



Commissioner Carlos Moedas

**Commissioner Moedas meets with Merck Executive Committee
and Board
Rue Montoyer 21, 1000 Brussels
18/05/2015
16:00**

Main contact person: [REDACTED], ☎ [REDACTED] RTD-E2, office [REDACTED]	Cabinet Member: DEL BRENNA Giulia
Contributor: [REDACTED], ☎ [REDACTED] RTD-E2, [REDACTED]	RTD colleague at meeting: [REDACTED] [REDACTED], ☎ [REDACTED] RTD-E, [REDACTED]
	Back up (in case of absence): [REDACTED], ☎ [REDACTED] RTD-E2, [REDACTED]

TABLE OF CONTENTS

KEY MESSAGES AND FIGURES	Page No 3
1. STEERING BRIEF	Page No 4
1.1 Scene setter	Page No 4
1.2 Objectives	Page No 4
1.3 Line to take	Page No 5
2. SPEAKING POINTS	Page No 6
3. DEFENSIVE POINTS	Page No 9
4. CURRICULUM VITAE	Page No 11
5. BACKGROUND INFORMATION	Page No 22
5.1 The European pharmaceutical industry, in key figures	Page No 22
5.2 Recent activities of IMI 2 and current issues	Page No 23
5.3 Background information on Merck	Page No 23

KEY MESSAGES

- The pharmaceutical industry and its research investments are vital for the European economy. Research investments in Europe are essential to maintain and strengthen the position of the industry, including for the creation of highly-skilled jobs.
- The European Commission is ready to work with all stakeholders including the pharmaceutical industry to improve the framework conditions for this key sector.
- The Innovative Medicines Initiative 2 (IMI 2) is a the largest public-private partnership in the world and aims at delivering better health for Europe's citizens and boosting jobs, growth and investments in the life sciences sectors.
- Continuous and systematic support from EFPIA companies for IMI projects that really have scope is needed (internal R&D). We are looking forward to projects with Merck in the lead.

KEY FIGURES	FP7	Horizon 2020
Total number of participations	37, of which 19 are in IMI projects with 0 EU contribution but with €28.2 million in-kind contribution	3
Total number of signed grant agreements	37	0
ERC – Number of grantees	0	0
Marie Skłodowska-Curie – Number of grantees	2	0
EU total financial contribution to participation	€4.3 million	€2.1 million

1. STEERING BRIEF

1.1 Scene setter

You will be attending the Merck Executive Committee and Board internal meeting to discuss EU's role in putting value into research in presence of Merck family, owner at 70% of the Group. Basing its origins on a pharmacy in Darmstadt founded in 1668, Merck KGaA is the oldest pharmaceutical company in the world and among the best established European pharma companies. It is a full member of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Merck KGaA is also participating in 19 IMI projects with an in-kind contribution of €28.2 million.

Your presence has been requested by Merck KGaA following your speech of 31 March on EU's innovation and competitiveness drive at an event organised by Friends of Europe.

The objective of the meeting is to discuss the role of research and innovation for delivering on jobs, growth and investment. With Merck making about 60% of its business, in pharmaceuticals, a particular focus will be on the role of pharma industries in research and its application in the development of drugs to reach better health in Europe.

The pharmaceutical industry is a key asset for the EU economy. Despite the financial crisis it is a well performing high technology sector, with a total of 700,000 employees in Europe and a trade surplus of € 87 billion in 2013. The pharmaceutical industry is also a key driver for innovation growth with the sector providing a significant share of EU business R&D investments.

The migration of research investments out of Europe in the last decade was one of the drivers for the Commission and the EU Member States for setting up the Innovative Medicines Initiative (IMI), now on its second leg with the Innovative Medicines Initiative 2 (IMI 2), launched in June last year with a total budget of € 3.3 billion.

IMI 2 is the largest initiative of its kind in the world. It provides a great opportunity for pharmaceutical companies to work together, including with other players in the health sector, to speed up the development of innovative medicines, particularly in areas where there is an unmet medical or social need.

The operations of IMI and IMI 2 have so far been very successful. The partnership has attracted investments from the participating EFPIA member companies, and the projects are widely promoted and communicated worldwide. IMI is often quoted as the best example of large scale collaboration between pharmaceutical companies that normally compete with each other. Importantly, the Scientific Research Agenda of IMI 2 addresses significant issues of public health interest, and is based on the recommendations of the WHO for priority medicines for Europe and the world (report funded by the EC and published in July 2013).

