Universidade de Aveiro Secção Autónoma de Ciências da Saúde
Ano 2015

Carla Raquel Xavier Pereira

A EVOLUÇÃO DO PERFIL, PAPEL E RELEVÂNCIA DO DIRETOR MÉDICO NUMA COMPANHIA FARMACÊUTICA

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Tese apresentada à Universidade de Aveiro para cumprimento dos requisitos necessários à obtenção do grau de Mestre em Medicina Farmacêutica, realizada sob a orientação científica do Prof. Doutor Bruno Miguel Alves Fernandes do Gago, Professor Auxiliar Convidado da Secção Autónoma de Ciências da Saúde da Universidade de Aveiro

Agradecimento

“Those who pass by us don't go all alone, don't leave us all alone. They leave a little of themselves, take away a little of ourselves.” Antoine de Saint-Exupéry

We are the result of our experiences in life and how we decide to let them influence us. I have been blessed to come across people who have deeply touched me, made me grow and look at things in different ways than before. They have guided me through this journey, and they are always in my memory. To all of them (they know who they are), I dedicate this work, humbled by the immensity of knowledge and wisdom that I can only grasp at the surface during a lifetime. From another perspective, I am happy and conscious that this is only the beginning, for new questions always lead to new roads ahead.

o júri

presidente

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palavras-chave

Diretor Médico, Assuntos Médicos, Indústria Farmacêutica, Medicina Farmacêutica, liderança, desenvolvimento.

resumo

Nos últimos anos, as operações das empresas farmacêuticas têm-se tornado mais complexas, tentando adaptar-se às novas exigências do ambiente de mercado. Globalmente, a mudança de paradigma observada requer adaptação, principalmente através do estabelecimento de novas prioridades, diversificação dos investimentos, estratégias de contenção de custos, explorando novos mercados e desenvolvendo novos conjuntos de competências. Neste contexto, novas funções foram criadas, a importância de algumas diminuiu, e a importância de outras emergiu. Entre estas, a estrutura médica dentro de uma empresa farmacêutica aumentou para responder às exigências, com as empresas a adoptarem diferentes modelos para responder a estas necessidades, tornando-se um pilar para o negócio.

Assumindo o papel de lider dentro de um departamento médico, a função de diretor médico permanece muitas vezes na sombra.

É uma função chave dentro da Indústria Farmacêutica, seja num país ou numa base global. Esta função tem evoluído e mudado nos últimos anos para responder às exigências constantes de um ambiente em mudança.

O Diretor Médico é um profissional altamente qualificado e diferenciado que confere orientação médica e científica dentro de uma empresa farmacêutica, desde as fases iniciais de desenvolvimento de medicamentos e até perda de exclusividade, não só mas também por liderar uma equipa de outros médicos, farmacêuticos ou cientistas, cujas funções incluem especificidades que o diretor médico precisa compreender, contribuir para, supervisionar e liderar.

Como a organização das empresas farmacêuticas tende a ser diferente, de acordo com os valores, cultura, mercados e estratégias, o âmbito das actividades de um diretor médico pode ser mais amplo ou pode ser limitado, dependendo do tamanho e do modelo de organização e governança, mas deve cumprir um largo conjunto de requisitos a fim de maximizar o seu impacto sobre os clientes internos e externos. Competências técnicas fundamentais para diretores médicos, como uma especialização em Medicina, uma forte base clínica, conhecimento de desenvolvimento de medicamentos, experiência em gestão de equipas e de projectos, e elevada capacidade escrita e verbal são relativamente fáceis de definir, mas competências comportamentais subjacentes são mais difíceis de encontrar, e estas são mais frequentemente os verdadeiros preditores de sucesso na função.

Além da proficiência irrepreensível em habilidades técnicas, a este nível as habilidades interpessoais tornam-se muito mais importantes, pois são o condutor e o factor distintivo entre um bom e um excelente diretor médico. E isso tem impacto no negócio e nas pessoas que nele trabalham.

keywords

Medical Director, Medical Affairs, Pharmaceutical Industry, Pharmaceutical Medicine, leadership, development.

abstract

Over the last years, operations in Pharmaceutical Companies have become more complex, trying to adapt to new demands of the market environment. Overall, the observed change of paradigm requires adapting, mainly by the setting of new priorities, diversification of investments, cost containment strategies, exploring new markets and developping new sets of skills. In this context, new functions have been created, the relevance of some has diminished, and the importance of others has arisen. Amongst these, the medical structure within a Pharmaceutical Company, increased to meet demands, with companies adopting different models to respond to these needs, and becoming a pillar to the business.

Assuming the leading role within a medical department, the medical director function often lies in the shadow.

It is a key function within Pharma Industry, either on a country or on a Global basis. It has evolved and changed in the past years to meet the constant demands of a changing environment.

The Medical Director is a highly skilled and differeniated professional who provides medical and scientific governance within a Pharmaceutical company, since early stages of drug development and up to loss of exclusivity, not only but also by leading a team of other physicians, pharmacists or life scientists whose functions comprise specificities that the medical director needs to understand, provide input to, oversee and lead.

As the organization of Pharmaceutical Companies tends to be different, in accordance to values, culture, markets and strategies, the scope of activities of a Medical Director can be broader or may be limited, depending on size of the organization and governance model, but they must fulfil a large set of requirements in order to leverage impact on internal and internal customers. Key technical competencies for medical directors such as an MD degree, a strong clinical foundation, knowledge of drug development, project and team management experience and written and verbal skills are relatively easy to define, but underlying behavioural competencies are more difficult to ascertain, and these are more often the true predictors of success in the role.

Beyond seamless proficiency in technical skills, at this level interpersonal skills become far more important, as they are the driver and the distinctive factor between a good and an excelent medical director. And this has impact in the business and in the people doing it.

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Abbreviations:

CEO – Chief Executive Officer

CRO – Contract Research Organisation

DM – Doctor of Medicine

EMA – European Medicines Agency

EUQPPV – European Qualified Person for Pharmacovigilance

GCP – Good Clinical Practices

GDP – Good Distribution Practices

GLP – Good Laboratory Practices

GMP – Good Manufacturing Practices

GVP – Good Pharmacovigilance Practices

HA – Health Authorities

HCP – Healthcare Practitioner

HR – Human Resources

INFARMED – Portuguese Health Authority

KPI – Key Performance Indicator

MA – Medical Affairs

MD – Medical Director

MI – Medical Information

MSL – Medical Science Liaison

PhV – Pharmacovigilance

R&D – Research and Development

SmPC – Summary of Product Characteristics

The evolving profile, role and relevance of the Medical Director in a pharmaceutical company

I – Introduction: setting the scene

We are living times of increasing change. Over the last years, operations in Pharmaceutical (Pharma) Industry have become more complex, trying to adapt to new demands of the market environment. This has meant moving from a so called classical research and development (R&D), marketing and sales centred model into a more diversified way of doing business, with new departments and new functions adding up to a conceptual matrix that is mainly driven by increasing demands from Health Authorities, additional hurdles in safety requirements, higher interdependency of numerous functional and technical activities involved in drug R&D, the evolving model of drug development to adaptive designs, the need to overcome patent cliff (driving to increased urgency to refill pipelines), longer times to marketing authorization (delaying and restricting accessibility to newer medicines and in the long run hampering the development of innovative drugs) and increasing pressure from shareholders in terms of return on investment.[1]

Overall, this change of paradigm requires constant adaptation, mainly by the setting of new priorities, diversification of investments, cost containment strategies, exploring new markets and development of new sets of skills. In this context, new functions/roles have been created, the relevance of some has diminished, and the importance of others has arisen. It is easily observed that in this transformation, sales departments have reduced in size and influence mainly due to access constraints to healthcare practitioners (HCPs) and increased activity of health authorities in regulating prescriptions, roles within Medical Affairs (MA) functions have specialized and gained strength as effective contributors to business and customers, and new areas such as Market Access and Legal Affairs have emerged with important roles with high impact on the business.[1]

Medical Affairs has been the medical function with greater projection and originating more publications, as these organizations grew over the past years in response to regulations around

the separation of medical and commercial activities within drug companies. Many companies also chose to focus R&D resources on developing new products and moved post-launch activities, such as finding new indications for existing drugs, into the MA function.[2]

Medical Affairs' core activity is thus delivering high quality, updated, non-promotional, unbiased scientific information to healthcare professionals, clearly independent from the commercial functions, but maintaining the connection between R&D and commercial areas. Consequently, MA has become an independent department/division, within the Medical Department, and continued pressure from regulatory agencies and public sentiment has pushed more and more activities into MA divisions.[2]

This is one important example that clearly shows that the medical structure within a pharmaceutical company, minimal and mainly supportive and administrative until around twenty years ago, increased to meet demands, with companies adopting different models to respond to these needs, and with Medical Departments becoming a pillar to the business.

As the leading person within a Medical Department, most often supporting other members of the team, developing people, solving problems, providing strategic medical insights to colleagues, dealing with constant changes and need of adaptation to keep the team and the business moving forward, managing complexity, the Medical Director (MD) often lies in the shadow. Nevertheless it is a key function within Pharma Industry, either on a country or on a global basis. It has also evolved and changed in the past years, and it will be subject of analysis in this paper, as there is currently no comprehensive review on this subject in published literature.

II – The Medical Department and its increasing complexity

Medical Departments' dimension is usually adjusted to the size of the company and may be large, as in the headquarters of a multinational company, or small, as in one of its subsidiary operating companies or a small biotechnological start-up. Due to the diversity and complexity of the activities developed by a pharmaceutical company, and the need to provide adequate support to several areas in a cross-functional way, a Medical Department is often put in place. The way it is organized can be different across countries or companies, and it can assume a horizontal, vertical or mixed hierarchical structure, with simple or complex lines of reporting. It greatly depends on cultural issues and different regulatory settings across countries.[3]

Despite national, cultural and regulatory differences between countries, which further complicate their structure, the influence of the EU, through the introduction of guidelines and directives, is leading Medical Departments across Europe to operate in similar ways. No matter how they are organized, there are certain responsibilities that all Medical Departments must assume, such as:[3]

- Provide a medical perspective and support to the development of new medicines (collaborating since the early phases up to phase IV clinical studies);
- Provide the medical input necessary to support marketed medicines throughout their life cycle;
- Provide specialized scientific and medical expertise, as required;
- Contribute to implementation of regional and local product strategies;
- Ensure the compliance with all applicable legal requirements, standard operating procedures and guidelines;
- Ensure that the overall drug safety reporting process fully adheres to applicable requirements;
- Perform internal audits and quality reviews;
- Identify risks from a medical point of view and implement risk management activities;
- Develop educational activities (for internal and external customers);
- Review promotional, educational and corporative materials;
- Act as the ethical conscience of the company;
- Act on behalf of the company next to Regulatory and Health Authorities, healthcare professionals and other external stakeholders.

The objective of all pharmaceutical companies is to discover, develop and market medicines with favourable risk/benefit ratio, which benefit the patients and are profitable to the company. To ensure that this happens, it is critical to have a medical and scientific oversight since early stages of drug development and up to loss of exclusivity and even beyond. The Medical Director (MD) provides this governance within the company.

Furthermore, the MD should be a member of the management team, being the voice of the Medical Department regarding its important role of keeping the company aware, at all times, of the needs of patients and of the HCPs, and thus by providing strong medical input into the company's strategy.[3,4]

Every pharmaceutical company has an MD. Usually this person holds a degree in Medicine (doctor of medicine – DM) although a degree in pharmacy (doctor of pharmacy – PharmD) is also feasible, although less common.[5]

The MD leads a team of other physicians, pharmacists or life scientists and administrative staff. They all play an important role supporting all phases of a medicine life cycle, from early stages of development until way past the loss of exclusivity (LOE), always partnering with commercial colleagues.[3]

Usually the Medical Department is staffed with the following key players, though not all companies will place all these specialists in the medical department:[3]

- Medical Director;
- Clinical Research specialists;
- Medical Information specialists;
- Medical/Scientific Advisors and Medical Science Liaisons (Medical Affairs team)
- Regulatory Affairs specialists;
- Drug Safety/Pharmacovigilance specialists
- Statisticians and Data Managers;
- Quality Assurance/Management specialists – may or may not be part of the medical department, as overseeing functions must be segregated from operating functions
- Pharmacoeconomics Advisors – these may be part of another part of the structure (Market Access department).

In whatever way it is organised, the Medical Department works closely with cross-functional colleagues such as Marketing, Market Access, Legal, Finance, Human Resources and other departments (Figure 1).[3]

Figure 1 – Main internal lines of constant interaction of Medical Director inside a pharmaceutical company

Thus, while it is not possible to propose any specific organisational structure for a Medical Department, the organogram presented in Figure 2 reflects the core functions that need to be considered when deciding on the preferred organisation within the company.

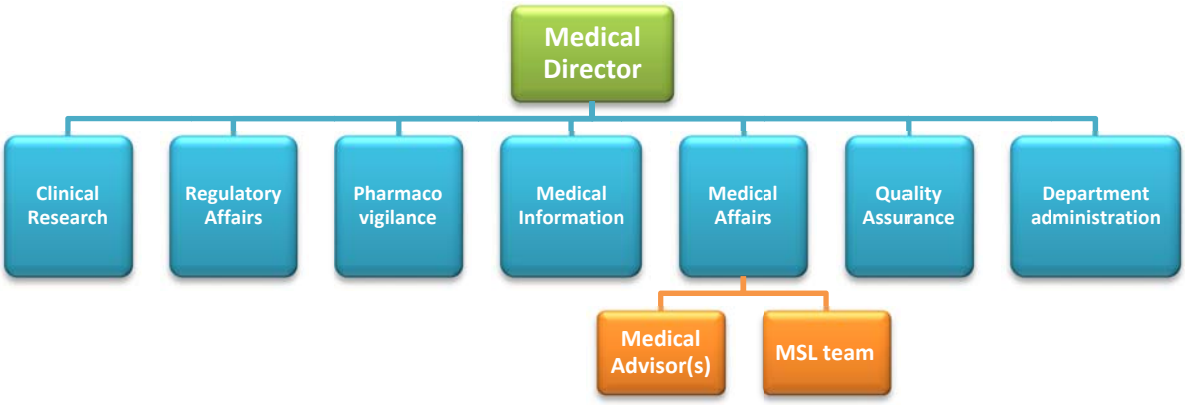

Figure 2 – Possible organisational chart for a Medical Department

Let us look at some of the functions composing a Medical Department in more detail, as they comprise specificities that the Medical Director needs to understand, provide input to, oversee and lead.

a) Clinical Research specialist

The Clinical Research specialist is involved in all aspects of clinical trials from planning and design, through initiation and monitoring, to report-writing and publication. The Medical Department is likely to be involved in organising late pre-licence or post-licence clinical studies (volunteer and phase II studies being the responsibility of the R&D part of the company). The primary objective of phase III studies is to contribute to the dossier for marketing authorisation which, once approved, is a watershed in a product's life. This will establish the initial profile of the product.[3]

The organisational structure for clinical research depends on size and whether the department is within headquarters or a local operating company.[3]

In most companies it is likely at some time that Clinical Research specialists within a company will collaborate with counterparts within contract research organisations (CROs). CROs range from small, often specialised, groups, to large multinational companies. The services offered cover virtually every facet of clinical research, as well as of the regulatory process necessary for obtaining a marketing authorisation. CROs provide a flexible resource to cope with peaks of activity without the need to employ additional staff.

Nevertheless, there are some disadvantages. For example, an in-house clinical research team will probably be more familiar with the company's products and, through closer relations with the sales force, have greater commercial awareness. In addition, while clinical investigators may see CRO staff as representing the pharmaceutical company, the company is unlikely to have direct control over their day-to-day activities. Finally, by using a CRO, there is less opportunity to develop professional relationships between clinicians and the company.[3]

b) Medical Information specialist

There may be two types of information support at the Medical Department level:[3]

- The external scientific service, usually provided by the Medical Information (MI) specialist
- Specialised information support to a product or therapy area within the company, usually provided by or in alignment with the Medical Affairs team.

Many MI specialists are qualified pharmacists.[3]

Requests for information about a company's products may arrive from many sources, both from inside and outside the company:[3]

- Hospital pharmacists, often on behalf of hospital doctors, are the most frequent source of enquiries
- Community pharmacists
- Individual clinicians
- Nursing staff
- Patients

The last type of external requester deserves a particular word. Until recently, the provision of information in response to enquiries from members of the public was not allowed, and individuals were referred to their medical practitioner. However, as the provision of information about medicines directly to the public has increased through such innovations as patient package inserts and greater access to the internet, so a better informed public now demands greater involvement in their own clinical management. This demand is likely to be fuelled further as an increasing number of medicines switch from prescription only medicines (POM) to over-the-counter (OTC).[3] Consequently, it is now accepted that members of the public can be provided with factual answers to questions about their medicines.

