Title: Innovative medicines in the portuguese private health sector: a strategic vision

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Innovative medicines in the portuguese private health sector: a strategic vision
Abstract

The present dissertation aims at contributing to a strategic view over the use of innovative medicines in the Portuguese private health sector, as a way of being complementary to public system that nowadays finances most of the innovative medicines.

With the rationalization of expenses in the public health sector, pharmaceutical companies tend to look for opportunities of expansion to the private sector.

The creation of innovative financial models for the private sector to cover innovative treatments is the proposed way of surpassing the restriction on the NHS sales of innovative medicines.

This can be both for differentiating private health providers from the NHS or for the creation of premium services that can be differentiated from other private providers of the Portuguese market.
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Innovative medicines in the Portuguese private health sector: a strategic vision

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**Acronym List**

- ACSS Administração Central do Sistema de Saúde
- ADM Assistência na Doença aos Militares das Forças Armadas
- ADSE Assistência na Doença aos Servidores Civis do Estado
- APHP Associação Portuguesa de Hospitalização Privada
- CNECV Conselho Nacional de Ética para as Ciências da Vida
- DGS Direcção Geral da Saúde
- DRG Diagnosis Related group
- EMA European Marketing Authorization
- ERS Entidade Reguladora da Saúde
- ESS Espírito Santo Saúde
- EU European Union
- FDA American Food and Drug Administration
- GDP Gross Domestic Product
- HPP Hospitais Privados de Portugal
- INE Instituto Nacional de Estatística
- IMI Inovative Medicine Initiative
- Infarmed - Autoridade Nacional do Medicamento e Produtos de Saúde
- JMS José de Mello Saúde
- MA Marketing Authorization
- MCDT Meios Complementares de Diagnóstico e Terapêutica
- MoU Troika Memorandum of Understanding
- NHS Portuguese National Health System
- OECD Organization for Economic Cooperation and Development
- OOP Out of Pocket
- PPP Public Private Partnership
• PT-ACS Portugal Telecom - Associação de Cuidados de Saúde
• SAD Serviço de Assistência na Doença PSP GNR
• SAMS Serviço de Assistência Médico-Social Bancários
• SIGIC Sistema Integrado de Gestão de Inscritos para Cirurgia
• SPC Supplementary Protection Certificate
1. Introduction

Management problem

Within the Portuguese health context, is the introduction of innovative medicines strategic to the private health providers?

Or, more specifically:

Within the Portuguese health context, can the private health sector absorb/finance the uncaptured pool of patients in need for innovative medicines?

Relevance of the management problem for business organizations

The management problem above described is relevant for the business organizations of the Portuguese private health sector: the private health providers, private health financers (health insurances, private subsystems) and it’s of major importance to the pharmaceuticals with innovative medicines patents.

This problem can also affect the performance of the other players of the health systems, namely the NHS (Portuguese National Health System) and the public subsystems. If put in practice may also call the attention of health regulators.

The private sector creates values either through complementary or alternative services to the NHS.

Expenses with medicines represented in 2010 24% of the total health expense: 17.300M € (OECD, 2012). Innovative medicines due to their usual high cost, have been contributing to an increase on the healthcare expenses. Oncologic + Rheumatoid Arthritis + HIV AIDS medicines represented 2,71% (469M €) of total health expenses in 2010 (Infarmed, 2012).

Pharmaceutical companies observe that not all the patients with a specific disease are being treated: there is an uncaptured pool of patient and therefore an uncaptured potential. These patients could be in part captured by the private health system, if a strategy to finance them existed.

The question in analysis arises from the project developed on the Consulting Lab: Unlocking the private sector, for innovative drugs of Novartis pharmaceutical. The project was developed having as sponsor the pharmaceutical company Novartis Portugal.

The relevance of the problem for the understanding of management

The question: Within the Portuguese health context, is the introduction of innovative medicines strategic to the private health providers? is a question about entering a new market with products that are the most innovative of the pharmaceutical industry, usually they’re also the most expensive and, it could be said, the most premium.

An analysis of innovation management through the entrance of innovative products in new markets is the paradigm analysed.
2. Literature review

(a) Review of conceptual frameworks

(a 1) Entering a new market with innovative products

In this work project it’s analyzed the entrance of pharmaceutical companies with innovative medicines into the Portuguese private health market.

Five forces model

From the five forces model of Michael Porter is possible to analyze the threat of new entrants, threat of substitute products or services, bargaining power of buyers, bargaining power of suppliers and rivalry among existing firms.

The threat of new entrants in the private market is high if these new entrants are the established innovative pharmaceutical companies already with sales on the public system.

The substitutes can be other innovative products, technology or treatments that can be a choice for the private providers to differentiate themselves. But the joint provision of the latest technology, of innovative products (from several innovative pharmaceutical companies), as well as of more effective treatments, can finally leverage all together the providers differentiation.

The bargaining power of the buyers of innovative medicines (centralized procurement centers by health group) depends on the patient pool they might be able to attract, in that case a price reduction might happen due to economies of scale.

The rivalry among existing firms is not usual for innovative medicines once there is usually only one product to treat, prevent or cure that disease. Actually many times two companies share the ownership of the same innovative product (because of the expensive cost of development). However competition may arise from off label products, or from less expensive medicines for different medical conditions (preventions, treatment, cure) – eg. acute asthma patients can punctually control an asthma attack with a cheap medicines but they could prevent it with a innovative but much more expensive medicine.

Innovation as a creative destruction

Pharmaceutical companies with truly innovative medicines seem to be the unlocking of a new market: the private health market. They already have on their product portfolio innovative medicines that are so disruptive that destroy other established firms competencies or complementary assets - creative destruction concept (Schumpeter, 1950). These companies products or treatments became obsoletes when compared with the truly innovative drugs. The process of entering the private market with effective innovative drugs is therefore an Architectural Innovation in the Abernathy and Clark adapted model, 1985.
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Innovative medicines that bring major benefits highly influence the patients (consumers) lives. Once again, these drugs disruptiveness may make obsolete established firms solutions to treat, prevent or cure a specific diseases. These truly innovative medicines are Strategic Innovation assets, they’re key success products that enhance the possibility of entering and dominating a new market.