1.2 Objectives

This meeting is an opportunity to take stock of the involvement of innovative industries such as pharmaceuticals and advanced materials in the European Research Area, and to discuss the

role of the innovative industries for Europe's competitiveness and for improving the regulatory framework.

1.3 Line to take

- Highlight the success of EU research and innovation programmes, providing support for basic research, collaborative research, public-private partnerships to financial instruments.
- Welcome the input of innovative industries for the identification of bottlenecks of a legislative and regulatory nature that limit EU's competitiveness in the domain.
- Underline that the pharmaceutical industry and its research investments are vital for Europe's economy.
- Encourage Merck to maintain and increase investments in R&D in Europe, as compared to the US and Asia. R&D and innovation are strong in the EU and these additional investments will be of mutual interest. The benefits are clearly illustrated by the success of initiatives like IMI.
- Suggest that the mobilisation of a relatively small percentage of the industry's internal R&D budgets for non-competitive/collaborative research could make a big difference in speeding up the development of diagnosis and treatments for significant public health issues, e.g. contributing to the implementation of stratified/targeted medicine.
- Convey that, in our view, IMI "1" is a success on which its successor IMI 2 should build: IMI has enabled the collaboration of academia, small and medium-sized enterprises, large industry, regulators and patient representatives for addressing public health challenges of concern to European citizens; further steps should also actively involve life science industries beyond pharmaceutical companies.
- Thank Merck for their significant involvement in IMI projects so far and invite them to continue to be involved.
- Convey that the continued commitment of the EFPIA companies is key to the success of IMI 2.
- Encourage Merck to continue their strong involvement in the different parts of Horizon 2020 beyond IMI2.
- Mention that an innovative financial instrument is being jointly developed between the European Commission and the European Investment Bank to increase investment in R&D of innovative drugs, vaccines, medical and diagnostic devices, and infrastructures for Infectious Diseases.

2. SPEAKING POINTS

- I thank you for the opportunity to meet the [REDACTED] of Merck.
- I welcome your decision to meeting in Brussels and wanting to discuss the European dimension of research and innovation.
- Working together in research and innovation is the only way for facing up to the global challenges. The success of the Merck group is a great example for that, with its activities in diverse businesses, with the common theme of chemistry.
- From pharmaceuticals to performance materials Merck demonstrates business success in very different markets.
- The Commission supports innovative companies such as Merck by promoting research and innovation in Europe in a number of ways.
- Firstly, it implements the highly successful EU research and innovation programme Horizon 2020. This programme spans the entire research and innovation value chain from supporting basic research (through the European Research Council) to financial instruments.
- Merck companies have been actively participating in a number of EU projects in the past, notably with very strong participation in projects supported under the partnership between the EU and the pharmaceutical industry, the Innovative Medicines Initiative (IMI).
- I encourage Merck to continue to participate in all kinds of EU projects and to also make use of the financial instruments available under Horizon 2020 for furthering research and innovation investments in Europe.
- To incentivise investment in R&D for uncertain markets such as the one for Infectious Diseases, the European Commission is working to create a specific new financial instrument to facilitate the development of novel interventions for Infectious Diseases.

- The Infectious Disease Finance Facility (IDFF) will operate via risk-sharing loans where loans are repaid depending on project success. It aims to attract co-investment from other investors.
- The European Commission has decided to look closely at barriers to research and innovation with the goal to significantly cut red tape. Services have solicited input from major industries and are preparing concrete actions.
- Continued dialogue with all relevant stakeholders will be essential to improve the framework conditions for research and innovation in Europe.
- Input from leading industries such as Merck is essential for succeeding in this endeavour and Merck should become involved in this.
- With healthcare business representing the majority of Merck's activities, some specific comments on the pharmaceutical industry:
 - The pharmaceutical industry is a key asset both for the European economy and for European citizens. It is a high tech industry where Europe is amongst the world leaders and it is an industry that contributes to addressing some of the most pressing societal challenges in health and the ageing of the population.
 - It also is a beacon of Europe's role in the world, giving rise to world-wide collaborations and delivering solutions for world-wide challenges.
- The Commission is proud to have entered into partnership with the pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations to create IMI.
- IMI has demonstrated its value also through projects with participation from Merck, for example by delivering tools for predicting drug safety or by creating the European Lead Factory, where drug discovery projects from large industry and SMEs as well as academia can use a very high quality European compound collection for screening targets.