The Medical Information scientist usually operates on a reactive (as opposed to proactive) basis. When providing information to a patient, the principle of providing substantiated, accurate, up-to-date, reliable and unbiased information is to be respected, as well as not providing counselling, but referring to the attending physician if a clinical decision is to be taken.

No company employee or person acting on behalf of the company may induce a request for information related to a non-authorized product or to the off label use of an authorized product. There must be assurance of the unsolicited nature of any such request for information.

Main lines of articulation between MI and other functions within Medical Department:

- Pharmacovigilance – in case a suspected adverse drug reaction lies behind an enquiry
- Medical Affairs – to provide sound scientific background and validation to responses – it is a current practice to develop "standard response letters" jointly, to respond to frequent questions
- Market Access – to provide bibliographical support to Value Dossier construction and support to clinical evaluation from Health Authorities (HA)
- Regulatory Affairs – questions related to labelling, Summary of Product Characteristics (SmPC);
- Quality Assurance – questions related to transport, conservation, changes perceived in packaging.

Challenges for Medical Information: meeting new and expanding scientific and medical demands

Of all the functions and responsibilities of Medical Affairs, perhaps none gets less respect – and investment – than the seemingly thankless task of providing medical information to physicians, scientists and regulators. It is a service often viewed as little more than a compliance requirement without broader benefits to the business. In fact, service levels among Medical Information (MI) teams across the industry vary significantly and in many instances, responses for requested materials can take up to a month and still go through regular mail.[6]

Ambiguous regulatory guidance, under-investment in technology, and a resistance to change have all played a role in retarding the use of new channels by this function. Now, however, a confluence of external pressures and internal opportunities has begun to overwhelm that inertia – namely from compliance risk, new and expanding scientific demands and the need to create

greater business value, since in recent years significant change in both customer preferences and the availability of communication technologies that aid in social collaboration has made *status quo* no longer an option.[6]

In addition to the opportunity cost of failing to engage the medical community at a much more effective and interactive level, recent regulatory initiatives by the European Medicines Agency (EMA) and new reporting requirements in emerging markets are raising the compliance risks for failing to modernize MI systems. The current country-by-country method of creating medical content and handling requests for Medical Information in isolation could leave global pharmaceutical companies vulnerable to a host of regulatory sanctions.[6]

Expert consultants in this field have recently issued recommendations for companies: meeting external demands and the internal potential for organizing and disseminating Medical Information today will require much more attention paid to MI than in the past, and four main components should be considered for a 21st century MI function:[6]

- Global platforms and systems support Medical Information delivery
- Proactive and value adding interactions with customers
- Analytic capabilities that bring insights beyond the data
- Improved overall content and case management.

c) Regulatory Affairs specialist

At global level, the Regulatory Department may be part of the Medical Department, the research division or report directly to the head of the company and its role is crucial to the success of the company. The regulatory area defines the pharmaceutical, toxicological and clinical data required to prove the quality, safety profile and efficacy of a product and to obtain a medically and commercially favourable marketing authorisation (product licence), thus defining the appropriate regulatory strategy to achieve rapid product development and registration, as reflected in its approved SmPC.[3]

The regulatory staff needs to be up to date with national, European and international regulations and guidelines, and with their own national regulatory authority's thinking, by building strong and effective working relationships with regulators. The regulatory executive also needs to keep the company informed of the potential impact of any proposed changes to regulations.

In the local operating unit much of the Regulatory Affairs specialist's role is to update and maintain company licences, and product information (SmPCs, patient information leaflets and packaging).

It is often not appreciated how much work is required to ensure that the marketing authorisations are kept up to date by being renewed and amended as necessary. Similarly, it may not be realised that a 'simple' variation to a product licence, such as a small change in the amount of excipient, will require the submission of a variation document to the Regulatory Authorities.

Other responsibilities include applications for regulatory approval of clinical trials and ensuring that promotional material for a product is in line with its licence.

Main lines of articulation between Regulatory Affairs and other functions within Medical Department and the company:

- Pharmacovigilance – risk management plans implementation monitoring (contacts with Health Authorities)
- Medical Affairs (and Business Units) – promotional materials development and approval
- Quality Management – technical issues related to products labelling or packaging
- Market Access – price information; licence renewals; contacts with health authorities
- Clinical Research specialists – contacts with authorities pertaining submission of clinical trials

d) Drug Safety/Pharmacovigilance specialist

One of the most important responsibilities of the Medical Department is effective handling of all information relating to drug safety, the main implication of which could lead to changes in the regulatory status of a product. The size of a company and the volume of work define the size of this team as to whether the responsibility for monitoring drug safety resides with members of staff who have other responsibilities for the various compounds, or with a specialised drug surveillance group.[3] In a small affiliate office, the minimum standards required by law are that the person responsible for drug safety must be a pharmacist and must have a backup, mainly for out-of-hours service (must be a 24/7 available contact).[7]

Every company is required by European law to have a nominated Qualified Person responsible for Pharmacovigilance (QPPV) (Directive 2001/83/EC Article 8(3)(n)). The QPPV need not be a

physician but must have access to one. In the Portuguese Law (Decree-Law 20/2013 of 14 February and Decree-Law 128/2013) it is stated on article 170, numbers 4 and 5, that "the marketing introduction authorization holder must nominate, in a permanent and continuous way, a person responsible for pharmacovigilance with proper qualification, living and working in the European Union (the European Qualified Person for Pharmacovigilance - EUQPPV) and must nominate, at INFARMED, a contact person for pharmacovigilance issues at national level, residing in Portugal, reporting to EUQPPV.[3,7,8]

The most important tasks related to drug safety monitoring are:[3]

- Timely processing of spontaneously reported suspected adverse drug reactions relating to marketed products, as well as adverse events reported in clinical trials of both pre-licensed drugs and marketed products;
- Undertake periodic safety update reports at predetermined intervals, in accordance with current International Conference on Harmonisation (ICH) guidelines (ICH E2C). Such routine analyses can identify new safety signals as soon as they become detectable;
- Post-marketing surveillance: this may include observational (non-interventional) studies, which may be retrospective or prospective, and other projects specifically designed to investigate a safety issue that may need input from clinical drug safety;
- Risk management plans implementation;
- Patient support programs monitoring (in alignment with Medical Affairs);
- Ensuring that all staff in the company is trained (and logging training) on adverse event reporting guidelines and the recognition of potential safety information and concerns relating to the company's products.

Main lines of articulation between Drug Safety and other functions within Medical Department:

- Clinical Research: processing adverse events in the context of clinical trials;
- Medical Information specialists: if a medical information enquiry is potentially related to a safety issue (suspected adverse event, off label use, exposure during pregnancy or lactation);
- Medical Affairs: mainly in the follow up contact after a report is made, namely to clarify some medical aspect of the correct use of a drug and to obtain more information for the report;
- Regulatory Affairs: mainly regarding monitoring of risk management plans implementation (contacts with HA);

- Medical Director: overall responsibility for clinical safety matters must rest with a senior pharmaceutical physician who will be able to provide appropriate professional opinion and advice.

e) Quality Management specialist

The general framework for Quality Management (QM) is composed of Quality Assurance (QA), including audits, and Quality Control (QC), and their contribution to quality and integrity of all areas of the business is becoming widely recognized, in particular, in activities conducted according to Good Practice guidelines (GxP) through most phases of a product lifecycle: Good Laboratory Practice (GLP); Good Manufacturing Practice (GMP); Good Clinical Practice (GCP) and Good pharmacoVigilance Practice (GVP) – figure 3:[9]

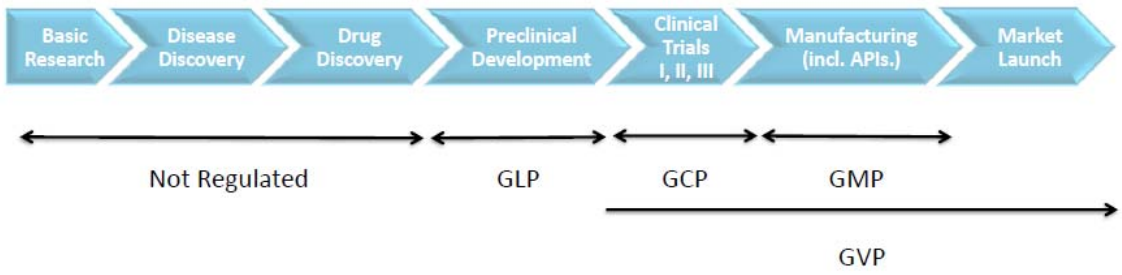

Figure 3 – Good Practice guidelines (GxP) through phases of a product lifecycle[10]

Useful explanation related to quality can be found at the ISO 9000 family of quality management systems standards, which is designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product. ISO 9000 deals with the fundamentals of quality management systems, including the eight management principles upon which the family of standards is based. For reference:[11]

- ISO 9000:2005 defines quality as 'The degree to which a set of inherent characteristics fulfils needs or expectations that are stated, generally implied or obligatory'.
- ISO 9000:2005 defines quality management as 'The coordinated activities to direct and control an organization with regard to quality'.
- ISO 9000:2005 defines quality control as 'The part of quality management focused on fulfilling quality requirements'.

Increasingly, the focus has become improving the manufacturing process rather than inspecting the final product by preventing errors instead of correcting them – that is 'assuring quality' instead of 'inspecting quality into a product or service'. The benefits of QA soon led to the insight that quality is an attribute that can be managed, more recently giving way to the "quality by design" concept. On one hand, quality can be influenced in that investments in process quality impact the outcome of the product or service. On the other hand, quality has increasingly become a task of management. ISO 9000:2005 describes the role of senior management and emphasizes the importance of leadership by top management in implementing quality management.[9]

Quality Assurance usually describes the audit function within a company. However, QA should not be limited to auditing but comprise all activities suitable to ensure that company procedures are designed so that the product or service will comply with pre-established quality requirements. QA activities are future-oriented and should focus on improving systems and procedures to be followed to ensure that these are set up in such a way that produces a quality result or service.[9]

The main responsibilities of a Quality Officer are (Figure 4):

- Lead and coordinate the implementation and maintenance of an appropriate affiliate Quality System (Figure 5) in compliance both with the company Quality Policy, Quality Directives & Standards and regulatory requirements, concerning all activities related to the clinical investigation, distribution and marketing of all products developed and/or marketed in the country by the company or through partnership agreements;
- Be the local focal point at affiliate level for the management of Product Technical Complaints and Quality Events;
- Provide Quality leadership across the affiliate organization with a priority focus on GxP and health regulated activities (quality of products, information and services).

Figure 4 – Main responsibilities of Quality Assurance in a pharmaceutical company (example adapted from Sanofi)

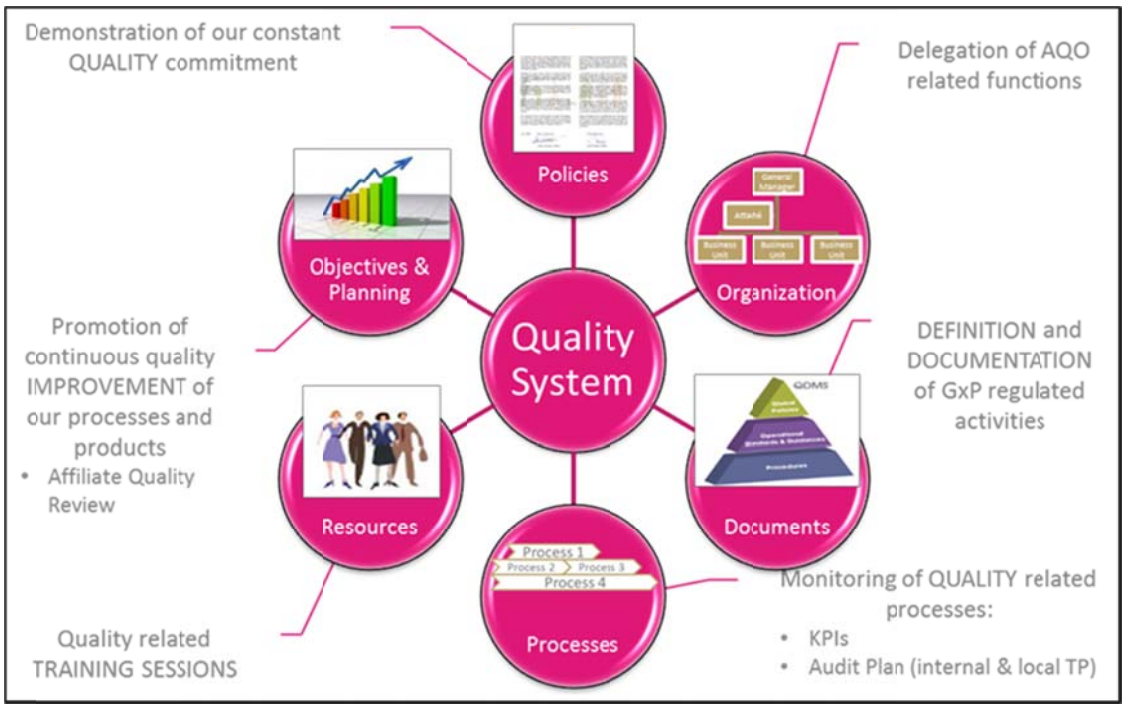

Figure 5 – Main components of a Quality System in a pharmaceutical company (example adapted from Sanofi)

The key accountabilities of a Quality Officer include:

- Define, implement and maintain a local quality system;
- manage local Quality Documents (QDs) through an appropriate affiliate QD management system, as a minimum for GxP and related health regulated activities;
- Ensure quality oversight of locally managed third-party suppliers/subcontractors for all GxP and health-regulated activities;
- Ensure continuous audit/inspection readiness and ensure management/coordination of inspections by Regulatory Authorities; including assurance that an appropriate crisis management process is in place in the affiliate (business continuity plan, systems backup)
- Ensure quality agreements are in place (with manufacturing sites as well as with any external contractor);
- Carry-out periodic (annual as a minimum) affiliate quality reviews;
- Manage Product Technical Complaints received and manage product-related quality events (quality alerts/ recalls/ notifications to & from local Health Authorities);
- Ensure that an appropriate process is in place regarding product protection (counterfeits) and management of parallel trade issues; when applicable, coordinate the availability of up-to-date lifesaving drugs lists; if required by local regulations, perform batch/product release.

Technical Responsibility for a pharmaceutical company affiliate

In the Portuguese Law (Decree-Law 20/2013 of 14 February and Decree-Law 128/2013) it is stated on article 97, number 1, that "distribution of medication is only authorized if the interested party has a technical director who ensures, in an effective and permanent way, the quality of activities developed locally and for which authorization has been granted by INFARMED".[7,8] The technical director is a pharmacist (in Portugal this is today the only university degree that includes the areas of training required for the function). This function may or may not be accumulated with Quality Assurance depending on the structure of the affiliate and the organizational model of the company.

Compliance management

"Compliance — with rules, with regulations, with societal values — is something that takes up more of a business leader's time now than ever before." – Daniel Vasella[12]

Compliance management can be considered as part of the Quality System, and this role can be performed by the person responsible for Quality Assurance at country level. Despite the fact that compliance is everyone's responsibility, as colleagues are expected to take ownership of compliance and to perform all tasks with integrity, pharmaceutical companies establish and maintain effective compliance programs in accordance with country and industry regulations and guidelines, and these usually include a comprehensive framework of compliance controls throughout various segments of commercial operations. These programs represent commitment to the highest standards of corporate conduct, and include, but are not limited to:

- Code of Employee Conduct;
- Policies and procedures that address specific areas of concern;
- Training and education programs;
- Multiple compliance communication mechanisms that may include an anonymous reporting system;
- Targeted monitoring and auditing;
- Disciplinary guidelines;
- Protocol for responding promptly to detected problems and implementing corrective action.

Organization and independence of QA

Quality Assurance's independence from operations should be identifiable in the organizational charts of a company. The reporting line of QA should go directly to senior management and in no case to any operational function.[9] Usually the Quality Manager reports to the General Manager and/or to the Medical Director at the affiliate level, as all tasks comprised in the Medical Department activities are GxP regulated and thus in constant need of internal monitoring.

