

## Interview with José Miguel Vela, research director of Esteve

**Please briefly describe the companies you explore, including their activities in research and innovation (techno-scientific area and scale) as a background for the following questions.**

Esteve is a Spanish pharmaceutical chemical business group with headquarters in Barcelona and offices in China, United States, Italy, Mexico, Portugal, Sweden and Turkey. Its products are directly marketed in 40 countries and in over 60 countries through the company's clients.

The origin of Esteve dates back to 1929 when the pharmacist Antoni Esteve i Subirana founded the first company in Manresa (Barcelona). Today, the management of this family business includes members of the second and third generation of the original founder.

According to data from 2014, 2.300 professionals were employed by the group; 245 of whom (12%) worked in research. Investment in R&D for the same year amounted to EUR 63 million. The total volume sales in 2014 reached EUR 830 million, of which EUR 498million (almost 60%) came from international markets.

The group is divided into three areas:

- Pharma, which brings together R&D activities and the commercialisation of health medications.
- Generics, which includes Pensa Pharma (the commercialisation of generic products), Pensa Dose (the development and commercialisation of generic products for third parties), and Operations (the manufacture of pharmaceutical products for the Group and for third parties).
- Chemicals, which includes the development, manufacturing and international marketing of active pharmaceutical ingredients.

Esteve also has Support Units which provide the areas with support in a transversal way and include departments such as Human Resources, Finance, Information Technologies, the Legal Department, Sustainability and Communications.

The main R&D activities are developed in the area of pain relief and analgesics, although Esteve also works on the development of products in other areas of health, such as AIDS, some minority illnesses and other areas. The R&D process takes in all stages, from the formulation of therapeutic hypotheses or pharmacological discoveries, to the launching of products on the market, during which the group also carries out monitoring activities.

In Barcelona, the company develops its R&D in a scientific infrastructure called the Barcelona Science Park, an infrastructure which is home to research centres, university centres and private companies, and which aims to promote research excellence and

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establish links between companies and research. The Park was inaugurated in 1997 and was an initiative from the University of Barcelona. Among its diverse objectives, it aims to promote scientific culture and to foster scientific vocations.

Dr. José Miguel Vela is head of Drug Discovery and Preclinical Development at Esteve. Within the R&D process, this department handles the stages during which therapeutic hypotheses are formulated, up to the point when preclinical developments turn these drugs into candidates ready to pass to phase I, in which tests are carried out to evaluate if the medicines are suitable for humans. Vela described other departments within the Pharma division which are involved in other aspects of the R&D process, such as the clinical development of molecules in phases I and II, pharmacovigilance, or the monitoring of products already on the market, institutional relations with the authorities, medicines agencies and the quality control of products.

The interviewee also highlighted the importance of the aforementioned Support Units, which are transversal in nature and responsible for producing reports on sustainability, the observance of the code of ethics, safety and prevention, good practices, and other questions related to the company's social and corporate responsibility, in addition to the departments mentioned above.

As well as drug research, Esteve also carries out R&D in other related areas, such as advanced intermediates and active ingredients for the pharmaceutical industry (both for the company itself and for third parties); the optimisation of synthesis processes of new products (a line in which extreme care is taken in relation to questions concerning the environment and sustainability); and R&D lines which focus more on pharmaceutical innovation or industrial pharmacy aimed at improving the parameters of medicines.

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### **How do the companies address issues of responsibility in research and innovation, and which dimensions of RRI can be identified in the organization of research and innovation activities at the companies?**

While José Miguel Vela is more than familiar with the concept of RRI, he tells us that it is not explicitly referred to in Esteve's strategic documents. Nevertheless, most dimensions of RRI are implicit in the company's plans and within its guiding philosophy. Vela says that this is largely due to the family nature of Esteve.

**‘Being a family company means that aspects such as human relations, image, our contribution to society and so on, are always high up on the agenda. This is a company that is highly aware of its role in society. There are not many large-sized companies in Spain that carry out biomedical research; there is a lot of small-scale biotechnology, and we are aware that we must be attractors of all these small companies and, at the same time, serve as an example of good practice in every possible way.’**

He explained how Esteve dedicates significant resources to its relation with society, to quality controls, sustainable development, ethical aspects in all R&D processes, and to production.