Truly innovative medicines are so disruptive, they’re new to the world and involved at a system level, they’re therefore breakthroughs for the pharmaceutical sciences and to the world. Being the intellectual property legally protected their strategic advantage is protected for the time the patent is protected, what makes the owner of that compound a monopoly owner if there is no other medicine to be prescribed for the same disease.
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**Fig. 3.** Dimensions of innovation and its examples

Source: Tidd, Joe et al., 2005

<table>
<thead>
<tr>
<th>SYSTEM LEVEL</th>
<th>COMPONENT LEVEL</th>
<th><strong>INCREMENTAL</strong> ('doing what we do better')</th>
<th><strong>RADICAL</strong> ('new to the world')</th>
</tr>
</thead>
<tbody>
<tr>
<td>New versions of motor car, aeroplane, TV</td>
<td>Improvements to components</td>
<td>New generations e.g. MP3 and download vs. CD and cassette music</td>
<td>Steam power, ICT ‘revolution’, bio-technology</td>
</tr>
<tr>
<td>New components for existing systems</td>
<td>Advanced materials to improve component performance</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**New market - new positioning**

The entrance on the new market: the private market is most probably to be done through financing institutions due to the usual high costs of innovative medicine. The health insurances would play a role associated with the private providers that supply the care to patients. A new positioning should be considered for health insurances to target Portuguese aware of the health risks they might face and of the probable rationalization of the public health system. The point of difference would be the availability and the reimbursement of not only innovative medicines, but also innovative treatments and the latest technology. The reason to believe of those innovative treatments would be the European Marketing Authorization (no need of the Infarmed approval for reimbursement) and the additional clinical efficacy and/or effectiveness when compared with the current care (Lievens, 2010).

Consequently, innovation would be more than only on the side of a product innovation, but also, on the side of the position innovation if entering a new market. Both together can initiate what could be a paradigm of innovation - 4 P’s of Innovation (Tidd, Joe et al., 2005).

The concept of market position, introduced by Francis and Bessans (2005), concerns especially the introduction of a established product/service on a new context;
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*Fig. 4. Innovation space (4 P’s of Innovation)*

Source: Tidd, Joe et al., 2005

**Blue Ocean Strategy**

Kim and Maubourgne (2005) present a reflection about how a *Blue Ocean Strategy* can be created. The entrance of innovative medicines in the private health sector can open a window to capture patients that are not nowadays receiving innovative treatments on the public sector for several reasons. The latest medical devices technology is being introduced in private providers as a way of differentiation, some of this technology is only existent on private sector what attracts the best doctors once they want to work with the latest technology. The introduction of innovative medicines should happen in partnership with the financing groups, since the target medicines are very expensive. An investment on patient education might be made announcing the benefits and effectiveness of those new drugs. Some patient pool might be uncaptured because few diagnosis were made, investment in rare diseases diagnosis might therefore be financed by pharmaceutical companies.
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In Resume

In the analysis of the problem of capturing patient pool for innovative medicines the entrance on the private health market is to be the trigger point. A source of radical innovation development as the innovative medicines are, enables a competition against the existing market (mostly the public health market), but, furthermore, a significant market change/disruption against non-consumption creates a complete new market, (Tidd, Joe et al., 2005 and Christensen and Raynor, 2003).

(a 2) Innovative medicines

The concept of innovative medicines is usually associated with higher cost of care. Long term calculations are then done to analyse the savings that can be made either for prevention, treatment/stabilization or cure of a disease, but still the vast majority lead to an increase in expenses. Therefore innovative medicines when compared with the existing care (if there is one), have a cost premium. But premium benefits might also come from the use of these medicines.

The quality of pharmaceutical innovation varies widely. It ranges from breakthrough treatments - for life threatening diseases to minor modifications of medicines that have been on the market for some time.

Valuable innovative medicines are both truly innovative and valuable. A drug can be called truly innovative if and only if it offers additional clinical efficacy and/or effectiveness as compared to
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Current care (Lieven, 2010). If, in addition these medicines fill an unmet medical need we propose to call them valuable (http://ec.europa.eu/pharmaforum/).

Important delays in market access to innovative medicines are observed (IMS Health, 2010). Time to access market is valuable to pharmaceutical companies due to patent expiration over time. Pricing and reimbursement decisions arise then, the magnitude of innovation should be measured through transparent and rational method.

Before a new medicine becomes available to patients it will have gone through a long process of research, registration and market introduction. On average there is a 12 year period between the discovery of a new active compound and the availability of a respective medicine to patients. In estimated numbers preclinical research takes 4 years and 25.2% of the total R&D investment, clinical trials take 6 years and 58.6% of R&D, and the registration and reimbursement procedures take another 2 years and 16.2% of R&D value. The remaining patent period is then of 8 years, after which a supplementary protection certificate (SPC) may be granted for a maximum of 5 years (Nefarma, 2011 and PwC, 2013). The period of time that elapses between the filing for an application for a patent for a new medicine and its marketing authorization (MA) may make the period of effective protection under the patent rules insufficient to cover the investment put into research (Lieven, 2010).

![Fig. 6. Development and patent period of a medicine. Average duration.](Source: Nefarma. 2011: AGIM, Recherche et Vie.)

There should be a clear definition of areas in the health care where there are unmet medical needs. However it’s known that the creation of new scientific knowledge usually depends on serendipity, pure luck or other factors that are difficult to steer, and not on demand pulled approach.
The Innovative Medicines Initiative (IMI) focuses on five disease areas that are considered of unmet need, neglected need or rare diseases: cancer, brain disorders, infectious diseases, inflammatory diseases, diabetes and other metabolic diseases (IMI, 2006).