Regarding the main lines of articulation between Quality Assurance and other functions within Medical Department and the company, they interact with all areas, but there are some which deserve a particular mention, due to their criticality for the business, namely with Supply Chain

[regarding assurance of compliance with GMP (Good Manufacturing Practices) and GDP (Good Distribution Practices) procedures] and all roles in the Medical Department (GxP related activities, Figure 3).

f) Medical Affairs

Traditionally, the Pharmaceutical Industry model includes two main pillars: an R&D group in charge of developing new medicines/medical devices and a commercial team in charge of marketing and selling those products. However, greater regulatory scrutiny and changes in the business model over the last ten years have led to many changes, with stakeholders' continuous demand that high levels of scientific rigor should be maintained across the industry and in its interactions with HCPs. As a consequence of this, the urge to create Medical Affairs teams was renewed.[5]

Medical Affairs (MA) originally appeared due to the need of having non-promotional, unbiased scientific communication to healthcare professionals, clearly independent from the commercial functions, while sustaining a bridge between research and development (R&D) and commercialization. Consequently, MA has become an independent department/division within the Medical Department.[1,5,13]

Pharmaceutical companies have for long viewed MA as a support function, and one that sometimes acts as a brake on the more commercially driven parts of the organization. This perception has been enhanced by information asymmetry: although the main areas of responsibility of MA are complex and data driven, and impact in the business is perceived but difficult to effectively measure, it can still be poorly understood in its full extension by those outside the role, setting the bar high for people embracing a position in this line of work (Figure 6).[1]

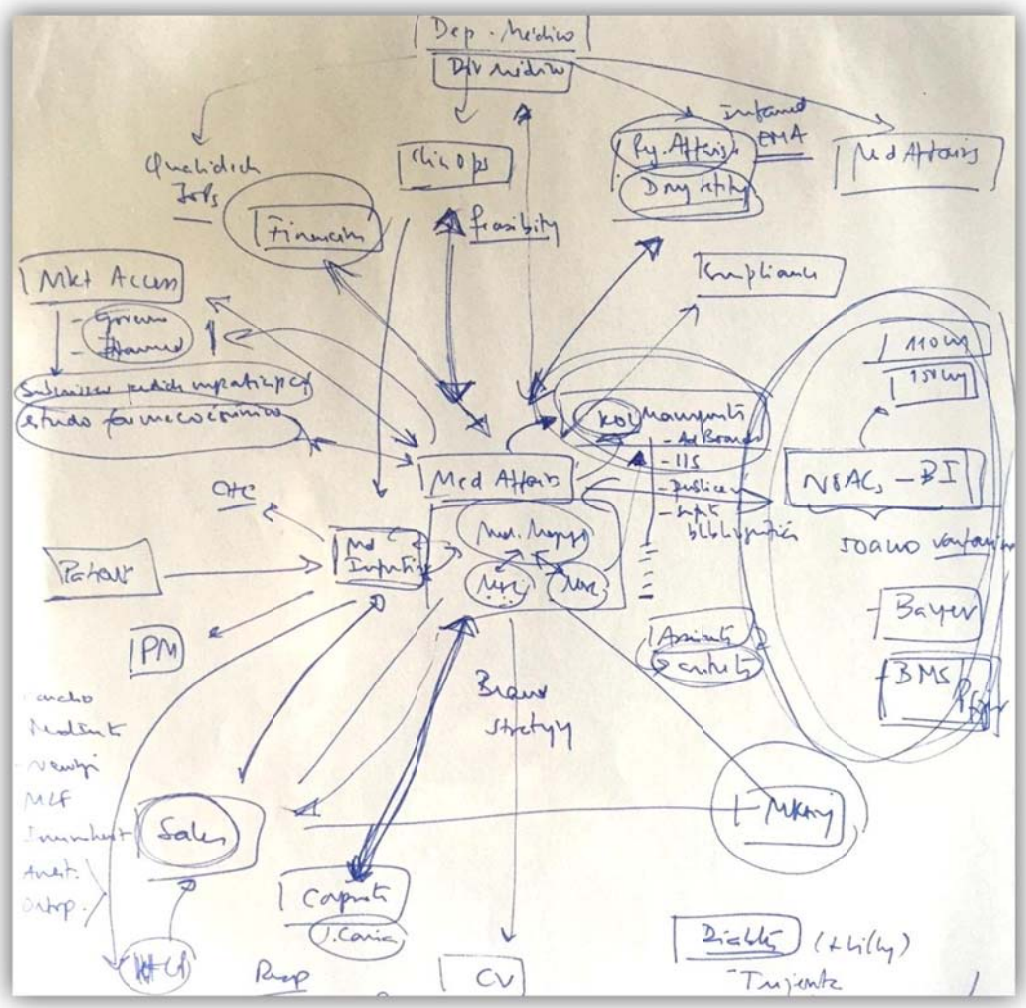

Figure 6 – Explaining Medical Affairs to a new hire (by Carla Pereira, 28 January 2014)

As a response to these challenges it has become widespread that Medical Affairs is now responsible for providing scientific and clinical expertise to support approved medicines, and working closely in the development of new drugs as early as phase 2 studies and throughout post approval activities.[2,13]

Furthermore, in a fast moving market environment, dynamic, innovative, engaging, and skilled MA teams are better prepared to respond to customer demands and to develop and maintain stronger long-term relationships with key opinion leaders, scientific societies, payers and patient groups.[1,2] All of this while keeping a link between R&D and commercial areas and focusing on the internal customer.

Medical Affairs is a global function, but when performed at this level it has a very limited role in country or region-specific activities because issues and regulations differ across markets. Global Medical Affairs defines a broad overall strategy by therapeutic area/product and ensures that the activities across markets are aligned, that redundant efforts are avoided and that possible synergies are maximized. It may also take the lead on activities that can span across all markets, such as:[5]

- Publication planning;
- Fostering long-term relationships with internationally recognized key opinion leaders;
- Drawing general guidelines for selecting which studies to fund (company owned or from investigator-initiative research);
- Defining real-world data and outcome research needs;
- Conducting global advisory boards.

Because MA works closely with both scientific and commercial leaders within a pharmaceutical company, the function could be positioned under either Global Commercial or Global Development.

However, as regulatory scrutiny has increasingly pushed by the need for a clear separation of commercial and educational/scientific activities, Global Medical Affairs has been generally aligned with Development (or sometimes in a direct reporting relationship to the CEO of a pharmaceutical company). It is also becoming more common for MA to derive its budget from Drug Development rather than from Marketing.[5]

Regarding the main lines of articulation, MA is a division within the Medical Department. It typically interacts with many different players, both internal and external. Regarding internal customers, it interacts with Marketing, Regulatory Affairs, Clinical Research, Medical Information, Pharmacovigilance, Quality & Compliance, Access, Sales, and Legal. Considering external customers, the MA team has a customer facing role and establishes peer-to-peer interactions with healthcare professionals, (mainly physicians, but increasingly with pharmacists and nurses), scientific societies and payers (Governments, Health Ministries, Hospital Boards, insurance companies, etc).[5]

Another distinctive feature in MA activity is that they can discuss “off-label” topics, usually in a reactive way, upon unsolicited request by a HCP (the term “off-label” can encompass any change

to the regulator-approved language regarding use of a drug, up to an entirely new indication), as well as the profile of a new drug before granting of Marketing Authorization Application.

In larger pharmaceutical companies, reporting to the Medical Director, there can be also a Medical Affairs Lead/Therapeutic Area Head. This person usually has a degree in medicine (DM) although a degree in pharmacy (PharmD) is not uncommon. Apart from the director, MA typically are staffed with Medical Managers/Advisors and Scientific Advisors (both mainly office based) and Medical Science Liaisons – MSLs /MSL Managers (who are field based), both of which are customer facing roles, but at different extents.[3,5]

Regarding the scientific background of people working in Medical Affairs (usually DMs, PharmDs, or holding any advanced master degree in life sciences), these are highly differentiated employees with in-depth knowledge of the therapy area, the relevant medicines in the company portfolio and its pipeline, capable of dealing with extremely complex scientific/technical information, which enables them to understand and effectively communicate the science behind a drug or device.

In some countries (like the UK), the development of pharmaceutical medicine into a specialty has strengthened the role of the pharmaceutical physician, who is qualified not only to provide medical expertise but also, through the tradition of the Hippocratic oath, to represent the needs and interests of patients inside a pharmaceutical company.[3]

Internally, MA often serves as a "bridge" between the research/clinical development and commercial sides of a pharmaceutical company (or of a biotechnology company with in-house commercial capabilities), synthesizing information and translating findings about a drug into language accessible to company professionals whose primary expertise is not necessarily scientific.[1]

Overall, the responsibilities of a Medical Affairs team may include (Figure 7):[5]

- Support to product research and development: perform in-country clinical studies feasibilities. Inclusion of countries in clinical trials is usually competitive and local teams are often challenged about their capability to run high quality clinical studies in the study population in scope. Medical Affairs' in-depth knowledge of the disease areas, reference centres and investigators (as part of KOL management), national clinical setting and regulations allows them to rapidly identify potentially capable/interested centres and investigators.

- Conducting non-registrational (typically Phase IV) clinical studies. After a drug is granted EMA approval, MA often assumes much of the responsibility for any additional clinical studies. Because these studies do not support the application for approval, they are known as non-registrational studies.
- Support to investigator-initiated studies. MA reviews the clinical trial proposals submitted by independent investigators and decides based on their scientific merits, which of the studies should receive financial support.
- In addition to non-registrational studies, MA is sometimes responsible for executing health economics and outcomes studies, in partnership with the Market Access department. These studies, which evaluate the impact of a drug's use on such variables as costs (direct or indirect) and patient outcomes or quality of life, can be used to demonstrate cost-effectiveness, cost utility or cost benefit, adding up positively to the value proposition presented to health authorities and more favourable positioning in therapeutic formularies (approved list of preferred drugs for use).
- MA may also be responsible for supporting the Brand team in formulating product messages. Insights from MA help Brand teams develop clear and scientifically accurate messages directed at real HCPs' needs in a given moment. Medical Affairs also develops and/or reviews scientific and medical content that is converted into course materials, for use with the Sales, Marketing, and enabling functions teams. The MA team may also be part of a promotional review committee.[14]
- As a result of its continued immersion in the field and contact with scientific community, members of MA learn a great deal about the market environment for company products and can share insights with internal leaders, paving the way for development of strategies or product messages that are responsive to the concerns of prescribers and other key stakeholders.

In addition to the above mentioned responsibilities, the MA team may also:

- Lead the implementation of Advisory Boards, meetings in which a usually heterogeneous (but highly representative) group of experts can freely discuss and provide credible advice on a predetermined subject, based on their clinical practice or scientific knowledge, in a closed setting. This can be very important for the brand team, which is able to make adjustments to its strategy.

- Play an important role in disseminating written information to the scientific community. One major contribution of Medical Affairs in this area is defining the publication plan for each product. It also coordinates clinical and scientific communications disseminated by the company at medical congresses.
- Outreach to key opinion leaders (KOLs) — often the foremost researchers in their fields of expertise. KOL insights and involvement are often critical to development of a successful product. This outreach is made by the members of the field-based Medical Affairs team, commonly called MSL/MSL Managers.
- May sponsor (or lead development of the sponsorship strategy for) external education programs for HCPs, particularly in areas of focus within the company product portfolio.
- Answer to unsolicited product inquiries from HCPs and (to a lesser extent) patients. The volume of calls is highest around the time of the market launch of a new drug or following a major alteration in a drug's approved prescribing information.
- Identify new business opportunities, unmet scientific/medical/patient needs and to contribute to challenge the *status quo* and suggest improvement actions, both for internal or external customers.

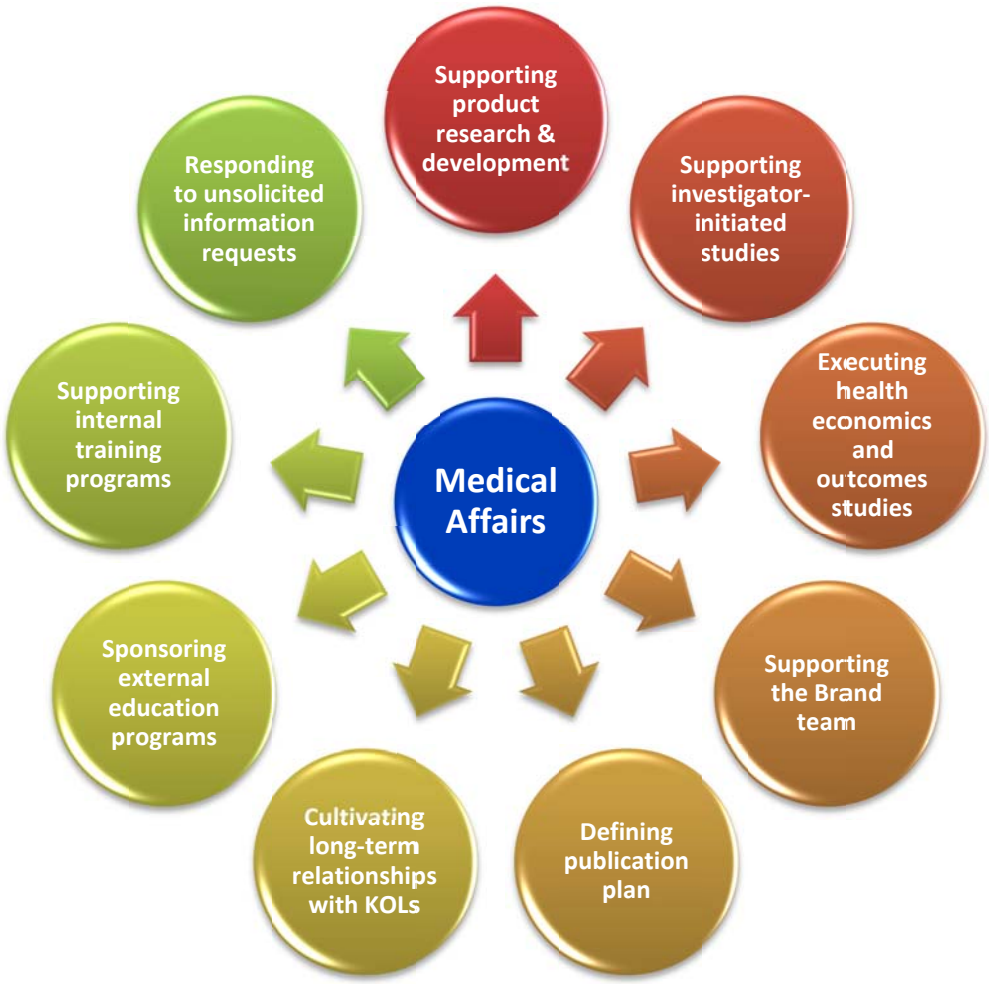

Figure 7 – The nine major responsibilities of Medical Affairs in a pharmaceutical company[5,15,16]

In conclusion, the role of Medical Affairs within a pharmaceutical company serves to lead the dissemination (and in some cases the generation) of unbiased clinical and scientific information about a medicine (to be launched or already on the market) to the healthcare community and to offer medical and scientific expertise to support the Brand teams. In the course of executing these duties, members of the MA team gather a great deal of market intelligence. Those findings are shared internally with senior management (in country and above country).

Rethinking the role of Medical Affairs: a rapidly changing world

It is known that one consequence of the shift happening in Pharmaceutical Industry over the last ten years has been a renewed emphasis on the importance of the Medical Affairs function. Nevertheless, using MA as a source of competitive advantage will pose a considerable challenge for most industry players. As the function grew and shifted its focus, companies did not always ensure they had the right talent in place to meet new demands.[1] Nowadays, and in the near future, companies do not need Medical Affairs staff to take on a merely supporting role, or even a partner role: what they need is leaders who can effectively engage with different stakeholders and senior colleagues.