- Like any partnership IMI requires the continued commitment from the partners. Active participation from Merck and the other EFPIA member companies is essential, in particular in light of the mid-term evaluation of Horizon 2020 in two years' time.
- At that point we must already be able to demonstrate the success of IMI2, both in inputs and outputs. As we have only little time, this is a challenge that EFPIA, the academic research community, SMEs and the European Commission, together with the IMI programme office can only meet together.

3. DEFENSIVE POINTS

How will the Commission create policy consistency in healthcare and pharmaceutical policies and ensure that, as well as its focus on financial sustainability, health systems are encouraged to reward quality and equity of access to care?

The Commission is aware of the importance of health and its implications for the competitiveness of the industry. In light of the increased co-operation between the services following President Juncker's announcement, high degree of consistency is to be expected.

How the Commission is going to reduce the fragmented approach to evaluating the value of new medicines for improved access?

The access to medicinal care raises specific concern. This was also raised in the Commission's Health Systems Communication of April 2014. Possible alternative approaches will be explored as part of a study launched in December under the Public Health programme, to be finalized by 2015. DG SANTE and DG GROW are co-operating on this initiative and will invite EFPIA to participate in a stakeholder review in the second half of this year.

The well-established cooperation between HTA bodies supported by the Commission through projects and most recently a Joint Action EUnetHTA, as well as the recently adopted Strategy for EU cooperation on HTA adopted by the HTA Network only few months ago (October 2014), are also key instruments, which can help reducing fragmentation in evaluating the value of medicines. The key role of HTA in this area is well acknowledged in the Council Conclusions on Innovation for the benefit of patients.

How will the Commission ensure that, as well as its focus on financial sustainability, health systems are encouraged to reward quality and equity of access to care?

It is clear that the importance of the effectiveness and accessibility of health systems has increased under the European Semester.

Specifically for medicinal care we need to consider accessibility issues. This was also raised in the Commission's Health Systems Communication of April 2014. Therefore, the out-of-pocket cost to patients for medicinal products is monitored specifically and, where relevant, will be reflected in the European Semester.

The role of the industry is crucial in order to deepen the understanding of challenges in the accessibility of medicinal care and related country-to-country variations bring forward further evidence and data.

Will the Juncker investment package mean that EU funds foreseen for health research and IMI 2 will be used for other initiatives?

IMI 2 is a key partnership for delivering better health for our citizens and boosting jobs, growth and investments in the European life sciences sectors. We are fully committed to IMI 2 and there will be no reduction of the IMI 2 budget.

Other innovative initiatives such as the Infectious Disease Finance Facility (IDFF) may be included under EFSI as IDFF clearly supports the Juncker's agenda for Jobs, Growth, Fairness and Democratic Change and his investment plan.

Despite major improvements, the Horizon 2020 rules are still seen as too cumbersome by a number of EFPIA members. They have asked for further derogations from the Horizon 2020 rules for IMI projects; can this be achieved?

Simplification was a leitmotif in our work on Horizon 2020 and we have received a lot of positive feedback from the research community about our new funding programme and the fact that we have slashed a lot of red tape. Of course things are never perfect and can always be improved. My services are committed to working together with EFPIA and the IMI office in order to find solutions to any outstanding issues. We will use all the flexibility in the Horizon 2020 rules to achieve it.

4. CURRICULUM VITAE

List of participants from Merck Group, as originally communicated



Additional participants from Merck side will be

[REDACTED], [REDACTED]
[REDACTED].