**Economics**

There should be distinguished several levels of innovation, regardless of the economic costs. Returns on health investments should be calculated including the patient well-being and the economic competitiveness. On a health economic analysis a comparative evaluation of at least two alternative medical interventions is made with both the costs and the health benefits/effects. The current therapy might also be a no action option (Drummond, 2008), if there is no actual treatment, cure, or preventive one. Variables as need, value for money and relative effectiveness could play a role in pricing and reimbursement decision, however nowadays criteria for MA remain to be safety, quality and efficacy.

**Complementary versus alternative service**

As it has been said the private sector creates value either through complementary or through alternative services to the NHS. To position innovative medicines in the private market an analysis should be made over the level of complementariness or alternation of the systems in what concerns truly innovative drugs.

An alternative service is a service that may substitute the other.

In the healthcare system when care is provided both by the public and private sector, patient may opt to choose one or the other. In the Portuguese health system were public care is a universal right the private sector might be considered duplicative (Barros and Siciliani, 2011).
A complementary service offers care that is not covered by the other.

In the health system, care that is not covered by the public can potentially be covered by the private sector. The *interface* between public and private is different: in this case private sector complements the public.

Private providers can also be complementary or alternative one to the others.

The provider offers the service, and it can be reimbursed by the private insurance, by the subsystem or paid directly by OOP or even by the state.

Colombo and Tapay (2004) distinguish the concepts of duplicative, complementary and supplementary for private insurance providers. The supplementary role of insurance is related to the coverage of co-payments of public system.

In Portugal nowadays patients may decide whether to go to public providers, paying the respective co-payment (might be equal to 0), or in the case they have insurance or subsystem go to the private paying a value for the co-payment.

The variables that influence patients choice are the price, the *clinical quality*, the benefit from becoming healthier, *level of amenities*, waiting time and *individual household net income* (Barros and Siciliani, 2011). Innovative medicines enter as a variable that influences *clinical quality*. Different funding systems have different budget possibilities. Nowadays public system has limited budgets, it aims to provide care that has the *highest benefits* or better to be said, the better *benefit cost ratio* for the politically allocated budget (Barros and Siciliani, 2011).

(a 4) Why do patients choose the private health sector

Barros and Siciliani in 2011 intuitively consider that the variables that make the patient choose between different health systems are the amenities, waiting times and clinical quality. Some other variable could be include, for instance the co-payments values or the distance to the health unit. The public and private systems have differences in terms of what they have best. The private health sector tends to be alternative or complementary to the public. In Portugal its usually considered that public hospitals have higher quality than the private – mostly because of its ability to have economies of scope and scale (Barros and Siciliani, 2011), but higher waiting times (Sistema Integrado de Gestão de Inscritos para Cirurgia - SIGIC) and less amenities than the private. It’s important to note that in Portugal doctors are able to practice medicine both on public and private sector at the same time, exclusivity is elective. Some diseases are only treated by the public sector and others by the private sector, the case of haematology for the public hospitals and haemodialysis (CEGEA, 2007), dental care or eye care for the private sector.

From Costa and Garcia study based in Catalonia (2003) evidence suggests than a decrease on the perceived quality in public system generates higher private health number of beneficiaries.
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From the interview with Multicare it was possible to learn that nowadays the public copayments are so high that private insurance plans have usually lower co-payments. Patients therefore weight constantly all the choosing variables to decide either to go to the private or public system.

In case of cancer treatments or emergency care waiting times can be zero or low in the public system (Barros and Siciliani, 2011), in that case the only variable that usually affects the choice is the difference in amenities.

![Fig.8. Choice between public and private care. Public and Private sector interface.](image)

Bigger attractiveness – higher patient pool.
Source: Barros and Siciliani, 2011.

If the public care is very inclusive the private sector can only exist on a duplicative or alternative way. Whilst if the public sector provides no care for a specific disease there is much more scope for the complementary existence of the private sector.

Certainly the presented framework is to be extended to the insurance providers. Patients can opt to pay a health insurance premium if they want to be covered by a private health insurance.

As there might be a reduction on innovative medicines prescription in the public sector, there might be a window for private sector to complement the offer of these medicines. However innovative therapies will require innovative financing models (Portuguese EU Presidency, 2007). Private insurance companies will have an important influence on the emergence of these new financial models. The past years trend of increasing the caps of coverage of insurance plans as a way of including more expensive/low probability diseases may be one of these innovative models. Another innovative financial model could arise from the partnership of pharmaceutical and insurance companies for the same differentiating objective. To acknowledge unmet medical needs, to improve medication adherence and clinical outcomes US insurance companies have demonstrated interest to partner with pharmaceutical companies (Health Research Institute, 2012).
(b) Review of pre-existing attempts to shed light on the problem

The problem in analysis has been more latent over the late years once more innovative and expensive drugs have been found, contributing to an escalation of medicine costs.

The actual economic crisis accentuates the need of rationalization on the public sector in Portugal and the recent entrance of Troika in April 2010 and its Memorandum of Understand (MOU) puts in place cuts in healthcare costs that affect directly medicines.

On their 2006 study Lafuna, and Tilluel analysed Germany, UK, France and Spain on the management of innovative medicines. In the Netherlands a list of ten very expensive medicines was identified in 2002, and they begun to be reimbursed by the Sickness Fund. Critics aroused once the list was based on price and not on cost/benefit ratio. This is a major concern in France where reimbursement of expensive indications by the French Sickness Fund pushed up dramatically the sales of the respective medicines.

How to manage innovative and expensive medicines was identified as a concern throughout the four countries studied, mainly in general hospitals with cancer services. In this case a annual increase in medicine budgets was from 10% to 25%.

In these hospitals campaigns as direct to consumer advertising (DTC) or specific formularies for very costly medicines are used to inform patients. It’s common to exist negotiation of the management of these medications with the hospital physicians and moreover with third party payers for extra budgets.