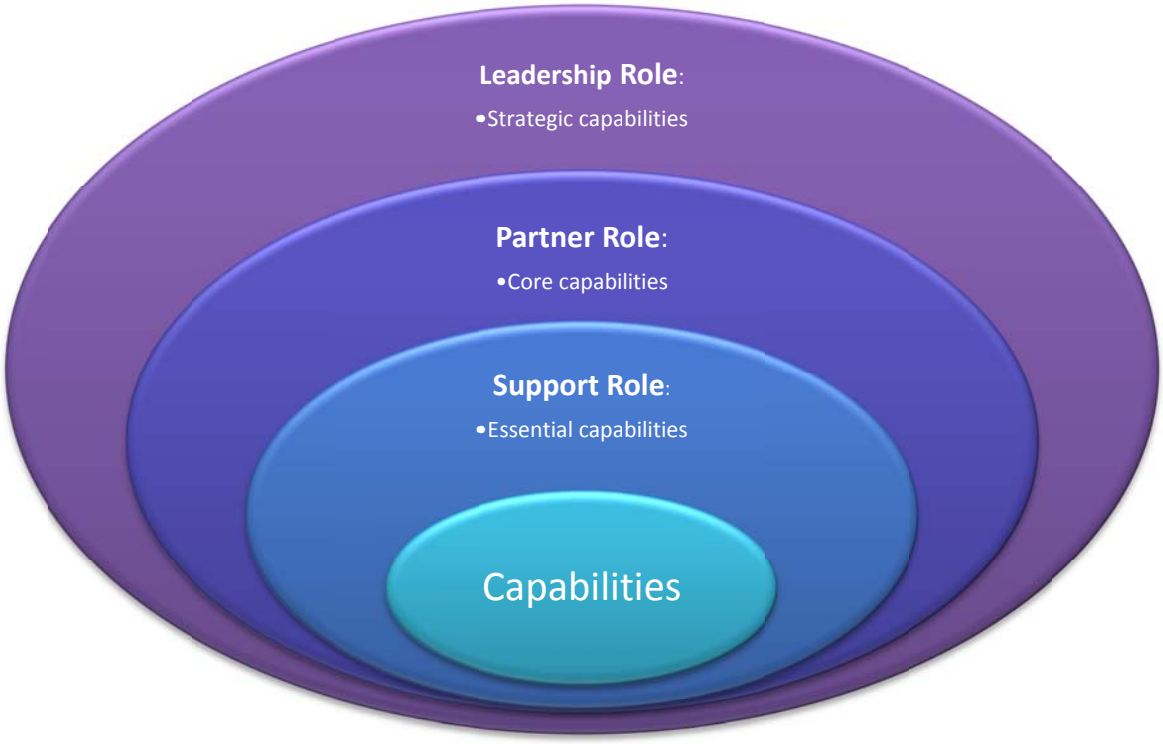

Figure 8 – Medical Affairs capabilities evolution roadmap

Even as the Pharmaceutical Industry is going through a period of contraction, the MA function is assuming new responsibilities and facing a wider range of expectations. Traditional medical backgrounds and capabilities are no longer enough to ensure competitive edge. The MA team must adapt to a wide range of external challenges, including a sharper focus on risk management, the growing prevalence of chronic diseases alongside an increased industry focus on speciality

and niche diseases, the emergence of new sources of data, and finally a more difficult market access environment.[1]

Adequately handling these challenges requires establishing and maintaining strong relationships with a broad range of stakeholders, including increasingly sophisticated payer, patient and advocacy groups.[2]

So, companies face a choice in their approach to MA: should they be satisfied with a function that meets their basic needs or commit to making it a genuine source of competitive advantage?[1]

There are some distinct areas in the current vision for MA that, once fulfilled, would enable this function to create significantly greater value for their companies, industry and society:[2]

1. *Enhance patient access to and best use of optimal medical treatment by clearly demonstrating value to practitioners and payers throughout the lifecycle of each product.*

   Medical Affairs must continuously upgrade its understanding of what value means from the perspective of a broad spectrum of healthcare stakeholders and to become more proactive about bringing insights from a wider range of external medical decision-makers and influencers into early clinical development.

2. *Embrace patient-centric healthcare by engaging and partnering with a broader range of healthcare stakeholders to more fully understand the different needs of patients and to be able to provide tangible value to patients.*

   The past few years have witnessed patients emerging as an important decision maker in healthcare, and a gradual shift in decision-making power away from physicians through an increasingly number of control mechanisms (e.g., treatment protocols, payer restrictions).

   Furthermore, the behaviour and expectations of both patients and physicians over the next five to ten years will increasingly follow trends enabled by technology advances (e.g., usage of mobile devices, remote data access, availability of real-time information, acceptance of social media as a new medium for interaction).

   The need to communicate with medical customers will remain constant, but how companies do it will evolve as technology improves. Medical Affairs leaders recognize that successful customer-engagement IT programs will be cross-functional and they see MA as

part of a medical continuum with Medical Information and Medical Education. This will require a more flexible engagement model that adapts to a changed communication landscape and captures opportunities utilizing multiple channels, including electronic and digital media.

More sophisticated systems and tools will be needed to prioritize and track interactions while new policies and processes will be required to avoid even the appearance of a conflict of interest in medical interactions, as, on the other hand and simultaneously, patients expect more information and two-way conversations, and Medical Affairs may have the opportunity to gain deeper insights into patients' needs through patient advocacy groups.

3. *Coordination and integration of different medical data sources and types of knowledge in the company and achieve external recognition for providing credible and unbiased medical information.*

   Medical information is increasingly complex and specialized, which makes it potentially highly valuable but often overwhelming to customers. Transforming this data into practical insights could drastically improve real-world medical decision making, providing value to physicians and patients. Medical Affairs should aspire to the greatest data quality and transparency (e.g., providing access to patient-level clinical trial data) in order to gain recognition as an unbiased source of medical information.

4. *Developing, managing, and retaining distinctive talent will be critical, and difficult. Performance management and succession planning must be taken seriously, which means training, building, and investing in core leadership competencies that leaders may not have acquired in the current clinical environment.*

   By being able to attract and retain the right talent, companies may build a dynamic, multi-faceted MA function, and create the conditions for individuals within it to grow and succeed.

Performance Management in Medical Affairs

Despite the evolving role and the sometimes significant headcount and allocated budget, many MA divisions have still not addressed performance management adequately. In some of these divisions the development of key performance indicators (KPIs) is ineffective, thereby validating the arguments that MA is 'different', hard to define, not possible to measure adequately, and that implementing KPIs can even be detrimental.[17]

The current understanding is that, if developed in a considered and holistic way, KPIs in MA can provide a valuable platform for continuous improvement and capability development, as well as organisational alignment.[17]

Furthermore, measuring the impact of MA has always been considered difficult due to compliance concerns, the wide range of MA activities and the overlap with activities from other functions.[18]

In recent years, there has also been much debate regarding the ability to quantify the financial contribution of the MA division, which is considered to be largely driven by the lack of understanding in many organisations as to what MA actually does. So the first goal here is to draw a clear definition of the deliverables and accountabilities of the MA division, which will clarify how partner/enabling functions can collaborate with MA to achieve the goals of the business.[17]

In addition to clearly defining Medical Affairs it is recommended to agree on strategic goals and priorities for the MA division and identifying related key business questions – critical success factors (CSF) – before moving on to define KPIs.[17]

Quite often, quantitative metrics will be hard to define for CSFs and some will need to be qualitative, based on a quantitative scale with a designated baseline. While there is a necessary upfront investment of time and effort in order to define qualitative metrics (e.g. around engagement with thought leaders or collection of Medical Affairs' customer insights, etc), this approach pushes the organisation to identify and focus on factors which are likely to be the best surrogate indicators of future success (Table 1).[17]

Table 1 – Evolving metrics of Medical Affairs performance (example: MSL metrics)[18]

Operating Metrics	Quality Metrics	Impact Metrics
-Number of MSL interactions by format -Number of MSL interactions by topic -Number of MSL interactions per provider	-Physician satisfaction with MSL relationship -Physician satisfaction with information provided by MSL -MSL responsiveness to requests	-MSL influence on safe and appropriate use of therapies to improve patient care -Overall satisfaction with conversation with MSLs -Frequency of information sharing provided by MSL with payers, providers, patients -Impact of MSL visit on strength of relationship with company

While it is often easy to measure how well people have planned and executed activities, it is more difficult to measure the impact of those activities. However, from a strategic perspective impact is a key priority.[17]

Measures of impact are likely to be a combination of qualitative and quantitative elements, and often no KPI will serve as an adequate indicator of impact. The risk therefore is that multiple KPIs emerge and the dashboard (the panel facing the "driver", containing instruments and controls that provide at-a-glance views of KPIs) becomes too complex.[17]

The need for hierarchy: not all stakeholders need the same view of the KPIs dashboard – in most cases the different levels of stakeholders will be interested in different questions (e.g. leadership teams are likely to want to focus on impact given that operations are generally running smoothly whereas country level MA Managers are likely to focus more on execution of major studies).

The pros and cons of standardization: it can be argued that KPIs should be standardised in situations where they will drive decisions across more than one part of the organisation or where comparability is necessary, as for example using standard KPIs to track resource allocation and budgetary performance. However, KPIs need to answer key business questions and different parts of the organisation will have different areas for improvement and different key business questions. Where KPIs are focused on a part of the organisation and its key business questions, standardisation is often counterproductive.[17]

Organizations present different levels of “maturity” regarding performance measurement models based on KPIs and there is much room for improvement in this front, which may start with a change in the attitude towards performance management in Medical Affairs: from a perception of control and measurement to one of empowerment and management.[17]

Effectively built KPIs will then provide the ‘vertical’ benefits of being able to report upwards and to drive performance, align and create buy-in within the MA division, but also the ‘horizontal’ benefits of being able to communicate with partner functions so that those functions can more easily recognize and use the potential value that MA increasingly offers.[17]

III – Becoming the boss: the evolving role of the Medical Director

Many physicians have successfully made their transition from clinical practice to the Pharmaceutical Industry, in positions ranging from entry-level Medical Advisor to CEO. But others have stumbled while navigating from clinical caregiver to leader in the corporate realm.[19]

It is consensual that physicians are, by and large, smart people with good work habits. But the behaviours and soft skills that are sought after and rewarded in clinical or academic environments are not exactly the same one looks for in the realm of drug development.[19]

A Medical Director (MD) must fulfil a set of requirements in order to leverage impact on internal and external customers, as he/she is the face of the company pertaining medical issues across all business units.

As the organization of pharmaceutical companies tends to be different, in accordance to values, culture, markets and strategies, a general description of what is currently the role of an MD is presented below, taking into account the comparison of several "Job Descriptions", which are internal guidance documents developed by companies. The scope of activities can be broader (usually in smaller companies, in which the MD may also accumulate other roles in the Medical Department or even Market Access) or may be limited (in larger companies, in which there are usually huge structures with multiple lines of cross-border reporting and distinct lines of function).

a) The purpose of a Medical Director

Ideally, the Medical Director is, beyond a leader, a supporter, and this must be the main guiding purpose, which can be further described in terms of actions as:

- Contribute strategically to the company's goals, by managing the medical team (including Regulatory, PhV, Quality, Clinical Research, Medical Affairs) following a clear-cut definition of objectives;
- Apply scientific know-how and overall business assessment to drive the implementation of the medical strategy, aligned with marketing strategy and customer needs in order to attain/maintain a therapeutic leadership position and drive business needs at a country level;
- Ensure highest ethical and scientific credibility and image of the company towards Health Authorities, scientific societies, patient associations and KOLs, creating partnerships that

represent mutual benefits in terms of research, development and access, and improving value perception of products (Figure 9);

- Be the external face of the company in relationships with medical associations, societies and academic medical centres that are not directly aligned to a specific business unit (external medical affairs);
- Be proactive in the identification of emerging trends from the market, translating them into business strategies;
- Oversight of the team leads regarding compliance (materials, transparency, training) and talent development.

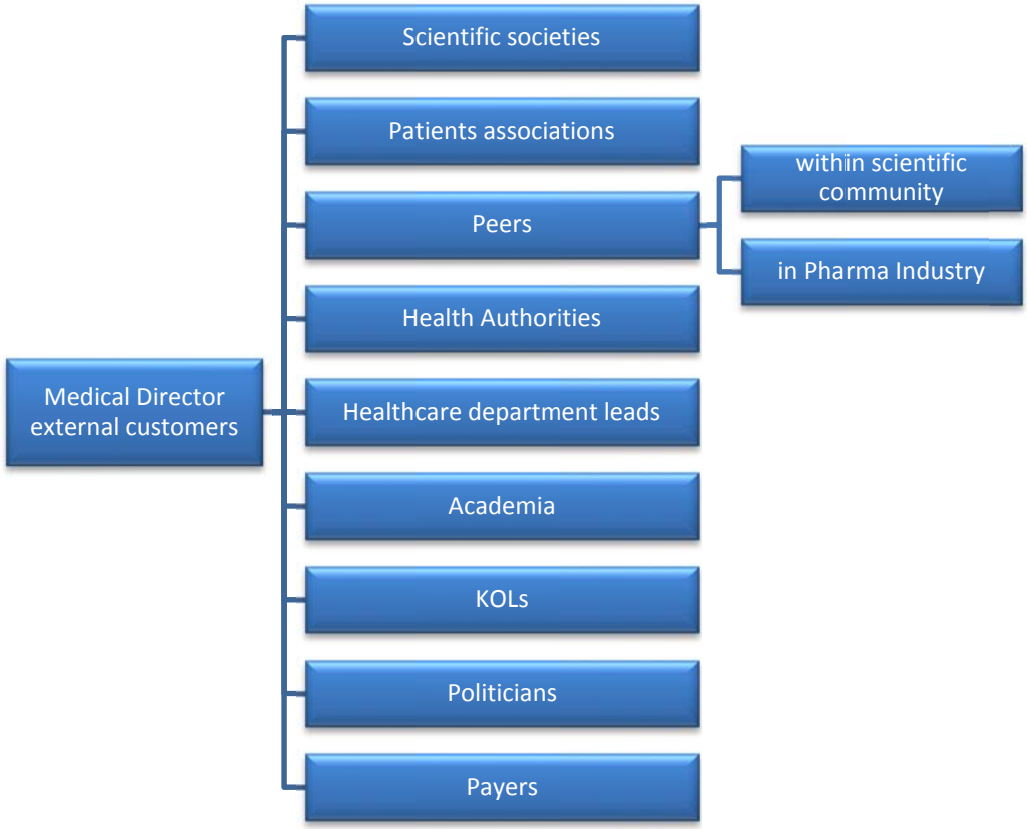

Figure 9 – Scope of external customers of a Medical Director

b) The responsibilities of a Medical Director

The responsibilities of a Medical Director are:

Medical Department Leadership

- Take collective responsibility with other department members for the vision, shape and direction of the team, aligning it with the business strategy and anticipating future needs.

Regulatory

- Provide strategic input on regulatory environment to ensure corporate compliance;
- Oversight of Regulatory Affairs activities with the aim of obtaining timely market introduction authorizations and adequate life cycle management according with the local and above country management (renewals).

Drug Safety

- Ensure that the overall drug safety reporting process fully adheres to national, European and Corporate drug safety reporting requirements in terms of time and quality.

Scientific and Medical Information

- Oversight of all medical communication to in-country external stakeholders.

Country Medical Strategy Development

- Participate in strategic planning process to provide insight, expertise and medical support to the business;
- Ensure that processes and procedures within medical are continuously reviewed and updated to meet current and future business needs.

Medical Marketing

- Contribute actively with input to products' launch plans;
- Contribute to excellent implementation of regional and local product strategies, adapted to the local environment.

In-Country Compliance

- Ensure consistent application of regulations and standards including those related to promotional material (country final approver), medical and scientific relations and transparency of transfers of value;
- Support the Quality Officer regarding Quality Plan and inspection readiness actions.

Country Access and Value

- Demonstrate the value of the company products to patients and payers through the support of pharmacoeconomic and health technology assessment data.

Clinical Research

- Cooperate in the local feasibility and effective implementation of international clinical trials, promoting transversal relations with the Clinical Research Unit (Medical Affairs and clinical research associates);
- Cooperate in the development, approval process and implementation of local trials, ensuring compliance with current regulations and standards.

People Management

- Lead, motivate and enhance the performance of colleagues in the team through coaching/mentoring and leading by example;
- Perform talent management within the Medical Department functions ensuring that medical staff gain the necessary experience to function optimally according to their potential and by ensuring they are aware of opportunities and feel encouraged to move across functions;
- Establish plans to attract and retain talent, which may include including a talent map, a career map and a succession plan in place.