There are no CVs for

[REDACTED]
[REDACTED]









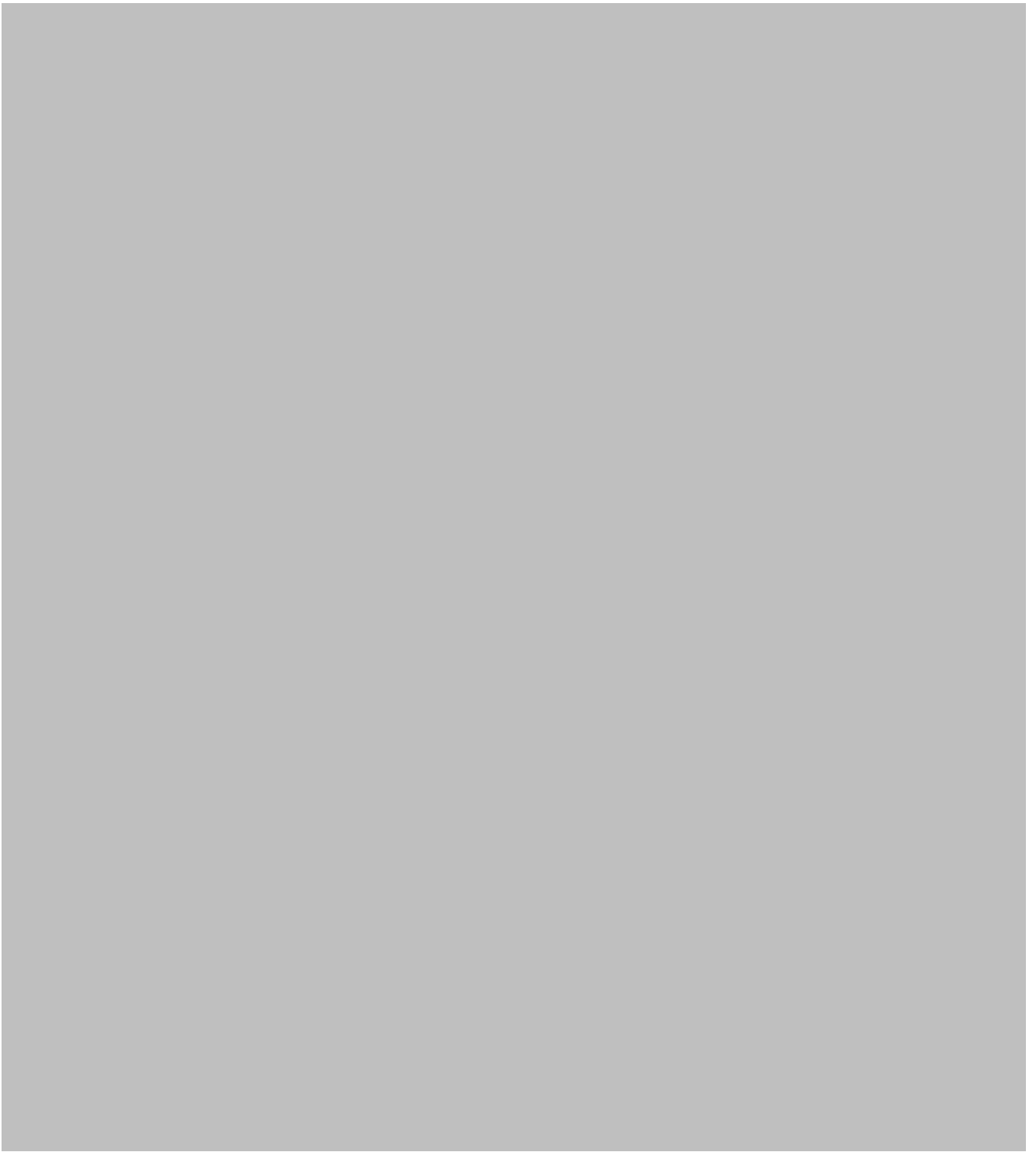












5. BACKGROUND INFORMATION

5.1 The European pharmaceutical industry in key figures (sources: EU Industrial R&D Investment Scoreboard; EFPIA)

The pharmaceutical industry is an important part of the European economy:

- Breakdown of the **world pharmaceutical market** (2013 sales worth €655 billion): North America (41%), Europe (27.4%), Africa-Asia-Australia excluding Japan (16.1%), Japan (9.7%), Latin America (5.8%)
- **EU-28 trade balance for pharmaceutical products:** in excess by €55.6 billion (2013)
- **Employment in the pharmaceutical sector** in the EU: approximately 700,000 people (in 2013), of which approximately 1 out of 6 in the pharmaceutical R&D. This represents close to 2% of the total manufacturing workforce.