The pharmacists of the general hospitals in Germany tended to consider the problem of innovative and expensive medicines in German hospitals of little concern. The first reason was that the drug budget(...) for innovative and costly compounds (...) represented less than 5% of the hospital’s total budget (Lafuna, and Tilluel, 2006).

(c) Macro and micro environment analysis: innovative medicines in the portuguese health system

(c 1) Health expenses and care distribution: public and private

The healthcare system is formed by two systems that coexist in the country: the public and the private systems. In 2010 10.7% of GDP was spent on health expenditure corresponding to 17,5 B€ (and 9,8 % of GDP in 2011). Public funding was of 67,3 % of total health expenditure in 2010 with the NHS representing 56,8% of the same total. Private funding is increasing, and was 32,7% of total health expenditure in 2010. The private financing is mainly in the form of OOP payments (co-payments and direct payments by the patient).
In terms of distribution of provided care 40% of the healthcare service was provided by the private sector. Private health expenditure was mostly concentrated in Dentistry, Ultrasound Scans, Clinical Analysis and Specialty Consultation.

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**Fig.9.** Health expenditure as a share of GDP, OECD countries, 2010.

Source: OECD, 2012.

**Fig.10.** Funding mix for the health system, 2005-2010.


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**Fig.11.** Public and private funding divided by service.

(c 2) Private Providers

The private sector is composed by the private providers, that are financed by private insurances, private subsystems, public subsystems, OOP payments, or by the state (in case the NHS doesn’t has enough resources).

The four major private providers represent 70% of market share, generating turnover of 924M € in 2011 corresponding to a 13% growth from 2010. The private providers sector is consolidating more than growing, new branded hospitals and clinics dry up existing small players.

The major player is José de Mello Saúde - JMS (404M €), followed by Espírito Santo Saúde – ESS (270M €) and Hospitais Privados de Portugal - HPP (190M €), with a smaller share, but still very representative there is the Trofa Saúde group (60M €) – values of 2011.

![Graph showing private providers' turnover](image)

Fig.12. Private Providers.

Build, operated and maintained by the private providers but serving the NHS patients there are the Public Private Partnerships (PPP). The Loures Hospital – ESS, the Cascais Hospital - HPP, the Braga Hospital – JMS and the Vila Franca de Xira Hospital - JMS. Currently PPP’s are struggling to break even due to effective risk sharing, to the financing model and to the unfinished restructuring of the hospital map.

(c 3) Private insurances

Roughly 20% of the population (2,15 M) has some form of Voluntary Health Insurance (VHI), 36% are individual insurance plans; the remainder 64% are corporate plans. Health insurance market has been growing but decelerating in 2011. In terms of volume, the market grew 1,5% in 2011 (compared to 7,0% in 2010). Multicare is the market leader, with 600.000 customers in end of 2010, Multicare counts with 16.000 providers, of which 70 hospitals.
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As per Associação Portuguesa de Seguradores, such growth has been fuelled by the growing limitations of the NHS, the increased confidence in the insurance industry, its relatively accessible cost, and the convenience and easy access to health care they provide. However the economic crisis has been hindering such growth.

Average premium paid per insured person was ~250€ per year in 2010. Mainstream insurance companies accept that some ambulatory expenses, which previously demanded the patient to stay over night, to be considered as hospitalization.

Hospitalization, Ambulatory and Dental care are the most contracted coverages.

Insurance companies are not obliged to accept all clients – they may practice skimming, selecting lower risk patients. Clients with pre-existing diseases, chronic or infectious diseases, are generally excluded. Direct skimming methods are expensive, thus indirect patient selection methods are used. There is no offer available for higher risk clients.

Conditions:
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- Waiting periods
- Fixed co-payments per service;
- Caps;
- Higher premiums when pre-conditions are identified.

Private health insurance has contributions (payments) based on risk of the population that take the contracts offered.

In many circumstances, the health insurance arrangement does require patients to make co-payments. Patients may go to health care providers they freely choose if they are willing to pay at the moment of consumption. Co-payments may differ according to existing agreement between the providers and the payers (health insurance companies).

The out-of-pocket payments constitute another source of funds. Part of it is due to pure demand decisions by patients while the other results from health insurance schemes.

(c 4) Subsystems

ADSE is the largest subsystem with 1,3M beneficiaries and is controlled by the Ministry of Finance. ADSE is financed through employee (1,5% on wages) and employer contributions (2,5%) (ADSE, 2011).

![Subsystems diagram](image)


Troika (European Central Bank + International Monetary Fund + European Commission) Memorandum of Understanding (MoU) determines that ADSE should be self-sustainable until 2016. Cost of ADSE, ADM and SAD are to be reduced 30% in 2012 and 20% in 2013, further reductions should be made in subsequent years until attain self-sustainability in 2016. The reduction of expenses is to be made by lowering employer’s contribution, adjusting the scope of health benefits.
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The in-network co-payment of ADSE is 100% for oncology, hemodialysis and child-birth and 80% for mostly all of the remainder acts.

In 2011 total expenditure was 559M €. Expenses with medication in ambulatory and hospitalization accounted for 19,4M €, (3,47% of total ADSE expenses) among which 6,2M € correspond to expenditure with antineoplastic (oncology) and immunomodulators (e.g. acute asthma medicines). The costs with oncology were 4,2M € in 2011.

(c 5) Health expenses with medicines

In 2009 the share of pharmaceuticals expenses in total health care expenditure in Portugal was of 21,5% and of 24 % in 2010 (OECD, 2012). For the average of the EU member states it accounted for 19%. Pharmaceutical expenditure was therefore the third biggest cause of the healthcare costs: after inpatient stay and outpatient care.

![Fig.16. Current health expenditure by function of health care, 2010.](source: OECD, 2012.)