Governance/Performance Management

- The MD is the Country Manager immediate point of reference for medical issues, while advising him/her on medical issues and ensuring appropriate response;
- The MD is the Medical representative on the local Management Team – takes collective responsibility with other Leads for the shape and direction of the affiliate company by actively participating in the development of local business strategy and objectives;
- The MD may chair a regular Department meeting with the purpose of maintaining compliance and information flow as well as to address and resolve any issues that arise within Medical and Enabling Functions;
- The MD addresses and leads responses to Regulatory, Safety, and/or Clinical Research issues with potential impact on public health, or a potential impact on the reputation of the organization;

- The MD or his/her delegate, is responsible for representing the company in medical related industry representative bodies;
- The country MD coordinates and is responsible for ensuring that the values and culture of the company are applied when interacting with important external customers that are not uniquely associated with a particular business unit or platform function, including professional societies, medical schools, media, government and payers.

c) Organizational relationships of a Medical Director

Generally an MD has a hierarchical report (also called "solid line report") to an above country medical lead, whose location and scope (in terms of countries allocation) depends highly on the geographical organization of a company and the size of the country, and may have a functional report (also called "dotted line report") to the Country Manager, but there are companies in which the reporting lines are the opposite of what is described here.

d) Resources managed/supervised by a Medical Director

Usually an MD manages two main types of resources, which vary widely between companies and between countries, and must find a correct balance in both dimensions, adjusting to the present business needs and bidding in anticipation of future business needs. These two main resources are:

<u>People:</u>

- Medical Information specialists;
- Medical/Scientific Advisors and Medical Science Liaisons (Medical Affairs team)
- Regulatory Affairs specialists;
- Drug Safety/Pharmacovigilance specialists ;
- Clinical Research specialists;
- Statisticians and Data Managers;
- Quality Assurance/Management specialists – may or may not be part of the medical department, as overseeing functions must be segregated from operating functions
- Pharmacoeconomics advisors – these may be part of another part of the structure (Market Access department);
- Departmental administrative staff

Budget:

- Country Medical Department budget (may include regulatory fees)
- Country Clinical Research budget (autonomy on this topic is reduced in smaller countries, and with tendency to decrease over the last years)

e) Qualifications required for a Medical Director

The heterogeneous set of qualifications looked for in an MD is not common to come across. They are usually, but not limited to, what is described below, depending on the culture of the company, the size of the country and the moment in the company's life (e.g. managing mature portfolio versus launching new products from pipeline):

- Physician with solid education and experience;
- Post graduate qualification preferred;
- At least 5 years of experience in medical functions in Pharmaceutical Industry;
- Proven experience & success leading the Medical Affairs function in a multinational company;
- Business management experience desired;
- Line management experience;
- Excellent verbal and writing skills;
- Fluent in native language and English;
- May be beneficial to maintain some clinical activity and/or lecturing activity in Academia.

f) Competency requirements and skills of a Medical Director

The MD is seen as a trustful business partner inside the organization offering added value medical expertise in a compliant and ethical manner, and supporting its assurance across the organization.

These are the skills most widely found, recognized and looked for when a MD is described. Figure 10 summarizes the skills of a MD in a schematic way.

Seriousness, credibility, impact and influence

- An example of living the company's values and procedures;
- Accountable for own decisions;

- Develops actions in order to achieve wide support within the organization;
- Able to lead towards alignment in a complex matrix organization;
- Strategic thinking, networking and teamwork;
- Creates future strategies and shares them with others;
- Assesses the organization's ability to meet long term objectives and re-evaluates them as necessary;
- Identifies and encourages opportunities for collaboration within and between groups;
- Actively promotes a friendly climate of cooperation and reputation of the group for people outside it;
- Initiates actions that contribute with innovative approaches and encourages contributions (encourages others to express their ideas); demonstrates ability to see things from the perspective of another person.

Customer focus

- Combines the customers' needs with services or products; addresses customers' unexpressed needs;
- Promotes the generation of ideas and solutions, presenting themselves as a competitive advantage in customer service, integrating and developing them in addition to its area of action.

Adaptability and catalyst for change

- Anticipates developments in the internal and external context, adapting or changing the strategy, objectives or projects according to the presenting situation;
- Serves as a leader in the face of change, assuming a key role in managing it and establishing its guidelines;
- Demonstrates ability to manage change effectively in crisis situations.

Analytical reasoning and problem solving

- Creates a range of solutions to problems that meet the needs of each situation;
- Develops and creates new concepts to explain or to solve problems and situations that may not be obvious to others;
- Can analyse complex situations and simplify approaches and processes;
- Acts in a global and long term perspective.

Management of conflicts and self-control

- Searches for a common ideal for all involved parts of a conflict;
- Maintains calm and is able to keep others calm in stressful situations (ability to cope with stress).

Leadership and development of others

- Looks for new challenges and opportunities, promoting a positive and optimistic attitude in others;
- Creates opportunities for continuous learning which serve short and long term development needs of the elements of the team, with a view towards developing the organization itself;
- Is seen as a leader, shows charisma and a vision of the future that will generate enthusiasm in others.

Organizational consciousness

- Promotes the culture of the organization. Disseminates its values and acts consistently with them;
- Encourages cooperation between different areas of the company, promoting balance between the needs and requirements of the organization;
- Operates on a rationale of medium-long term protection of the interests of the organization.

Good communication and Negotiation skills

- Clearly communicates with others and can adapt to different levels of audience, maintaining high level of understanding;
- Negotiates in a positive way in adverse environments and uncertainty contexts with impact on the business and organization;
- Gets consensus/agreements in beneficial commitments to both parts without jeopardizing the relationship and without giving up goals;
- Seeks to develop win-win strategies.

Excellent planning and organization skills

- Understands the impact of the external environment on the strategy;

- Has a global perspective of the market, evaluates opportunities and ways to keep involved in the organization;
- Able to prioritize, delegate, and to keep focus in view of multiple requests.

Broad and deep knowledge of the business, therapeutic areas and local pharmaceutical legal codes and processes

- Proposes innovative and robust solutions based on the solid scientific background and knowledge of the market and its stakeholders.

g) Replacement: difficulty and impact

It may be difficult to replace a Medical Director in the short term. This position entails a very profound expertise on both medical, pharmacovigilance, quality and regulatory issues with senior level relationship and team management skills, alongside with an evolving business dimension.

Another issue is the scarcity of eligible candidates in the market, mainly because there are few physicians with specialization degree and with the additional set of skills required to thrive in the Pharmaceutical Industry, as discussed below.

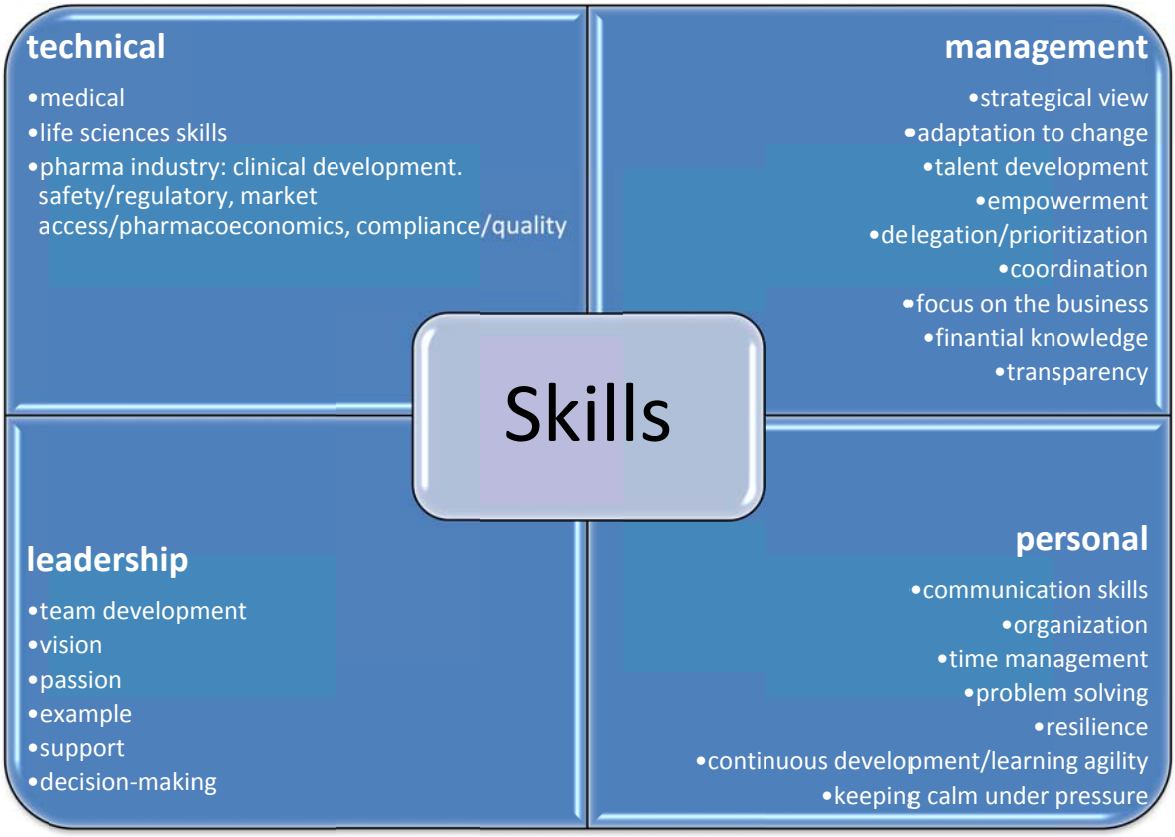

Figure 10 – Proposed set of skills for a Medical Director

IV – More than medicine: the evolving profile of the Medical Director

a) From clinician to Industry leader: extending the vision

While behavioural competency models — detailed pictures of the behaviours that define outstanding Medical Directors— exist for jobs across all business sectors, few pharmaceutical companies have developed competency models aligning the drug development process with behaviours that are expected of physicians with management capabilities in R&D functions. If more emphasis were placed on identifying and articulating behaviours that predict future success, causing greater collaboration and inspired teamwork, we might see a higher level of productivity and a greater number of drug candidates submitted for approval.[19]

Some forward-thinking Pharma and biotechnology organizations have begun to set competency models, along with developmental roadmaps, to help physicians learn new behaviours and gain the emotional intelligence that research suggests goes hand-in-hand with success in the pharmaceutical sphere.[19]

b) Emotional intelligence: a valuable leadership asset

Physicians who have made the transition from academia or clinical practice to Pharmaceutical Industry tend to possess competencies associated with high emotional intelligence (EI): in addition to strong medical and scientific knowledge, these physicians are highly self-aware – they know the effect of their behaviour on others.[19]

Everyone is aware of the classical stereotype of the physician working in a surgery room or an emergency room, making quick decisions that can make a huge difference in patients' lives. In these occasions, controlled social behaviour gives way to orders shouted across a room and dispensing niceties. In the Pharmaceutical Industry, however, displaying these behaviours do not quite drive to success.

On the other hand, at the patients' bedside in the ward or during programmed appointments, the physician classically shows empathy and deep understanding of the patient's suffering and individuality. It is critical for physicians working in Pharmaceutical Industry to make good use of this particular set of behaviours and transport them to the corporate context: active listening, empathy, respect for others are traits not only valued, but expected, as they support insightful and informed decision making.

One example of a successful transition from the clinical to the corporate world is physician Daniel Vasella, chairman and CEO of Novartis AG between 1996 and 2013. Initially trained as a psychiatrist and psychoanalyst, he has credited his own work as a therapist as a contributing factor to his success in the Pharmaceutical Industry, including ability to self-reflect, balance the rational and emotional elements of decision-making, and take other points of view into account. "It gave me the self-assurance to be self-determined rather than determined by circumstances."[19]

In a 2003 interview at Harvard Business School, he said "First of all, I believe that the corporate world can be a fantastic experience, and what you can learn from others across cultures and countries and businesses is incredibly enriching. Second, I think, if one enters into a profession, one needs to be competent and rooted in one area. You may be very good in a specific area, but for more general management or for leading groups, interpersonal skills become very important — more important than technical skills. So I would say do everything you can in order to get to know yourself, how you react and what your strengths and weaknesses are and then work on your interpersonal skills."[12]

Another good example of this type of transition is Olivier Brandicourt, appointed as Sanofi's Chief Executive Officer on February 2015. Brandicourt, a physician trained in Paris, over his 28 years of experience in the Pharmaceutical Industry had already been CEO of the healthcare unit at Germany-based Bayer since 2013 and prior to that had risen through the ranks at Pfizer Inc. to lead the U.S. company's Emerging Markets and Established Products business units. Earlier in his career, he was a malaria researcher in Paris and spent two years working as a doctor in the Republic of Congo.[20]

In a recent video interview he stated that his initial choice for tropical medicine aimed to have a positive impact in patients' lives, and after some time he realized that he could have even bigger impact by working in Pharmaceutical Industry. His career changed and his life too.[20]

What distinguishes great leaders from merely good ones is not intelligence quotient or technical skills. It is emotional intelligence (EI): a group of five skills (as described by D. Goleman) that enable the best leaders to maximize their own and their followers' performance. When senior managers at one company had a critical mass of emotional intelligence capabilities, their divisions outperformed yearly earnings goals by 20%.[21]

The emotional intelligence skills are:[21]

- Self-awareness — knowing one's strengths, weaknesses, drives, values, and impact on others
- Self-regulation — controlling or redirecting disruptive impulses and moods
- Motivation — relishing achievement for its own sake
- Empathy — understanding other people's emotional makeup
- Social skill — building rapport with others to move them in desired directions

We are each born with certain levels of EI skills. But we can strengthen these abilities through persistence, practice, and feedback from colleagues or coaches.[21]

c) Competency-based model versus behavioural-based model

Key technical competencies for Medical Directors such as a medical degree, a strong clinical foundation, knowledge of drug development, project and team management experience and written and verbal skills are relatively easy to define, as written above.

Underlying behavioural competencies are more difficult to ascertain, and these are more often the true predictors of success in the role.

A competency model for MDs defines the critical behavioural competencies such as delivering scientific and medical insight, building credibility, inspiring people and driving the business. Committing oneself to treat patients in a clinical setting is quite different from extending that vision of healing to drug development and thus considering the behavioural model of a physician in a new and relevant context.[19]

The behavioural competency model describes behaviours that allow MDs to broaden their clinical understanding and develop strategies that result in successful new therapies, such as:

- Passion to address unmet medical needs with a far-ranging impact on patients;
- A love for learning;
- A drive to search for new insights;
- The ability to recognize patterns and translate complex findings into meaningful conclusions.

In short, it is all about the ability to influence R&D's scope and direction by balancing technical expertise with interpersonal skills.

Building internal credibility in a corporate environment requires skills and behaviours that often differ radically from building credibility in a clinical setting. The former requires demonstrating respect for other people's input and expertise. That often means reaching out, being an active listener, showing adaptability, and collaborating cross-functionally. It requires knowing how to "speak one's mind" without alienating people, and simultaneously listening to other points of view.[19]

d) The distinctive anatomy of physicians working in Pharmaceutical Industry: one size does not fit all

To deal with profound uncertainty and high risks, allow closely interdependent problem solving, and harness the collective experience of disciplines throughout the organization, Medical Directors need a specific anatomy (or design). Anatomy helps understand what a given species is capable of and why certain species can thrive in some environments but not others. The fit between anatomy and environment matters in economics, too.

Companies at the vanguard of the pharmaceutical and biotechnology sectors that have developed a behavioural competency model for MDs are considered to be well positioned to make better recruitment and hiring decisions and have a clear direction on the development and retention of physicians.[19]

Let's now look closer at one example of a competency model.

One pharmaceutical company had a particular competency model taking into account that different physicians will exhibit different levels of the desired behaviours based on their personalities, life experiences, and experience working in corporate settings.[19]

Competency models – which had been used for other functions at the pharmaceutical companies before the value of creating one specifically for MDs was recognized – segments MDs by their years of industry experience (less than 5 years, 5–10 years, and more than 10 years), and defines the minimum and target levels of behaviour required. For example, in the model, under "Driving the Business," MDs with:[19]

- less than 5 years of experience are expected to understand the business context, set standards, and measure performance;
- 5 to 10 years should additionally be driving business goals and acting with a sense of urgency to make improvements;
- more than 10 years of experience ought to be having an impact on the prioritization and specification of goals and making wise choices on when to move forward or halt a project.

The consequence was that this company faced a "revolving door" high turnover rate among its MDs, and changed to a behavioural competency based model, resulting in wiser choices, hiring MDs based on their fit into the corporate culture, and their demonstration of the sought-after behavioural competencies, with better results after one year than benchmarked peer group data.[19]

Authors with experience in working with and for the Pharmaceutical Industry believe that a robust competency model for MDs, similar to competency models designed for other positions in other functions, encourages and rewards the right behaviours. It is an invaluable tool for hiring, developing, and retaining physicians who possess – or are able to develop – the competencies that will enable the Pharmaceutical Industry to unleash the so far unexplored potential of the drug development process.[19]

Now let us consider some points that need to be taken into consideration when working and building a career path as MD: they are almost the same as those that leaders need to consider, with the particularity of the field of work – Pharmaceutical Industry – being the most regulated activity sector in the world.

e) Learning on the job – experience is a valuable asset

Even for the most gifted individuals, the process of becoming a leader is an arduous, but rewarding, journey of continuous learning and self-development.