The pharmaceutical industry is one of the cornerstones of a knowledge-based economy given the complexity of production processes and development as well as the nature of many new medicines:

- According to the 2014 EU Industrial R&D Investment Scoreboard, the **Pharmaceutical R&D expenditure** was in 2013: €27.5 billion in the EU, €41 billion in the USA, €10 billion in Japan, €18 billion in other countries.
- According to the 2014 EU Industrial R&D Investment Scoreboard, the pharmaceuticals and biotechnology sector amounts to 18.0% of total business R&D expenditure worldwide in 2013 (higher than all other sectors).
- **R&D intensity of the sector of Pharmaceuticals and Biotechnologies, as percentage of net sales** (2012): 14.4% (to be compared to 9.9% for the sector of software and computer services)
- **Top 5 investments in pharmaceutical R&D in Europe** (2012): Germany (€5.8 Billion), United Kingdom (€5.2 Billion), Switzerland (€5.0 Billion), France (€4.4 Billion), Belgium (€2.3 Billion) (2012).
- According to the 2014 EU Industrial R&D Investment Scoreboard, the **10 top R&D investors in 2013 include 3 pharmaceutical industries:** Novartis (5th; €7.2 billion) and Roche (6th; €7.1 billion) from Switzerland, and Johnson & Johnson (8th; €5.9 billion) from the US.

Some further key figures related to pharmaceutical industry:

- Developing medicinal products is increasingly complex, expensive and risky. **Cost for bringing a new chemical or biological entity to market** is €1.15 billion in 2013, compared to €0.87 billion in 2000.
- On average, only one to two of every 10,000 substances synthesised in laboratories will **successfully pass all stages of development required** to become a marketable medicine.
- By the **time** a medicinal product reaches the market, an average of 12-13 years will have **elapsed since the first synthesis of the new active substance**.

5.2 Recent activities of IMI 2 and current issues

The Innovative Medicines Initiative (IMI) launched its **4 first calls for proposals** since 7 July 2014. In particular, the second call for proposals was launched on 6 November, under a **new Ebola+ programme for Ebola and other filoviral haemorrhagic fevers**. The call was closed on 1 December. The evaluations took place in mid-December and 8 proposals for research on Ebola (vaccine development, manufacturing capability, deployment and compliance of vaccination, and rapid diagnostic tests) have been selected for funding, representing **more than €114 million from Horizon 2020 as well as more than €101 million from EFPIA companies through in kind contributions** (however not including Novartis). A press release was published by the Commission on 16 January, informing about the selection of the **8 projects** and the on-going signature of grant agreements¹. Based on the outcome of this call and taking into account additional research needs, further calls of the Ebola+ programme will likely be launched in the first half of 2015.

Six Strategy Governing Groups have been established to give advice to the IMI2 Governing Board about call topics to be launched. These six thematic groups have now started their work. Nevertheless, the final **commitment of the EFPIA industries** to the identified topics will remain the limiting factor for successfully launching the calls and achieve the budget foreseen for 2015. In 2014, there had been some concerns that the overall EFPIA commitment from EFPIA companies would by far not match the foreseen EU contribution, an issue that was resolved only late in the year, with contribution from EFPIA industries to call 2 about Ebola research.

5.3 Background information on Merck

Merck KGaA is a multinational company based in Darmstadt, Germany. It was founded in 1668 making it the world's oldest pharmaceutical and chemical company. Shares in Merck are part of the DAX, the index of the 30 largest German companies. *It should not be confused with Merck & Co (also called MSD), a US based pharmaceutical company.*

Merck Group is a conglomerate organised in three business sectors: Healthcare, Life Science and Performance Materials:

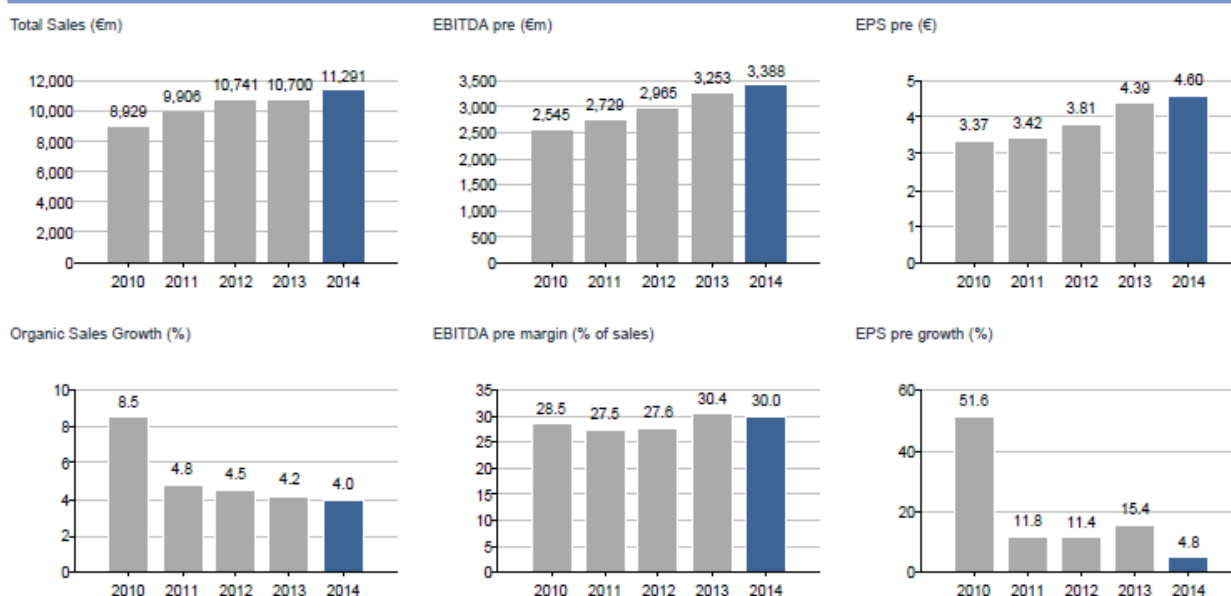
- Healthcare comprises the business of Merck Serono (biopharmaceuticals), Consumer Health (over-the-counter products), Allergopharma (allergen immunotherapy) and Biosimilars.
- Through Merck Millipore, Merck develops over 60,000 tools for the research, development and production of biotechnology and pharmaceutical drug therapies. Merck Millipore is a top tier supplier to the life science industry.
- Performance Materials comprises Merck's entire specialty chemicals business. The portfolio includes high-tech performance chemicals for applications in fields such as consumer electronics, lighting, coatings, printing technology, plastics, and cosmetics. Merck is the world leader in liquid crystals for displays, used for example in TV screens. The strong position of Merck in this business is due to its leading technology position and the high quality demands of customers from the consumer electronics industry worldwide. All such leading companies worldwide are customers of Merck (notably from Korea and China).

¹ http://europa.eu/rapid/press-release_IP-15-3343_en.htm

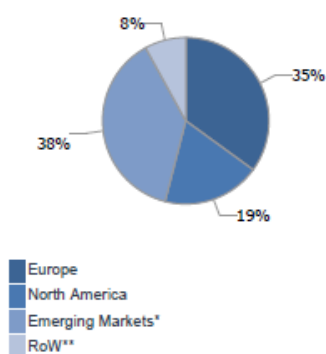
In 2014, Merck generated total revenues of €11.3 billion. When considering its pharmaceutical activities, Merck KGaA ranks in the world top-25 of pharmaceutical industries. The Group invested €1.7 billion in R&D; it employs 4,700 researchers worldwide, more than 1 out of 10 employees, working in one of its 14 global R&D hubs.

Merck KGaA is a full member of EFPIA (the European Federation of Pharmaceutical Industries and Associations) and it participating in 23 IMI projects for an in-kind contribution of more than €1.6 million.

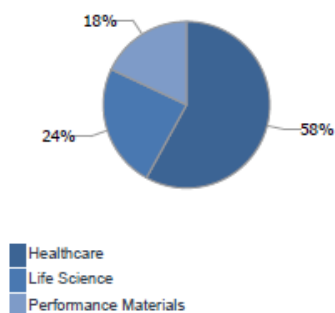
Key figures for Merck Group



Sales by Geography (2014)



Sales by business sectors(2014)



* Emerging Markets: Latin America & Asia w/o Japan

Contribution of different business units to sales and earnings:

Business unit	% of sales	% of EBIDTA**
Merck Serono*	51	51
Consumer health*	7	5
Performance materials	18	25
Merck Millipore/life science	24	19

* Merck Serono and consumer health have been combined as of Jan 2015 into a single healthcare unit

** Earnings before interest, taxes, depreciation and amortization