This represented 2% (public + private health expenditures) of Portuguese GDP and it represented 349€ per capita in 2010 (OECD, 2012).

Portuguese healthcare expenses have been said to be of 10,7% of Portuguese GDP in 2010. In relation health expenses with medicines was of 0,95% of GDP for 2009. What represents 18,5% of the NHS budget.
Innovative medicines in the Portuguese private health sector: a strategic vision

From the overall medicine expenses of Portugal in 2009, it cost 68.9% to the NHS, 11.8% to the subsystems with ADSE having the biggest share, 8.4% in 2009. Out of the Counter + Remaining market was 19.4%.
Innovative medicines in the Portuguese private health sector: a strategic vision

Total number of medicines with no reimbursement in 2009 was 42,441 over the 50,118 total medicines in the market. This value has been increasing from 2005 where the number of non-reimbursed medicines was 27,655.

The value of NHS expenditure with the most expensive medicines (≥ €250) was of 0.3% of total NHS expenditure with medicines.

The antineoplastic medicines and immunomodulators agents (medicines used in cancer treatment and intestinal infections respectively) account for 0.46% of the total expenses with medicines.
Innovative medicines in the portuguese private health sector: a strategic vision

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**Fig. 21.** NHS Expenditure Distribution by Pharmacotherapeutic Groups. 

The top substance that had in 2009 the highest number of packages sold was the paracetamol with around 3.6M €. But the top active substance with highest expenditure was the Omeprazol representing about 60.5M € for 2M packages sold. Olanzapina the 4th largest costs 22 M € but has only 0.29M packages sold.

In terms of pharmaceutical companies and what they represent to the NHS cost AstraZeneca is the highest with around 94M €.

(c 6) Are innovative medicines being used by public NHS

Over the past years an intense discussion has occurred over the prescription restrictions and controlled hospitals drug formulary, the discussion has been intensified once Troika entered in Portugal.

The MoU established measures over the necessity of reducing public health expenditure with medicines: reduction of 1.25% of GDP until the end 2012 and about 1% of GDP in 2013 (in line with the EU average). This implies a reduction of 841.857M € until the end of 2012 on the public expenses with medicines, what means about 46.8 M € per month (Costa, et al., 2011).

The health minister asked to Conselho Nacional de Ética para as Ciências da Vida - CNECV for a study about the ethical financing of the very costly medicines for Oncology, HIV AIDS and rheumatoid arthritis. Those medicines expenses represented in 2011 a health expense of 513M €.
Fig. 22. Yearly expenses with medicines

In the US, during the 2010 decade, the total expense with subsidies for cancer drugs has risen from $65M to more than $500M. The cancer researcher Dr Karikios from the University of Sydney, said: "We are seeing some drugs approved that extend median survival by only a few months, yet they add hundreds of millions of dollars to health system costs," "many are asking whether that money could be better spent" (Forbes, 2010).

Rationalization of medicines is one of the top concerns of the NHS. The report of CNECV suggests that the NHS should move from an *implicit rationalization*, what has been happening; to an *explicit and transparent rationalization*. CNECV also considers that ethical fundament exists to promote the cost containment with medicines in the NHS. Those measures should at the same time guarantee the equal distribution of resources. Two visions exist: to give the *major good for major number of people* (Rawls, 1971) and what is considered more realistic view: the major possible good for the major number of people. The CNECV proposes a criteria of choice for two comparable medicines (comparable effectiveness) the *cheapest from the bests* and not the *best of the cheapest*.

*The primary goal of any healthcare policy should be to maximize the health of the population within the limits of the available resources* (Lieven, 2010).

### 3. Method

Methods of research and analysis that were employed:

- Health sector in context
- Study of the literature
- Stakeholders interviews
- Hypothesis matrix that assesses the private market from relevant angles for innovative medicines
- Assess fit of innovative medicines portfolio with providers offer and financing models, identification of opportunities
- Evaluate trends within the health care industry with scholars and major players
- Recommendations
Innovative medicines in the Portuguese private health sector: a strategic vision

Fig. 23. Methodology for the Work Project

Primary data: interviews with some of the major relevant players of the health system.

<table>
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<th>INSTITUTION</th>
<th>ROLE</th>
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<tr>
<td>Universidade Católica</td>
<td>Professor</td>
<td>Miguel Gouveia</td>
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<td>Observatory of PPP’s</td>
<td>Ricardo Reis</td>
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<td>Administrator of Hospital da Luz</td>
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<td>ADSE</td>
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<td>Sofia Araújo Fernandes</td>
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<tr>
<td>Entidade Reguladora da Saúde</td>
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<td>Carlos Coutinho</td>
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<tr>
<td>Parliament</td>
<td>General Director</td>
<td>Maria Jesus Fernandes</td>
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<td></td>
<td>President</td>
<td>Luís Pires</td>
</tr>
<tr>
<td></td>
<td>Former Health Minister</td>
<td>Jorge Simões</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maria de Belém Rosaia</td>
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Fig. 24. Interviewees list

Secondary data: data research from entities like OCDE, Infarmed, INE, APHP, ERS, CEIS and others; and existent literature about the topic – see references list.
4. Results

Public sector
1. High pressure for cost reduction in hospitals, impairing service by lack of resources.
2. Infarmed delaying approval on reimbursement of new indications as means to control total costs in NHS.
3. Troika promotes rationalization of medicine expenses.
4. The public hospitals of NHS may go from implicit rationalization to explicit rationalization as per CNECV document.

Private sector
1. Main players growing by consolidation.
2. Strong reliance on insurance and sub-systems for financing.
3. Size of financing organisations client pool is crucial to secure competitive margins with in network providers and affordable pricing to patients.
4. Insurance companies shifting coverage of ambulatory to hospitalisation.
5. Insurance companies increasing caps values of coverage plan in hospitalization to cover illnesses with very expensive treatments like cancer treatments and cardiac surgeries.
6. Increase in coverage caps and increase in client payment of the insurance plan are not proportional once the probability (risk) of having a very expensive treatment is very low when compares for instance with the number of consultations per year (what is more certain).