The earliest test of leadership comes with that first assignment to manage others. Most new managers initially fail this test because of a set of common misconceptions about what it means to be in charge.[22]

One of the first things new managers discover is that their role, by definition a stretch assignment, is even more demanding than they had anticipated.[22] The skills and methods required for success as an individual contributor and those required for success as a manager are starkly different— and that there is a gap between their current capabilities and the requirements of the new position.

In their prior jobs, success depended primarily on their personal expertise and actions. As managers, they are responsible for setting and implementing an agenda for a whole group, something for which their careers as individual performers have not prepared them.[22]

Learning to lead is a process of learning by doing. It cannot be taught in a classroom. It is a craft primarily acquired through on-the-job experiences — especially adverse experiences in which the new manager, working beyond his current capabilities, proceeds by trial and error. Most star individual performers have not made many mistakes, so this is new for them. Furthermore, few managers are aware, in the stressful, mistake-making moments, that they are learning. The learning occurs incrementally and gradually. As the process slowly progresses, a new professional identity emerges.[22]

We know that to be a good leader, it helps to be intelligent, able to think conceptually. Leaders also have to have a certain level of ambition; they need to be people who take pleasure in creating, growing, and building. But those qualities need to be balanced by scepticism — recognition that not everyone wants you to succeed and that sometimes bad things do happen.[12]

And leaders have to be able to resist seduction. If we look at all the reasons leaders fall, it is usually the soft factors. Several seductions come with taking on a leadership role. There are many different forms: sexual seduction, money, praise. You need to be aware of how you can be seduced in order to be able to resist and keep your integrity.[12]

f) The importance of resilience in leading large organizations

Organizational resilience is an enterprise's capability to respond rapidly to unforeseen change, even chaotic disruption. It is the ability to bounce back — and, in fact, to bounce forward — with speed, grace, determination and precision. In many respects, resilience represents the next phase in the evolution of traditional place-centric organizational structures to highly virtualized, people-centric structures that enable people to work anytime, anywhere. The virtualized organization is

emerging as a preferred strategy for many leading global businesses, including Pharmaceutical Industry, to work across boundaries of time, distance and culture, as organizations move from being mainly reactive to being agile, responsive and resilient.[23]

Moving from organizational into personal terms, resilience is the process of adapting well in the face of adversity, trauma, tragedy, threats or significant sources of stress, that include, among others, workplace and financial stressors. It means "bouncing back" from difficult experiences.

And if it is consensual that resilience is, for every team member, a fundamental tool for competitiveness and survival in the 21st century, it assumes even greater importance, in the scope of this paper, to the Medical Director, as it will enable to adequately respond and flourish in an environment of hyper-change, as it is also strongly associated with leadership skills such as:[23]

- The capacity to make realistic plans and take steps to carry them out
- A positive view of self and confidence in own strengths and abilities
- Skills in communication and problem solving
- The capacity to manage strong feelings and impulses

Resilience is also closely associated with enterprise culture (namely principles of organizational empowerment, purpose, trust and accountability), despite the fact that developing resilience is a personal journey in which different people use different strategies. With growing cultural diversity, organizations have greater access to a number of different approaches to building resilience.[23]

Additional foundation principles for resilience in a Medical Director as a leader that are worth mentioning are: supporting people as they are the bedrock of organizations (select, motivate and support people who have the requisite skills to flourish in ambiguous and uncertain environments); foster systems development (highly robust and collaborative information technology infrastructure to efficiently connect and inform the organization); and plan the settings (workplace agility relates to workplace resilience).[23]

g) Coaching and mentoring

Every leader needs someone who can listen — a board member, an adviser, a partner — someone to whom he can speak in total confidence, to whom he can say, “I’ve had it.” You need someone who understands and can help you to keep the balance, as you tend to get more isolated the

higher you get on the corporate ladder.[12] Leaders ask for help, especially as they try to put together their personal managerial puzzle. The insights a manager does possess come over time, through experience. And it has been demonstrated that it is easier to learn on the job if you can draw on the support and assistance of peers and hierarchical superiors. The inherent conflict between the roles of evaluator and developer is an old dilemma. Such fears are often justified. Many recent managers regretted trying to establish a mentoring relationship with the boss, by fear of being taken by naïve or incompetent.[22]

When a new Medical Director can develop a good relationship with his boss, it can make a big difference, but sometimes, the most expert mentors can seem deceptively hands-off: it is important for the bosses of new MDs to understand how difficult it is to step into such a role for the first time. Helping a new MD succeed does not benefit only that individual, but can also be crucially important to the success of the entire organization.

h) Being a Supporter or a Leader?

"Good leaders must first become good servants" – Robert Greenleaf.

Leaders who nurture the misconception that power comes from authority often face a rude awakening: they are involved in a web of relationships — not only with subordinates but also with bosses, peers, and others inside and outside the organization, all of whom make relentless and often conflicting demands on them. The resulting daily routine is pressured, hectic, and fragmented.[22]

To lead effectively, they need to negotiate interdependencies, going beyond managing the team of direct reports, but requiring management of the context within which the team operates: they are network builders who need to identify and build effective relationships with the key people the team depends upon, so the team will have the resources necessary to do its job.[22]

Nevertheless, there is power in being the leader, but it must be underlined that authority emerges only as the manager establishes credibility with subordinates, peers, and superiors. To build credibility they need to demonstrate:[22]

- character: the intention to do the right thing. This is of particular importance to subordinates, who tend to analyse every statement and nonverbal gesture for signs of the new boss's motives.
- competence: knowing how to do the right thing, which despite being important to gain subordinates' respect, it is not ultimately the primary area of competence that direct reports are looking for. They must find the right balance, as a too much "hands-on" approach can be considered as micro-management, thus unworthy of respect.
- influence: the ability to deliver and execute the right thing, which can be particularly difficult if the person is new to a director's role. One must not rely too heavily on formal authority as a source of influence; instead, influence must be built by creating a network of strong, interdependent relationships, based on credibility and trust, throughout the team and the entire organization — one strand at a time.

Leaders do not believe in gaining control through compliance. In fact, the more power managers are willing to share with subordinates through **empowerment and commitment**, the more influence they tend to command. When they lead in a manner that allows their people to take the initiative, they build their own credibility as managers. If people are committed, they will take the initiative. And if they are taking the initiative, the manager **can delegate effectively**. In this setting, the direct reports will probably take the calculated risks that lead to the continuous change and improvement required by today's ever changing and increasingly complex business environment. Leaders are **team players** that recognize and address their team-building responsibilities, going far beyond building the most effective relationships they can with each member of the team and managing the individual level. They pay attention to team culture and performance. They rely on group *fora* for identifying and solving problems and they make decisions based on relevant information collected from multiple perspectives, making the most of the collective power of the group to improve individual performance and commitment, and of the diverse talents that make up the team.[22]

Leaders are **agents of stability**, but also **agents of change**. Ensuring everything is operating smoothly is an incredibly difficult task, requiring a manager to address several issues at a time, and the complexity of maintaining the *status quo* can absorb all of a recently appointed Medical Director's time and energy. But they also need to realize they are responsible for recommending and initiating changes, within and outside their areas of responsibility that will enhance their

groups' performance, which can mean challenging organizational processes or structures that exist above and beyond their area of formal authority.

This broader view benefits the organizations as well as people in them, as organizations must continually revitalize and transform themselves through effective leadership, capable of both managing the complexity of the current business and initiating change.

i) Work-life balance

Of course physical stamina is a fundamental requirement to lead; there may be frequent travelling and different time zones, different languages from one's mother tongue and all kinds of demands. But psychological stamina is probably even more important. Medical Directors need to be able to switch on and switch off, to be entirely present when present. And in reverse, to be entirely away when away. There needs to be a moment to say, "I'm home now," and work is set on hold.[12]

Learning to say "no" can be one of the most valuable assets in business. Many people fear that saying "no" to a colleague, whether a senior, equal or junior, can somehow damage their image. No one wants to seem like they are less than fully dedicated. Nevertheless, saying "no" can show capability of prioritizing workload, and leave more time for tasks that are really important. Additionally, burnout is costing businesses billions in lost productivity: long working hours correlate with distress, bad temper and impulsiveness. Leaving the office on time, or even introducing a 'work at home' program to be used on occasion, can really improve work-life balance.

Turning your notifications off is also an important learning in the post internet era, as it can reduce distractions and anxiety, helping to keep focus.

Leaders often forget the importance of stable emotional relationships — especially outside the company. It helps tremendously to manage stress. Your partner will do a lot to help keep you in sync.

Finally, as a manager, the Medical Director must also focus on helping teams eliminate the unending chaos of work that kills productivity, drains motivation and stifles creativity, streamlining processes whenever possible.

j) Women medical directors – taking work-life balance to a new level

Nailing the work-life balance equation right has been the Holy Grail of people with a career, but women still suffer most of all because they carry a constant feeling of "guilt" and sense of “failure” for not being able to excel all the time in both areas: the career and the family, and the need to prioritize and make difficult choices to strive in the corporate ladder escalade, as in the Pharmaceutical Industry.

In most cultures masculinity and leadership are closely linked: the ideal leader (like the ideal man), is decisive, assertive, and independent. In contrast, women are expected to be nice, caretaking, and unselfish. The mismatch between conventionally feminine qualities and the qualities thought necessary for leadership puts female leaders in a dilemma. Numerous studies have shown that women who excel in traditionally male domains are viewed as competent but less likable than their male counterparts. Behaviours that suggest self-confidence or assertiveness in men often appear arrogant or abrasive in women. Meanwhile, women in positions of authority who convey a conventionally feminine style may be liked but are not respected. They are deemed too emotional to make tough decisions and too soft to be strong leaders.[24]

Additionally, more traditional organizational structures and work practices were designed to fit men’s lives and situations at a time when women made up only a very small portion of the workforce. For example, career- enhancing international posts often assume a “coming along spouse” who has no career and can easily move—a family situation much more common for men than for women. How work is valued may similarly give men an advantage: research indicates that organizations tend to ignore or undervalue behind-the-scenes work (building a team, avoiding a crisis), which women are more likely to do, while rewarding heroic work, which is most often done by men. These practices were not designed to be discriminatory, but their cumulative effect disadvantages women. A vicious cycle is created: men appear to be best suited to leadership roles, and this perception propels more of them to seek and attain such positions, thus reinforcing the notion that they are simply better leaders.[24]

Another important point is women’s lack of access to networks and sponsors. Informal networks are a precious resource for would-be leaders, yet differences in men’s and women’s

organizational roles and career prospects, along with their tendency to interact with others of the same gender, result in weaker networks for women. Moreover, the connections women do have tend to be less efficacious: men's networks provide more informal help than women's do, and men are more likely to have mentors who help them get promoted. Meanwhile, men in positions of power tend to direct developmental opportunities to junior men, whom they view as more likely than women to succeed.[24]

Women leaders must take the step to become harbours of trust in themselves and in their capabilities, not letting themselves undermine by the status quo. If they manage this, they feel empowered, not victimized, because they can take action to counter the effects of the gender bias. They can put themselves forward for leadership roles when they are qualified but have been overlooked. They can seek out sponsors and others to support and develop them in those roles. They can negotiate for work arrangements that fit both their lives and their organizations' performance requirements. Finally, women leaders must also remember that disconnecting, making regular pauses and profiting from flexible work schemes and IT infrastructure that organizations nowadays put at their disposal can be very important to help reverse this frequent situation and create that feeling of gratification that brings high commitment along.

V – Surveys

a) Methods

Three surveys were conducted to complement this report. The questions, as viewed by the respondents, and data collected are displayed in the Appendix section of this document under Appendix 1 and 2.

1-SurveyMonkey® questionnaire 1: "Profiling Medical Directors working in Pharmaceutical Industry". This questionnaire was applied to a convenience sample of 23 Medical Directors working in Portugal (Appendix 1). Selection criterion for this sample was availability of an email address.

The questionnaire was sent in May 2015. The questionnaire was open to responses for 30 days; 11 complete answers were retrieved.

2-SurveyMonkey® questionnaire 2: "Profiling Medical Directors working in Pharmaceutical Industry". This questionnaire had exactly the same content as questionnaire 1 but was applied to a convenience sample of 25 Medical Directors working in Sanofi Affiliates in Europe (Appendix 1). Selection criterion for this sample was availability of an email address.

The questionnaire was sent in May 2015. The questionnaire was open to responses for 30 days. 13 complete answers were retrieved.

3-SurveyMonkey® questionnaire 3: "Access to Medical Directors working in Pharmaceutical Industry in Portugal". This questionnaire was applied to a convenience sample of 42 HCPs working in Portugal (Anesthesiology, Cardiology, Endocrinology, General Surgery, Hematology, Internal Medicine, Neurology, Oncology, Orthopedics, Pulmonology, Vascular Surgery) (Appendix 2). Selection criteria for this sample were previous personal knowledge of these customers nd availability of email address.

The questionnaire was sent in June 2015. The questionnaire was open to responses for 30 days. 18 complete answers were retrieved.

b) Snapshot of current Medical Directors' perceptions in Portugal

The purpose, the responsibilities, the relationships, the qualifications, the broad scope of activities, the competency requirements and set of skills of a Medical Director in the

Pharmaceutical Industry have been presented and discussed above, based in extensive literature revision and personal experience.

Nevertheless, I performed a survey, involving Portuguese Medical Directors, in order to gain deeper knowledge on some aspects of their current function and how they perceive its evolving role and relevance (ref. 1).

The survey was sent to a convenience sample of Portuguese MDs. Eleven complete answers were retrieved, containing the information described below. This data has no statistical power, as the sample size does not cover a representative portion of MDs in Portugal (in 2012, 122 pharmaceutical companies were APIFARMA affiliates[25]), so the analysis is descriptive in nature; nevertheless we can observe trends, which can generate hypotheses that may be further deepened by dedicated research.

The majority of those who responded are in the age group of 51-60 years (one respondent below 40 years old), 80% have been working in Pharmaceutical Industry for more than 15 years, and 55% report being or having been active in their clinical career for up to 10 years.

Regarding their reasons for joining the Pharmaceutical Industry, they report, in order of preference, the following:

- trying something different with previous knowledge from clinical setting (reported by 67% of respondents),
- were tired and with no motivation for clinical everyday work (reported by 56% of respondents)
- wanted to have an active role in the clinical development and access to new treatments in the country (reported by 22% of respondents)
- conditions offered by the hiring company were much better than previous ones (reported by 11% of respondents).

Other reasons that were reported for joining Pharmaceutical Industry were gathering the clinical development and clinical practise in one and have more time for family, and a medical condition that made it impossible to continue the exercise of the respective specialty.

Interestingly no respondents ticked one of the options provided, “It was always my objective since medical school”.

Regarding additional specialization beyond medical degree, 64% of respondents declared one or more, ranging from formal medical training (Public Health, Surgery, Paediatrics, Pulmonology, Epidemiology, Family Medicine), to Competency in Pharmaceutical Medicine from the Portuguese Medical Association and Master degrees, either MBA and Pharmaceutical Medicine MSc degree.

None of the respondents reported a PhD degree.

Regarding the traits perceived as essential for a Medical Director, the graphic below depicts how the respondents prioritize the items on the provided list.