‘In a way, we are even ahead of legislation itself.’

As an example of the company’s social conscience, Vela explained two current lines of research. One is the HIVACAT project being carried out by the company alongside Barcelona’s Hospital Clinic and Germans Trías i Pujol Hospital of Badalona, for the development of a vaccine against AIDS. The other is SANFILIPPO and consists in the development of a gene therapy to cure the rare illness that bears the same name. This is an illness of genetic origin that causes the death of the children and young people who suffer from it. This second project is being carried out with the Autonomous University of Barcelona’s Centre for Animal Biotechnology and Gene Therapy.

According to Vela, although there is hope that a product will one day be launched on the market, these actions represent more of a social investment rather than a measure calculated to obtain any kind of financial reward. These are lines that generate many articles and significant knowledge, but that do not generate returns on investment given the nature of the groups this research is aimed at (developing countries and very small groups of people).

‘These are activities that we fund to generate knowledge and with a social purpose.’

The interviewee also emphasised that Esteve does not see itself on the margins of society but, rather, as an active part of it. To undertake research and development on new therapies, the first thing they do is to define the medical and therapeutic needs that are currently unmet. In fact, this constitutes one of the three basic pillars of Esteve’s R&D strategy, as described on their website: ‘to respond to unmet medical needs through scientific excellence’. And this process is made possible by locating society at the heart of its strategies.

‘In the academic world, one can carry out research in order to generate knowledge, whether this will have any applicability or not. You do not have to contemplate whether this will be applied in society. In this industry, if you do not carry out research aimed at responding to an unmet medical need, then you have a problem. You’ll spend a lot of money on something that is not useful’.

Vela highlights the fact that Esteve is part of Farmaindustria, the business association of the Spanish pharmaceutical industry, and of the European Federation of Pharmaceutical Industries and Associations (EFPIA). Through these organisations, and within the European

framework, aspects that are closely related to RRI are covered and initiatives are taken to respond to, raise awareness, and open up the research carried out by the pharmaceutical industry, in line with the concept of 'responsibility' which is a component part of RRI.

As described in the following sections, the implicit dimensions of RRI that Esteve addresses in its R&D lines are communication and public engagement, the promotion of scientific vocations, ethics, open access and equal opportunities. The company also places great emphasis on sustainability and the environment, particularly in production processes.

All these dimensions are addressed not only by the company's Support Units, but also by the Dr Antoni Esteve Foundation, which promotes links between the company and society, and some policies of the Barcelona Science Park to which the company's R&D subscribes.

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## **How does RRI relate to CSR aspects and activities? Are these separate or intertwined domains, and how is this visible in research efforts and company strategies?**

Since RRI is not explicitly mentioned in Esteve's strategic lines, the concept is not referred to in relation to Corporate Social Responsibility (CSR). However, to a certain extent, the dimensions of RRI are inscribed within the company's CSR.

As cited by José Miguel Vela, aspects such as ethics, gender questions, communication, sustainability measures and the environment are considered by the company's Support Units. It is worth noting that these dimensions are regulated in a transversal way across the whole company.

A part from this, other entities linked to Esteve also assume some dimensions of RRI. One of these is the Dr Antoni Esteve Foundation, created in 1983 by the founder's sons and daughter. The organisation's main objective is to promote advances in pharmacology and medicine through communication and scientific discussion. In order to do this, it organises round tables, discussion groups, training seminars and research awards and also coordinates publications in different formats which are generally related to scientific communication. In addition to carrying out communication activities, it also carries out training for communication researchers and for communicators in the treatment of scientific data.

Esteve also addresses some of the dimensions of RRI in the context of the strategies and actions carried out in the Barcelona Science Park, in which the company develops its R&D. As explained in the previous section, the park drives forward questions of ethics and scientific education and Esteve supports these initiatives and participates in them to the best of its ability.