Private providers – implications for pharmaceutical companies
• Private health sector is concentrated in four 4 major players. Addressing them would cover 70% of the market.
• However private Ophtha small clinics have high market share, representing the main segment to be addressed by pharmaceutical companies for ophthalmologic products.
• Major private players provide services on some therapeutics which fit innovative pharmaceuticals portfolio, having agreements with major insurance companies and health subsystems.
• Hospital’s specialty doctors endorse the medication, but the allocation of funds is made by Therapeutics Committee.
• Procurement for each group is centralized, handling negotiations with pharmaceuticals by portfolio.
Financing – implications for pharmaceutical companies

- Private health sector is financed by health care subsystems, private insurance, and out of pocket patients.
- Spending in private is increasing in comparison to public.
- ADSE covers 80% of most therapies and 100% for oncology, including medication not reimbursed by NHS.
- Mainstream insurance packages also cover oncology, but with caps that can limit treatment.
- Pre-existing conditions such as diabetes or asthma limit the probabilities of getting health insurance or constrain coverage.
- Relevance of subsystems increases dramatically in catastrophic diseases once they do totally reimburse the treatment contrary to private health insurances.
- Rare diseases although they might have very costly innovative medicines to threat them as they are rare the risk could be spread out throughout the beneficiaries pool without much weight in terms of payment.
- The use of the innovative medicines by the private players can attract more clients by covering those diseases on their health plans.

![Fig.26 Services and financing distribution of main groups.](source)

Source: Interviews.

One of the specialty considered is not so concentrated on the private four major groups, their market share is spread in smaller clinics.

The portfolio fit can be measured by indication considering the pool of patients with the disease, and if they’re approved or not for reimbursement by the Infarmed. The funding should be accessed to verify if the patients can have this expensive medicines reimbursed, either if they are...
ADSE beneficiaries or have a voluntary health insurance (VHI). Of course the disease can only be treated privately if the private providers have the means (human capital, equipment and infrastructures) to treat it. The four major players were analysed: JMS, ESS, HHP and Trofa.

![Portfolio Fit Diagram]

Fig. 27. Portfolio fit

The same product can be indicated for the treatment of several diseases. Pharmaceutical companies estimate the size of target Pool of Patients based on epidemiological data. Products can be prescribed even if not approved for reimbursement by Infarmed, but the probability of capturing patients is very low once these innovative medicines are all very costly not less than 2,000 a year, not more than 50,000 a year.

Financing:
- ADSE Reimburse 80%
- ADSE Reimburse 100%
- Voluntary Health Insurances cover but has co-payment values
- Voluntary Health Insurances doesn’t cover patients with pre-existing conditions/diseases
- Not reimbursed by Voluntary Health Insurances once it is not approved for reimbursement by Infarmed
- Almost no fit for out of pocket, due to the high cost of medicines

Private Providers:
- Private specialists and resources able to give treatment to the disease
- Private specialists and resources NOT able to give treatment to the disease
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Analysis of the Portfolio Fit:
Indications R and S have no fit once they’re not treated by the private sector, not possible technically and financially not attractive, due to the fact that only the public health system has the scale to maintain its attractiveness.

Indication Q has all the patients already captured, therefore there is no fit for an increase in sales.
Indication W and O have 100% fit for ADSE beneficiaries but very low fit for VHI (it’s usually a pre-existing condition when a health insurance plan is signed).
Indication X and Y has lower fit for ADSE (80% reimbursement) and the pool of patients to capture is the highest of all. Almost no fit for VHI.
Indication K, M and Z as they are not reimbursed by Infarmed they have only fit for ADSE beneficiaries (100% reimbursement – Indication K and M; 80% reimbursement - Indication Z)

Fig.28. Actual situation in Portuguese healthcare

Fig.29. Possible trends in Portuguese healthcare sector
5. Conclusions

Presentation of conclusions and implications

Within the Portuguese health context, can the private health sector absorb the uncaptured pool of patients in need for innovative medicines?

Private providers' ability to absorb the uncaptured pool of patients in need for innovative medicines depends on financing models.

Recommendations
1. Make the most use of subsystems, a nearly uncapped financing model, more importantly even for non-reimbursed medications in public.
3. Generate incentives to private insurances to cope with innovative medicines not yet approved for reimbursement as a way of differentiation and complementarity to the NHS.
4. Share efficiency cost studies with private players to allow them to know the cutting expenses, for instance in terms of the duration of inpatient stay.
2. Provide support in co-payments for ADSE patients, in the case of 80% reimbursement, through third parties.
3. In the case of medicines with several annual doses ensure care giving patients with a bundle offering that provides adequate first dose and maintenance therapy.
4. Promote non-explored private market for oncology products in major providers.
5. Educate patients about the best therapies of the market – transparency.
6. Some diseases are not treated in private due to technical and financial reasons.
a-The treatment of the disease requires, moreover than a specific innovative medicine, specialized resources and infrastructure;
b-It is a rare disease therefore it’s not profitable to have the specific resources (medical doctors and nurses or equipment).
7. Incentives to private providers like insurances: agreements could be based in success fees based effectiveness.

Assist in co-payment:
• Support subsystem co-payment cash back via third party.
• Patients submit (partial) reimbursement request to third party.
• Third parties can be patients associations by disease.
• The pharmaceutical company may distribute money to the associations of patient.
• Third party required due to the prohibited contact between pharmaceutical companies and its patients.
The alignment of the private industry players: private providers and private insurances with pharmaceuticals that develop innovative medicines can improve the value creation for the three players. Private providers and insurances by differentiating them from the rationalized NHS and from other private players they would attract more clients to their services. Pharmaceutical companies of innovative medicines would generate value for higher sales of these medicines. Covering the patient pool of patients not covered.