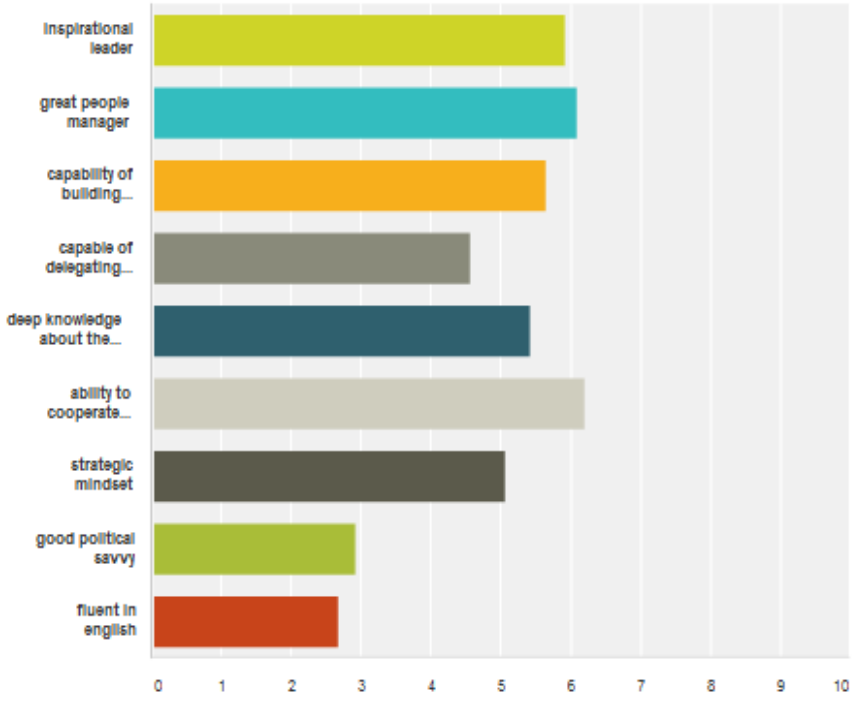

Figure 11 – prioritization (1-9) of traits considered as essential characteristics of a Medical Director: Portuguese MDs

The most valued characteristic of a MD is the ability to cooperate transversally, followed by being a great people manager, closely followed by being an inspirational leader, capability of building trustworthy relationships, good knowledge about the business, strategic mind set and capability of delegating tasks.

The respondents classified lower in the list of priorities characteristics such as good political savvy and fluency in English – these are also required, but in front of them it is very clear that

Portuguese MDs themselves consider that leading and management skills and their connected capabilities as the most important for the job.

Regarding the workload in the exercise of their present job, here is where the respondents spend the most of their time:

- internal meetings (including travel time and teleconferences)
- managing the mailbox
- supporting other functions ensuring timely delivery of projects
- coaching and developing people in the team and/or in the company
- meeting external customers (HCPs, scientific societies, regulatory authorities, politicians)

Other activities mentioned were: attending congresses, conferences, lectures, seminars related to business, thinking strategically with the team to drive medical input to the business, self-development and training activities and managing the medical budget and phasing.

Bearing these results in mind we can conclude that strategic thinking, which is one of the most widely recognized core competencies of MDs, and one of the main reasons for looking carefully for a profile that can effectively assist the business when hiring, is not at all one of the top tasks in which Portuguese MDs that responded to this survey currently spend their time on, since administrative and bureaucratic tasks still lead the way by a somewhat long distance, as seen in figure 12 below. Possibly there is some “waste” of highly skilled and differentiated resources in administrative tasks, and maybe this should be looked upon more carefully by Human Resources and high rank business planning executives.

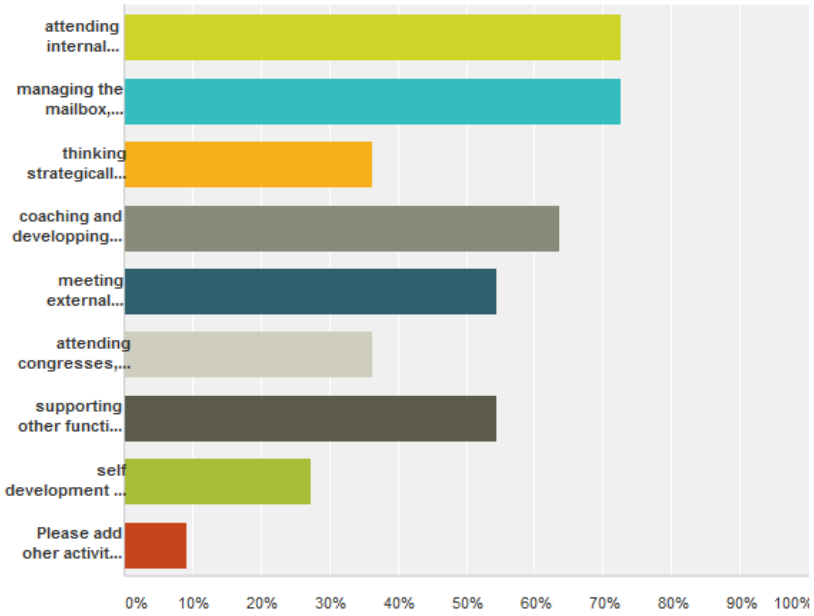

Figure 12 – hierarchy of activities by time spent: Portuguese Medical Directors

Moving on to the development of the Medical Directors, 82% of the respondents considered that the most important improvement area for them is work-life balance, followed by improvement in finance/legal skills (45%), business management and communication/negotiation skills (both 27% respectively). Other areas identified, but with lower scores were: time and email management skills, improving proficiency in a foreign language (English), and team management skills.

The last question of the survey was about evolutionary pathway. The majority of respondents want to keep developing themselves in their current role (55%), and 45% express that they would like to become Medical Directors of a multi-country organization. These two career developments were followed by becoming Country Manager (27%), moving to an above country position in a Therapeutic area, changing into a more commercial position such as Business Unit Head and changing into a policy related job.

Bearing these results in mind, we can say that the Portuguese Medical Directors who responded to this survey are senior differentiated medical experts with experience both in the clinical setting and in the Pharmaceutical Industry, spend most of their time in administrative tasks, consider that they are good team and time managers, are working many hours, reducing their time for other activities, with impact on their personal lives, and they need to improve their skills in areas outside their background technical skills. Most would prefer developing their career inside the medical domain, but some consider moving into more commercial roles.

c) Snapshot of current Medical Directors' perceptions in EU affiliates of a pharmaceutical company

This survey was sent to a convenience sample of Medical Directors working in European countries, all in the same company (ref. 2). Thirteen complete answers were retrieved, containing the information described below. This data has no statistical power because the sample is small in scale, was not calculated to be representative of MDs in Europe, belongs to one single pharmaceutical company, and responses can vary widely between different company cultures, business models, lifecycle phases and regarding the nature of the portfolio (innovative, mature, biotech, generics). The analysis is therefore descriptive in nature, but we can observe hypothesis-generating trends, which can in turn be further ascertained by more specific research.

The majority of those who responded are in the age group of 41-50 years (one respondent below 40 years old and none above 60), 85% have been working in Pharmaceutical Industry for 11 to 20 years, and 69% report being or having been active in their clinical career for up to 10 years, with 15% always being active in the clinical setting.

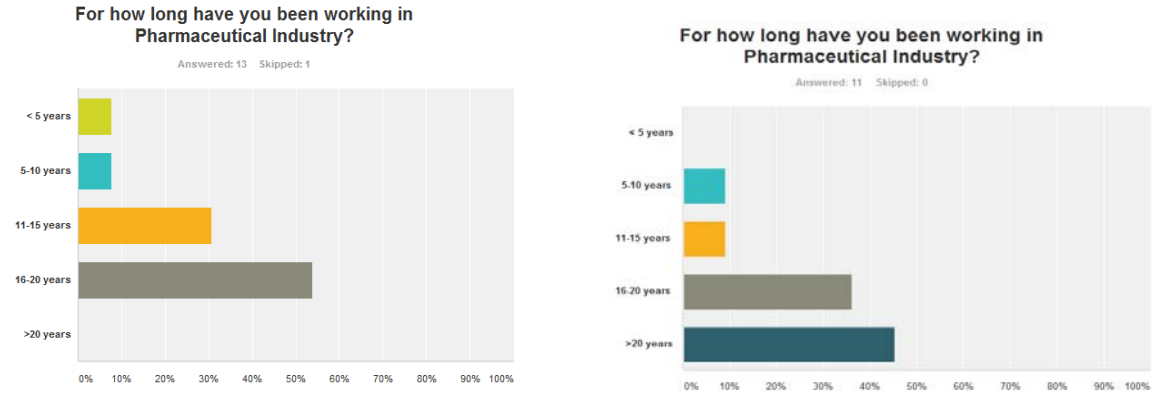

Figure 13 – years of experience in Pharmaceutical Industry: EU versus Portuguese MDs snapshot

Regarding their reasons for joining the Pharmaceutical Industry, they report, in order of preference, the following:

- wanted to have an active role in the clinical development and access to new treatments in the country (reported by 36% of respondents)
- conditions offered by the hiring company were much better than previous ones (reported by 27% of respondents)
- trying something different with previous knowledge from clinical setting (reported by 18% of respondents)

- were tired and with no motivation for clinical everyday work (reported by 18% of respondents)

Other reasons that were reported for having joined Pharmaceutical Industry were appreciation and recognition of results and achievements, long term contract instead of short term, highly hierarchical structures and personal reasons related to family.

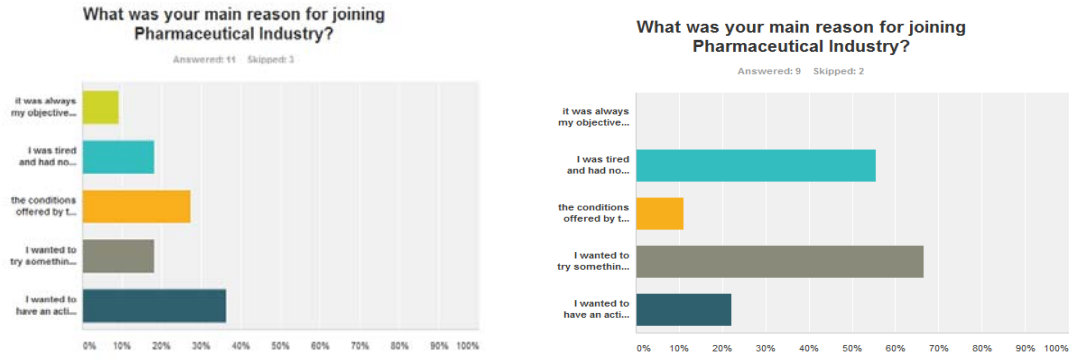

Figure 14 – reasons for joining Pharmaceutical Industry: EU versus Portuguese Medical Directors snapshot

Among EU Medical Directors, one respondent answered that it was always an objective since medical school.

Regarding additional specialization beyond medical degree, 69% of respondents declared one or more, ranging from formal medical training (Haematology, Internal Medicine, Family Medicine), to Master degrees (MBA, Pharmaceutical Medicine, Health Economics and Regulatory Affairs MSc degrees were mentioned).

Two of the respondents reported a PhD degree.

Regarding the traits perceived as essential for a MD, figure 15 below depicts how the respondents prioritize the items on the provided list.

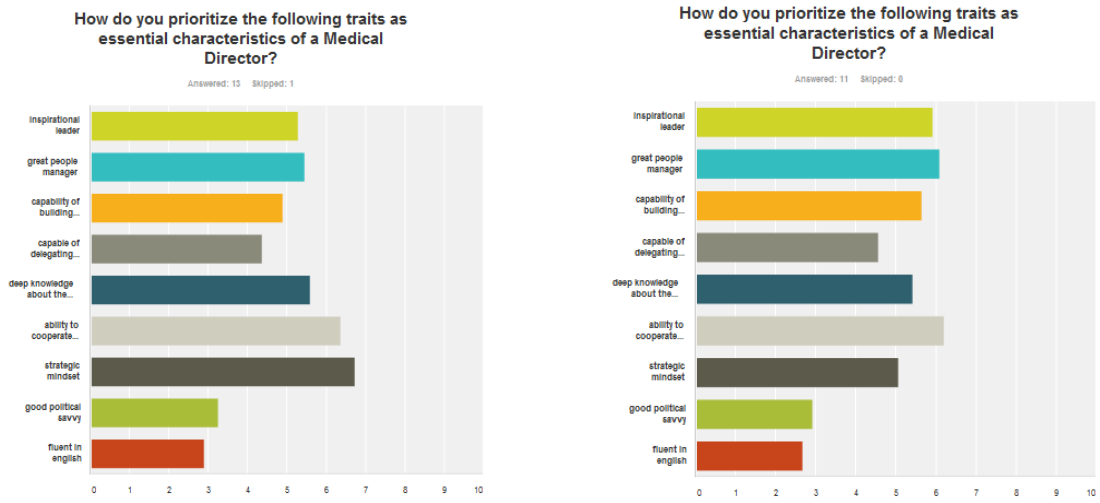

Figure 15 – prioritization of traits considered as essential characteristics of a Medical Director: EU versus Portuguese Medical Directors snapshot

The most valued characteristic of a Medical Director is strategic mind set, followed by ability to cooperate transversally, good knowledge about the business, being a great people manager, closely followed by being an inspirational leader, capability of building trustworthy relationships, and capability of delegating tasks.

The respondents classified lower in the list of priorities characteristics such as good political savvy and fluency in English – these are also required, but in front of them it is very clear that European MDs, as Portuguese MDs (as explained above and expressed on figure 15), consider that leading and management skills and their connected capabilities as the most important for the job.

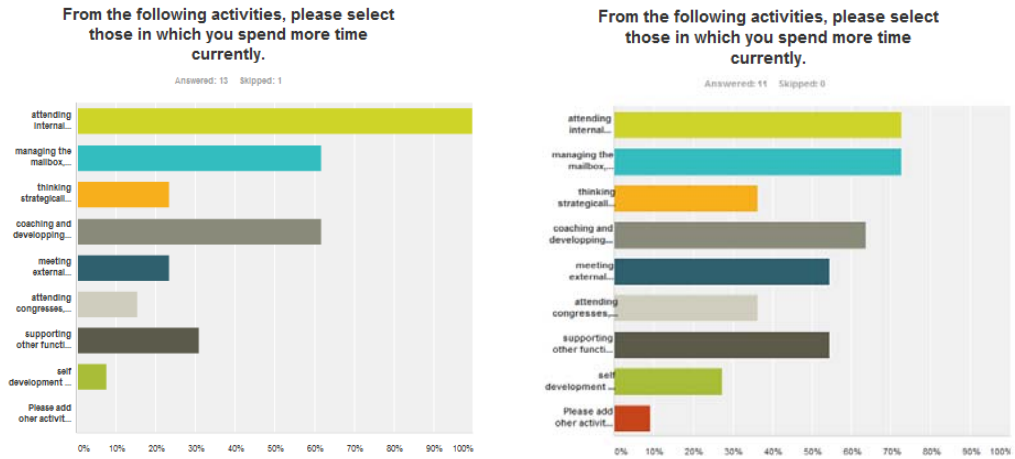

Figure 16 – hierarchy of activities by time spent: EU versus Portuguese Medical Directors snapshot

Regarding the workload in the exercise of their present job, respondents spend the most of their time in the following tasks, as depicted in figure 16:

- internal meetings (including travel time and teleconferences)
- managing the mailbox
- supporting other functions ensuring timely delivery of projects
- coaching and developing people in the team and/or in the company.
- meeting external customers (HCPs, scientific societies, regulatory leaders, politicians)

Other activities mentioned were: attending congresses, conferences, lectures, seminars related to business, thinking strategically with team to drive medical input to the business and self-development and training activities.

Bearing these results in mind we can see that they are very aligned with the responses provided by Portuguese Medical Directors, but the internal meetings here were chosen by all respondents unanimously as the activity in which more time is spent.

As mentioned above, at EU level the issue of strategic thinking being pulled further down the list can have even greater proportions, since it is one of the main components of a leader's profile. Also as stated above, possibly there is some "waste" of highly skilled and differentiated resources in administrative tasks, and maybe this should be looked upon more carefully by HR and top level management.

Moving on to the development of the Medical Directors, 46% of the respondents considered that the most important improvement area for them is work-life balance, followed by time and email management and communication/negotiation skills (both 38% respectively).