Other aspects, such as open access, are carried out by Esteve thanks to its participation in European Union projects that emerge from collaborations with other entities as well as public centres and universities. These are projects that enjoy public and private funding, as is the case of Esteve.

All these dimensions are carried out with mechanisms that are described in detail in the next section.

## **Which, if any, mechanisms are in place to accomplish RRI?**

### **Science and society**

José Miguel Vela showed awareness of the fact that, in general, the image of the pharmaceutical sector in society is not good compared to other sectors. He attributes this to cases of bad practice by various companies carried out over the years. In this sense, the interviewee emphasised the need to raise awareness among society of the whole process of

discovery, research, development and innovation in relation to drugs. The need to improve this poor image and to highlight, for example, that the pharmaceutical sector invests more in R&D than any other; all of this falls unquestionably under the banner of communication and dissemination.

‘The global pharmaceutical industry falls short when it comes to explaining itself.’

In terms of scientific communication and dissemination, of particular note is the European and IMI project in which Esteve collaborates, titled European Patient’s Academy on Therapeutic Innovation. The aim of this project is to provide scientific, objective and comprehensive information to patients on research and the development of medicines. This initiative also allows the group to maintain a dialogue with patients and to obtain information about their real needs.

With regard to specialised communications, the company contributes to congresses and other events related to Esteve’s main lines of research. It also carries out ongoing training for medical professionals, researchers and university students. Vela also highlights the development of mobile applications promoted by Esteve to facilitate relations and dialogue between doctors and their patients, to establish better communications between both parties, and to carry out more precise health monitoring. An example of these applications is *ExpertSalud*.

Parallel to this, Esteve puts the company’s aim to raise awareness of research in society into practice mainly through its foundation, the Dr Antoni Esteve Foundation, as already mentioned above. Since its creation in 1983 up to 2013, the entity has organised 239 activities and has launched 218 publications. Among these many different actions we find an abundance of communications for scientists, doctors and for the media, to train them in how to raise awareness of science and research in society.

On the other hand, the fact that Esteve’s R&D in the Catalan capital is developed in the Barcelona Science Park, where it is in close contact with other companies, research centres and universities, means that the company is actively involved in the dissemination activities that are developed in the Park. Specifically, the Park is home to the Research in Society programme, with over 80 activities aimed at pre-university and university students and the general public.

‘As a company, we could have closed ourselves off from all these initiatives aimed at disseminating scientific research that take place in the Park. But no, we have opted to participate as fully as possible in all of them.’

### **Scientific education / vocations**

Of the projects carried out with EFPIA and IMI, Vela highlighted the European Medicines Research Training Network, an educational and training platform that covers the whole research life cycle for medicines, from basic science to clinical development and pharmacovigilance.

In the context of the Barcelona Science Park, which is home to the company’s laboratories, the Research in Society programme includes activities aimed at students of Primary, Secondary, High School and University. Different events are organised within this context, including scientific seminars, open days and student placements, in which Esteve is also

involved. The company also advises students who are carrying out research projects in their institutions. Furthermore, the company also welcomes both undergraduate and postgraduate students who wish to carry out placements.

## Open access

Esteve is involved in a total of nine European projects through EFPIA and the Innovative Medicines Initiative (IMI), which are public-private consortiums (a collaboration of European funds and company funds). Of these projects, José Miguel Vela wished to highlight some whose objectives are to collect and publish data and information through open access.

- **e-TOX.** A project about toxicity studies of companies' pharmaceutical products. These companies collect information about the toxicity of their products during development and production processes, which can be of great use to other companies. The project consists in collecting all the information and then sharing it on an open access database.
- **OPS, Open Pharmacological Space.** This consists in creating databases which can be consulted by anyone, with information for the selection of compounds, using chemical libraries and targets of pharmacological interest. This information can contribute to public and private biomedical research.

## Ethics

José Miguel Vela explained that Esteve has a strict code of ethics which must be adhered to by all. This is not just restricted to the company's R&D, but covers all business practices.