**Discussion of main limitations of study**

After defining this global strategy on how to tackle the private sector, and what are the specificities of each players and the respective trends, a indication by indication analysis should be done.

As this is a holistic strategic overview of the problem, some difficulties could arise during the implementation of a recommendation. To minimize that risk interviews could be done now not to management level of the hospitals but to doctors that prescribes innovative medicines.

**6. Self-evaluation**

With the process of the work project what I retain the most is the immersion process were I was able to acquire an immense knowledge of the healthcare sector in Portugal.

I do also retain that the most important aspect to define a strategy for any sector is to hear in person their players concerns. Detecting the problem is much more than half the way for arriving to a solution.

Lastly I would like to comment that this project was what enabled me to start working on a consulting company on the healthcare area and for that I’m very grateful.
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http://ec.europa.eu/pharmaforum/


http://www.min-saude.pt/portal/conteudos/informacoes+uteis/lista+de+inscritos+para+cirurgia/Apresentacao+sigic.htm


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Articles on the news


8. Appendices

Players of the Portuguese Health System

The system is constituted by public and private providers, and is financed by the state, by the subsystems, by private health insurances or by out of pocket payments (OOP). The providers are composed by the primary centers, the hospitals, long term care, Meios Complementares de Diagnóstico e Terapêutica (MCDT) clinics and pharmacies, and they’re supplied in pharmaceutics and medical products and equipment.

The states legislates the healthcare system through the Ministry of Health, Ministry of Economy and Ministry of Finance. The regulators are the Entidade Reguladora da Saúde (ERS), Direcção Geral da Saúde (DGS), Administração Central do Sistema de Saúde (ACSS).

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Fig.30. Portuguese healthcare system: public and private financing flows.

## Infarmed Cost Tables

### Fig. 31. Yearly expenses with HIV AIDS.

Source: Infarmed, 2012

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<td>Enfuvirtide</td>
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### Fig. 32. Yearly expenses with Biological Medicines for the treatment of Rheumatoid Arthritis.

Source: Infarmed, 2012

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<tr>
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<td>3.961.303</td>
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<td>Diffiotox denileucina</td>
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<td>963.155</td>
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<td>2.422.778</td>
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<td>465.853</td>
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<td>787.274</td>
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<td>3.741</td>
<td></td>
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<tr>
<td>Gonadorelinia</td>
<td>22.797</td>
<td>20.668</td>
<td>14.495</td>
</tr>
<tr>
<td>Goserelina</td>
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<td>5.808.399</td>
<td>5.370.495</td>
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<tr>
<td>Hidroxibeberidamida</td>
<td>529.094</td>
<td>546.934</td>
<td>585.592</td>
</tr>
<tr>
<td>Ibrutinomab tiuxetano</td>
<td>157.500</td>
<td>84.100</td>
<td>42.300</td>
</tr>
<tr>
<td>Idarubicina</td>
<td>432.883</td>
<td>489.343</td>
<td>370.900</td>
</tr>
<tr>
<td>Ilfosal</td>
<td>293.863</td>
<td>432.917</td>
<td>368.963</td>
</tr>
<tr>
<td>Imatinib</td>
<td>21.500.573</td>
<td>22.579.609</td>
<td>25.241.624</td>
</tr>
<tr>
<td>Interferon alpha-2a</td>
<td>227.539</td>
<td>182.760</td>
<td>144.883</td>
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</table>

Appendices page 3
Innovative medicines in the Portuguese private health sector: a strategic vision

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Interferão alfa-2b</th>
<th>Interferão gama-1b</th>
<th>Ipilimumab</th>
<th>Irinotecano</th>
<th>Lapatinib</th>
<th>Lenalidomida</th>
<th>Letrozol</th>
<th>Leuprolrelina</th>
<th>Lomustina</th>
<th>Medroxyprogesterona</th>
<th>Megestrol</th>
<th>Melfalan</th>
<th>Mercaptopurina</th>
<th>Metirapona</th>
<th>Metotrexato</th>
<th>Miltefosina</th>
<th>Mitomicina</th>
<th>Mitotano</th>
<th>Mitoxantrona</th>
<th>Nelorabina</th>
<th>Nilotinib</th>
<th>Nilotamida</th>
<th>Nimotuzumab</th>
<th>Ofatumumab</th>
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<tbody>
<tr>
<td></td>
<td>185.907</td>
<td>162.722</td>
<td>207.730</td>
<td>121.968</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>375</td>
<td>369</td>
<td>431</td>
<td>279</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fig. 33.** Yearly expenses with medicines for Oncologic disorders.


Appendices page 4
Innovative medicines in the portuguese private health sector: a strategic vision

Important Concepts

IMI: joint effort of the European Union and pharmaceutical industry in order to boost investments in bio-pharmaceutical research and to overcome bottlenecks in the development of innovative medicines (IMI JU Factsheet).

EMA: European Marketing Authorizations is a centralized approval for new medical products. It requires acceptance in all EU member states.

Off label: (unlabelled or unapproved) prescription of a medicine is the prescription of a registered medicine for a use that is not included in the product information. The practice is common, with rates up to 40% in adults and up to 90% in pediatric patients. Clinical, safety and ethical issues may arise (Gazarian, et al., 2006).

Rare diseases: A rare disease is a disease with a very low prevalence. In the EU, rare diseases are defined as life-threatening or chronically debilitating diseases that have a prevalence of 50 per 100,000 individuals. There are currently 5,000 to 7,000 rare diseases. Drugs for theses diseases are less likely to be developed by the industry since the market is small and R&D costs are usually too high to make the products profitable.

