servier)
Alberto Grua, (Grünenthal)
Jerzy Gruhn, (Novo Nordisk)
Guido Guidi, (Novartis)
Gary Hendler, (Eisai)
Kirsten Hoefer, (Abbott)
Andrew Hotchkiss, (Eli Lilly)
Peter Hug, (Roche)
Tim Kneen, (Merck)
David Loew, (Sanofi)
Pio Mei, (Menarini)
Peter Nicklin, (Baxter)
Andreas Penk, (Pfizer)
Philippe Robert-Gorsse, (Ipsen)
Jean Scheftsik De Szolnok, (Boehringer Ingelheim)
Joris Silon, (AstraZeneca)
Trevor Smith, (Takeda)
Bruno Strigini, (MSD)
Carsten Thiel, (Amgen)
Ole Vahlgren, (Otsuka)
Patrick Vink, (Cubist)

Member associations
Anders Blanck, (LIF – Sweden)
Heitor Costa, (Apifarma – Portugal)
Thomas Cueni, (Science Industries – Switzerland)
Birgit Fischer, (VfA – Germany)
Enrica Giorgetti, (Farmindustria – Italy)
Ida Sofie Jensen, (LIF – Denmark)
Philippe Lamoureux, (Leem – France)
Leo Neels, (AGIM / pharma.be – Belgium)
Anne Nolan, (IPHA – Ireland)
Stephen Whitehead, (ABPI – UK)

General Management
Richard Bergström, (EFPIA Director General)
Marie-Claire Pickaert, (EFPIA Deputy Director General)
Guest: Rod Hunter, (PhRMA)

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 - **Pius Hornstein**, Sanofi Vice-Chair - **Gisela Payeras**, GlaxoSmithKline
Intellectual Property Policy Committee (IPPC)	Chair - **David Rosenberg**, GlaxoSmithKline Vice-Chairs - **Stephane Drouin**, UCB; **Lise Ryberg**, Lundbeck
Research Directors Group (RDG)	Chair - **Peter Hongaard Andersen**, H.Lundbeck
Scientific, Regulatory and Manufacturing Policy Committee (SRMPC)	Chair - **Sue Forda**, Eli Lilly
Trust, Reputation and Compliance Policy Committee (TRCPC)	Chair - **Stefan Gijssels**, J&J Vice-Chair - **Michel Dutree**, Nefarma

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

Thomas Cueni
Special Adviser to the EFPIA Director General

Chester 'Chip' Davis
PhRMA

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 Corporate Members

Abbott
Abbvie
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
Otsuka
Pfizer
Roche
Sanofi
Servier
Takeda
UCB

EFPIA Affiliate Corporate Members

Bial
Celgene
Cubist
Shire
Vifor Pharma

EFPIA 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)

Switzerland
scienceindustries

Turkey
Arastirmaci Ilac Firmalari Dernegi (AIFD)

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)

Vaccines Europe

Vaccines Europe, formerly European Vaccine Manufacturers (EVM), is the specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA), the professional association of the pharmaceutical industry in Europe.

Formed in 1991, Vaccines Europe represents all the major vaccine companies operating in Europe which account for the majority of human vaccines used worldwide. Companies represented within Vaccines Europe are involved in research and development (R&D), clinical trials, production and marketing of vaccines and are dedicated to improving public health through immunisation.

President: **Andrea Rappagliosi**

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: **Roberto Gradnik**

Vice-President: **Carsten Thiel**

www.efpia.eu ✱ www.vaccineseurope.eu ✱ www.ebe-biopharma.org

efpia

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