'Albert Esteve, managing director of the company, personally sends the code of ethics to each and every employee, and each of us has to read it and sign it.'

Esteve is also creating a mailbox that will help to ensure compliance with the code of ethics. Some employees will be tasked with the job of receiving anonymous complaints that may be sent from anyone within the company who has observed or suspects that the code of ethics is being breached, in order for the company to be able to take corrective measures.

Apart from the company's own code of ethics, and through the Barcelona Science Park Ethical Committee, Esteve is also committed to ensuring compliance with legal standards on the well-being and health of the animals used in preclinical research.

## Gender

The Department of Prevention and the Environment carries out ongoing training on labour risks, psychosocial risks, etc., and, according to Vela, the question of gender is given particular consideration.

'In fact, here in R&D there are even more women (60%) than men (40%). And the way this balance is achieved is, quite simply, by not discriminating by sex but rather by seeking equality'.

Apart from this, its policies on work-life balance are flexible, even more so than those stipulated by law.

‘As soon as a woman knows she is pregnant, she stops working in the laboratory and carries out office work, for example.’

### **Which are the perceived barriers to accomplishing RRI?**

According to José Miguel Vela, the main impediments in the way of RRI are economical and practical. Because of this, many of the measures and instruments used to comply with RRI aspects constitute a set of actions that do not produce direct economic returns.

It is precisely this, the quality systems, control systems, communication, training, and the participation of all the European projects that fund companies such as Esteve, without expecting any economic returns, that represents a barrier to the achievement of RRI in José Miguel Vela’s opinion.

Vela contextualised this reflection within the economic Spanish crisis of recent years. In general terms in relation to the pharmaceutical sector, having people working on European projects in which private companies invest significant quantities of money comes at a price. If companies are only motivated by the returns they can make on such investments, then in a situation of crisis the company’s expenditure is cut back and this has a detrimental effect on everything else.

‘I think that we are living through a period in which many companies have had to make cutbacks and reduce their structures. And what has happened is that everything that is not directly linked to economic returns has been got rid of. And I think this is a great threat’.

To illustrate this, he gives the example of highly competitive countries such as China, who produce at lower costs not just because they have lower salaries, but also because they do not take into account the other aspects. In other words, we are talking about production models in which investment is only made if economic returns can be expected.

‘Esteve is also in China, but it has maintained a presence there while also trying to maintain its quality standards. If we said that we had gone to China to produce more cheaply, you would think that we had made an error. Well, in fact, what we have done is to implant our standards there, the very same ones as here.’

In Spain, during the crisis, pressures increased in relation to the price of medicines to such an extent that this seriously affected the pharmaceutical sector. Despite this, José Miguel Vela pointed out that Esteve opted to maintain its structures and its activities of low economic return.

‘But if this had not been the family business that it is, and if a CEO had been contracted to get the company out of a difficult situation, then they would have got rid of all of this. They would only have left those aspects that serve to comply with current legislation and nothing else.’

From these reflections we can gauge that one of the impediments in the way of RRI in the private pharmaceutical sector is the extent to which the management boards of private companies take on board the social conscience. Moreover, Vela also highlighted that RRI brings returns in relation to brand image in the long-term, but not in the short-term. To some extent, being conscious of this long-term return could help to improve the poor image

that society has of the pharmaceutical sector. And this is something that the management teams of other companies in the sector would do well to consider.

On the other hand, Vela did not think that there is a lack of awareness among researchers of RRI issues. He considers that all researchers are ultimately motivated by thinking that their work may help or benefit people in some way, thus suggesting that researchers feel a sense of responsibility towards society.

‘Doing R&D is of course a job, a way of earning money. But in the end, what motivates you is that what you discover with your team will be of some use. It is true that the medicines will be commercialised and have to bring with them some kind of economic return to guarantee the sustainability of the company, but in the last instance, the motivation is more moral than economic. **As a researcher, when you discover something and you are excited about it and see that it is going well, you are not thinking about how much money your company is going to make; you are thinking that this is going to be useful.**’