Products and Companies with top medicines expenditures

When people talk about expensive drugs, they usually are referring to drugs like Lipitor for high cholesterol ($1,500 a year), Zyprexa for schizophrenia ($7,000 a year) or Avastin for cancer ($50,000 a year). But none of these medicines come close to making Forbes' exclusive survey of the most expensive medicines on the planet. The nine drugs on our list all cost more than $200,000 a year for the average patient who takes them. Most of them treat rare genetic diseases that afflict fewer than 10,000 patients. For these diseases, there are few if any other treatments. So biotech companies can charge pretty much whatever they want. Alexion Pharmaceutical's Soliris, at $409,500 a year, is the world's single most expensive drug. In the inverted world of drug pricing, the fewer patients a drug helps, the more it costs. Amazingly, many brutally expensive cancer drugs don't make the cut. Targeted cancer drugs only help a small minority of patients for a few months. This reduces their average cost. Selling drugs for rare diseases has become immensely profitable. There are so few patients that companies don't have to invest as heavily in marketing. Specialty drugs have gotten more expensive than anyone imagined. For years drug companies ignored any disease that didn't afflict millions of patients.

Innovative medicines in the portuguese private health sector: a strategic vision

Fig. 34.  Top MA holders with the highest expenditure in the NHS.

R&D expenditures

The pharmaceutical industry spends more on R&D than any other industry. The majority of the studied substances do not lead to new medicines, on average there is only 1 in 10,000 probability of a researched substance to lead to a new medicine (Nefarma, 2011).

In 2010 the biotechnology and pharmaceutical industry had a 19,2% share of the invested capital in worldwide R&D, this represents 15,9% of its revenues invested in new medicines, when the majority of the other industries invest only 5% of its turnover in R&D (Nefarma, 2011).

![Fig.35. Worldwide expenditure on R&D per sector over the years (B €) and in percentage.](source)

### Table: Top MA Holders with the Highest Expenditure in the NHS

<table>
<thead>
<tr>
<th>Position/Ranking</th>
<th>Titular do AIM / MA Holder</th>
<th>PVP / R$</th>
<th>%</th>
<th>SNS / NHS</th>
<th>%</th>
<th>Embalagens / Paciência</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AstraZeneca</td>
<td>144 128 047</td>
<td>6,31%</td>
<td>23 705 259</td>
<td>6,01%</td>
<td>3 919 707</td>
<td>2,68%</td>
</tr>
<tr>
<td>2</td>
<td>Sanofi Pharma EMS</td>
<td>94 571 561</td>
<td>4,24%</td>
<td>70 550 457</td>
<td>4,52%</td>
<td>2 525 103</td>
<td>1,84%</td>
</tr>
<tr>
<td>3</td>
<td>Laboratórios Pfizer</td>
<td>113 208 593</td>
<td>4,65%</td>
<td>87 016 040</td>
<td>4,34%</td>
<td>5 046 392</td>
<td>3,07%</td>
</tr>
<tr>
<td>4</td>
<td>Merck Sharp &amp; Dohme Limited</td>
<td>93 487 398</td>
<td>3,86%</td>
<td>90 533 483</td>
<td>3,83%</td>
<td>1 404 251</td>
<td>1,02%</td>
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<tr>
<td>5</td>
<td>Merck Sharp &amp; Dohme</td>
<td>75 030 886</td>
<td>3,20%</td>
<td>51 332 947</td>
<td>3,30%</td>
<td>2 986 661</td>
<td>2,16%</td>
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<tr>
<td>6</td>
<td>Sanofi-Aventis</td>
<td>80 192 952</td>
<td>3,51%</td>
<td>50 300 617</td>
<td>3,29%</td>
<td>7 004 700</td>
<td>5,03%</td>
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<tr>
<td>7</td>
<td>Novartis Farma</td>
<td>70 026 404</td>
<td>3,09%</td>
<td>49 334 058</td>
<td>3,16%</td>
<td>3 942 568</td>
<td>2,05%</td>
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<tr>
<td>8</td>
<td>Servier</td>
<td>74 796 293</td>
<td>3,20%</td>
<td>43 257 398</td>
<td>2,77%</td>
<td>5 365 728</td>
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<td>9</td>
<td>Eli Lilly Nederland</td>
<td>42 582 380</td>
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<td>36 228 056</td>
<td>2,52%</td>
<td>876 552</td>
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<td>10</td>
<td>Gencris Farmacologia</td>
<td>43 082 773</td>
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<td>34 855 300</td>
<td>2,24%</td>
<td>3 306 262</td>
<td>2,40%</td>
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</table>
Innovative medicines in the Portuguese private health sector: a strategic vision

Innovation requires ever increasing investments. The international spending on R&D by American pharmaceutical companies has steadily increased from $2B in 1980 to nearly $48B in recent years. In Europe, pharmaceutical companies spent between €7B and €8B on R&D in the early 1990s and this rose to almost €27B in 2009.

Fig. 36. FDA- approved medicines containing a new active compound, versus R&D investment (1980-2008). Source: Nefarma: DiMAsi, Center for study of drug development, FDA PhRMA.

As per the American Food and Drug Administration (FDA) over the last 50 years, there has been an increasing trend in the number of registrations of medicines with new active compounds.

Marketing Authorizations

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<th>Year</th>
<th>MA Applications</th>
<th>Granted Authorizations</th>
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<td>678</td>
<td>580</td>
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<td>2006</td>
<td>778</td>
<td>488</td>
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<tr>
<td>2007</td>
<td>941</td>
<td>623</td>
<td>66.21%</td>
</tr>
<tr>
<td>2008</td>
<td>1170</td>
<td>773</td>
<td>66.07%</td>
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<tr>
<td>2009</td>
<td>924</td>
<td>853</td>
<td>92.32%</td>
</tr>
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</table>
Fig. 37. MA applications, Granted Authorizations.

Fig. 38. The average time that elapses between commercial licensing of a medicine and its availability to patients.

Before patients have access to the latest medicines time is lost with the procedures for reimbursement. In Portugal the W.A.I.T. indicator (waiting to access innovative therapies) in 2010 was of 349 days.