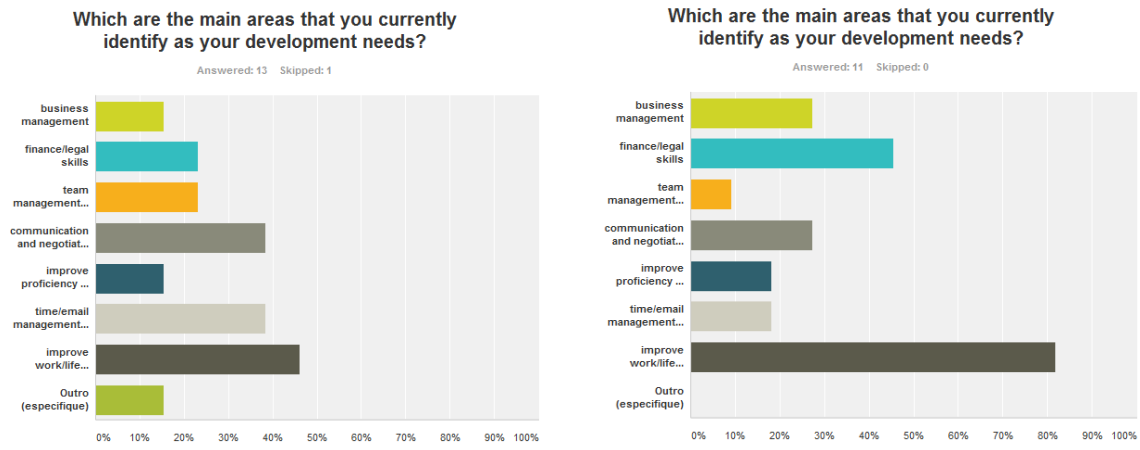

Figure 17 – Main areas identified as development needs: EU versus Portuguese Medical Directors snapshot

Other areas identified, but with lower scores were: improvement in finance/legal skills (23%), team management skills (23%), business management and improving proficiency in a foreign language (both 15%), change management (8%) and MBA (8%).

As for the Portuguese MDs, work life balance is also considered as the most important issue requiring improvement by European MDs, though in a lower magnitude. European MDs refer more frequently the need to improve in email/time management and communication/negotiation skills, and Portuguese MDs refer financial /legal skills as important points for development.

The last question of the survey was about evolutionary pathway. The majority of respondents want to keep developing themselves in their current role (46%), and 38% express that they would like to become Medical Directors of a multi-country organization. These two career developments were followed by moving to an above country position in a Therapeutic area (31%), becoming Country Manager (23%), changing into a more commercial position such as Business Unit Head, market access director and moving to one Therapeutic area in the same country.

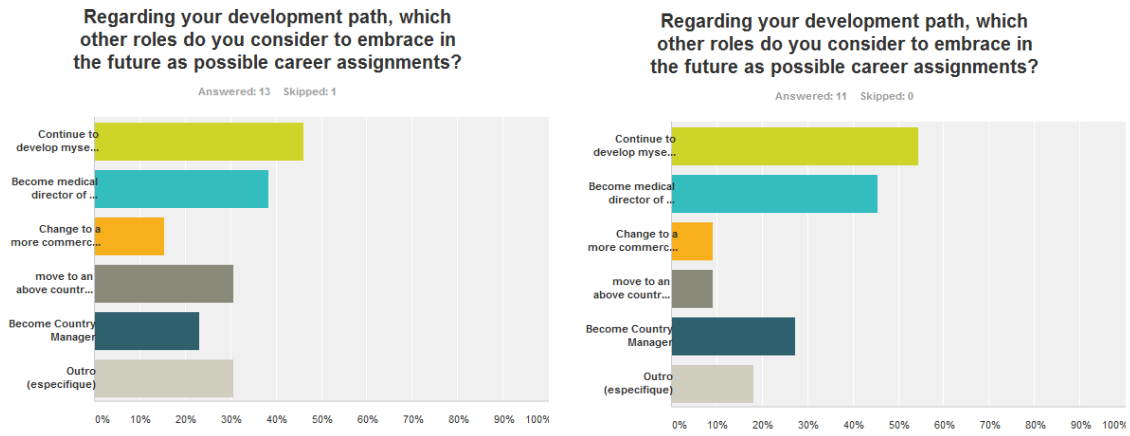

Figure 18 – career evolutionary pathway for Medical Directors: EU versus Portuguese MDs snapshot

Bearing these results in mind we can say that, according to this survey, the European MDs who responded are senior differentiated medical experts (but younger in average than Portuguese MDs) with experience both in the clinical setting and in the Pharmaceutical Industry, spend most of their time in administrative tasks, consider that they are good in time/email management and good business managers, are working many hours, but with less impact reported than felt by the Portuguese sample, and they need to improve their skills in areas outside their background technical skills. Most would prefer developing their career inside the medical domain, but some consider moving into more commercial roles.

d) How Medical Directors are perceived by external customers in Portugal

As stated above, under chapter 3b), one of the responsibilities of a Medical Director is to coordinate and be responsible for ensuring the values and culture of the company are applied when interacting with important external customers that are not uniquely associated with a particular business unit or platform function, including professional societies, medical schools, media, government and payers. Therefore, optimally a MD must allocate a considerable amount of his/her time to customer facing activities, and is the face of the company in many institutional occasions, including medical related industry representative bodies, complementing and eventually adding another layer of commitment to trustful long term partnerships built by Medical Affairs colleagues.[26]

In this context, I considered it would be relevant and interesting for the scope of this report to include a questionnaire directed at a sample of external customers (ref. 3). Physicians were selected for this purpose because they have for the longest time span been the preferred external destination of Pharmaceutical Industry communication and their position in the health system has undergone major changes in recent years, as a wide variety of players have emerged and complexity has increased to a new level.

The survey was sent to a convenience sample of physicians working in Portugal, from the following specialties: Anaesthesiology, Cardiology, Endocrinology, General Surgery, Haematology, Internal Medicine, Neurology, Oncology, Orthopaedics, Pulmonology, Vascular Surgery. Eighteen answers were retrieved, containing the information described below. This data has no statistical power because the sample is small in scale and was not calculated to be representative of all physicians in Portugal. The analysis is therefore descriptive in nature, but we can observe hypothesis-generating trends, which can in turn be further ascertained by more specific research.

Physicians were asked 8 questions, scoring their answers from 1 to 5, in which 1 is “not important/relevant at all”, and 5 is “very important/relevant”.

When asked how they value the importance of having access to a Medical Affairs colleague, 50% of respondents consider it as very important (5), with 100% of questions located between 3 and 5 (dark blue bar below).

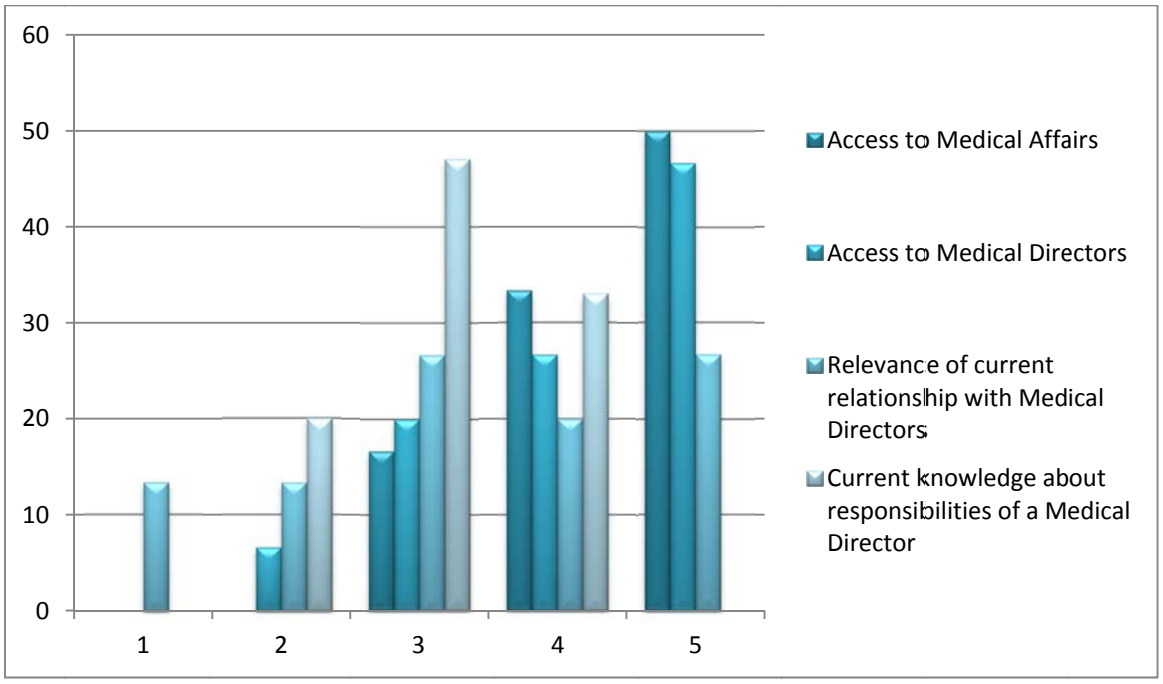

Figure 19 – Main results of survey sent to a convenience sample of physicians working in Portugal, from the following specialties: Anaesthesiology, Cardiology, Endocrinology, General Surgery, Haematology, Internal Medicine, Neurology, Oncology, Orthopaedics, Pulmonology, Vascular Surgery. Answers (in %) were scored 1 to 5, in which 1 is "not important/relevant at all", and 5 is "very important/relevant".

When asked to classify current access to a Medical Director, 46% of respondents consider it as very important (5), 27% consider it rather important and 20% consider it important (middle blue bar above).

When asked about the relevance of their current interactions with MDs of Pharmaceutical Industry, the distribution is rather balanced across the scale, with 27% considering it to be very relevant, 20% rather relevant, 27% relevant, 13% somewhat relevant and 13% not relevant at all.

Regarding current knowledge about responsibilities and tasks of a MD, the distribution was centralized: 33% of respondents classified it as "good", 47% as "moderate" and 20% as "low".

When asked about which traits were considered as differentiating capabilities of an MD, the degree of scientific knowledge was clearly the preferred (53%), with others being mentioned, such as previous clinical experience, capability of thinking "out of the box", generating innovative ideas and availability for projects.

The next question was about the kind of support that is currently provided by an MD:

- none (38%)
- scientific information (31%)
- strategic partnerships in training and research (8%)
- discussion of projects and clarification (8%)
- innovative therapies or new therapeutic perspectives (8%)
- regular meetings/availability for meetings (8%)

Bearing this in mind, physicians were then asked about the kind of support they would like to get from an MD that they are not getting today. Answers included the following main activities:

- in depth scientific information about new products, products under development and new areas of development (45%)
- training (18%)
- support in the development of innovative projects (9%)
- act as interface with colleagues from other countries involved in similar projects (9%)

The last question of the survey was about the preferred means of getting contacted by a Medical Director, and selection was as it can be appreciated on the graphic below:

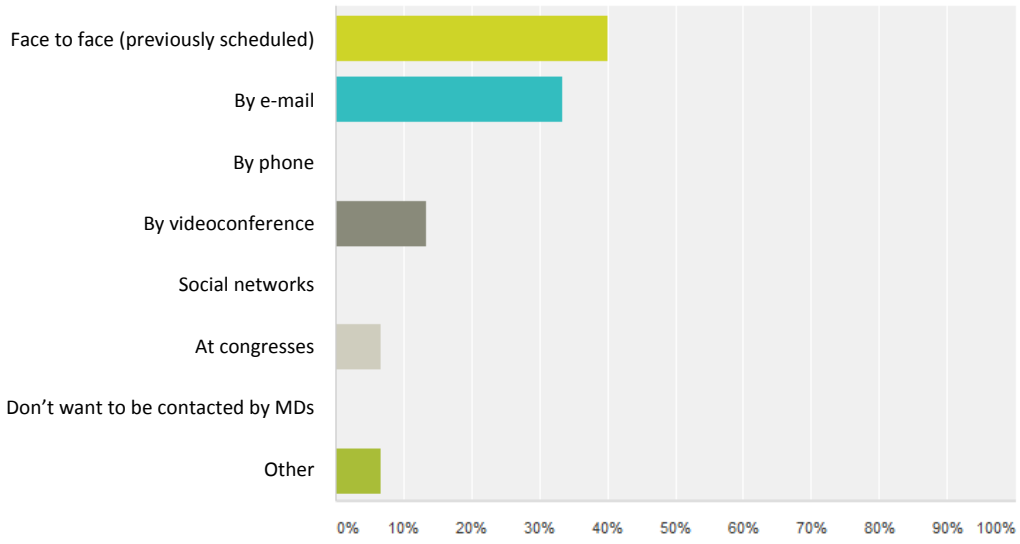

Figure 20 – External Experts' preferred means of getting contacted by a Medical Director of a pharmaceutical company in Portugal

Respondent physicians prefer face to face contact (40%), followed by email (33%) and, far behind, videoconference (13%), and at congresses or meetings (7%). None chose telephone, social networks or refused being contacted.

This small (n=18) survey to external experts demonstrated that access to Medical Affairs colleagues is recognized as quite important. Access to Medical Directors was also valued, but in a somewhat shorter extent, due to the fact that MDs are not so focused in external relations with customers as MA colleagues, that have this task as one of the core activities. The interactions MDs have with external experts are considered relevant, but also less than the relationships established with MA, as documented in previous studies, since the Medical Director is usually perceived as less accessible and less available to direct contact. External experts who responded to this survey consider that they know relatively well the tasks and responsibilities of an MD, but none consider their knowledge to be very good, and it depends on how well they know and consistently interact with MDs over time.

Respondents consider that the most important trait of a Medical Director is the level of scientific knowledge, previous clinical experience and capability to accept innovative ideas.

They would like to receive more support from MDs in gaining deeper knowledge about new products and product pipelines, training, developing their projects and establishing cooperative networks of scientific expertise across countries.

Regarding preferences for contact by MDs, respondent external experts prefer face to face contact, through a previously scheduled meeting for which they block time in their agendas and can prepare, if applicable, making the contact more productive for both sides. Nevertheless, email is also a preferred means of communication, probably because it can act as a reminder and it can be answered in a reflected, more formal way.

From what is described above, we can hypothesize that, despite the current overall good level of knowledge, communication, accessibility and recognition of external experts towards Medical Directors in pharmaceutical companies, there is room for a fair amount of improvement in the way MDs relate with their peers in the clinical setting, in order to bi-directionally leverage this valuable and unique interaction between physicians with highly differentiated expertise in their respective fields of action.

VI – Conclusions

Pharmaceutical Industry has been traditionally centred on the business of selling drugs, and is nowadays the most regulated health activity, as the bottom lies in its impact on peoples' lives. The progressive increase in multiple hurdles regarding access to the market, access to the prescribers and access to patients has dictated that physicians have been called to the battle field over the last years, initially holding mainly supportive and bureaucratic tasks, aiming at giving the business a more patient and medically focused approach, but progressively assuming more responsibilities and conquering more impactful positions in the business, as they are uniquely capable of "speaking the language" of the health system and their peers, and they are therefore placed in a pivotal position that translates genuine medical unmet needs into powerful insights, and these in turn are incorporated into answers that change the way medical practice is performed and evolves.

Of course the conundrum remains: is a Medical Director a clinician with a solid foot in the business, or a businessman with the backbone of a clinician? All MDs, when asked about what they do, say they are physicians before anything else. Despite change and evolution over the past years, the medical training imprint is always there, in the top shelf of defining traits, providing solid background and a sound basis of knowledge and human ethics to decisions.

Now, this combined with a set of distinctive interpersonal skills is what makes the difference at the end of the day, because inside a pharmaceutical company, there may be no one with a broader view and capability to drive others and the business with the necessary balanced vision, patient centricity and human dimension defended by modern thinkers, than its Medical Director.

Surely there are marked differences in the work of an MD if we consider different dimensions:

- Working in a small versus a big country (dealing with multitasking and managing scarce resources versus managing complexity and distance from all team members);
- Working at local level (dealing with the proximity of people and somewhat limited influence of decisions and actions, concentrating all areas of a Medical Department), versus regional or global level (dealing with the need to think abstractly and in very broad terms that cannot dive into detail at the risk of being locally deemed obsolete and classified as too distant from the field, specializing in one therapeutic area or task);

- Being new to the challenges of the job (that can make it dominate all other aspects in life until balance is found) versus having a long experience that can sometimes drain self-motivation away;
- Being a man in the obvious evolutionary journey in his career versus being a woman in charge (needing to work harder for the same level of recognition but always trying to hide the permanent underlying guilt of not being able to fulfil perfectly every role in her life).

Nevertheless, if initially the switch of physicians from clinical practice setting to Pharmaceutical Industry was pointed out by many has the result of being tired and somewhat frustrated with an unfulfilling daily routine, or they made the transition immediately after completing their medical degree (which meant scarcely any clinical experience in managing patients), recent times have witnessed more physicians embracing a career in Pharmaceutical Industry that is motivated by the challenges of the role and the broad scope of influence that it can have, as Medical Departments grow in dimension and in relevance for the business.

This review has summarized the scarce existing literature on this topic, and through a small experimental evaluation, aims to raise awareness to the poignant fact that more in depth, well-structured and representative research is needed in order to further help understand the evolving profile, role, relevance and evolutionary path of a Medical Director in a pharmaceutical company.

VII – References

1. SurveyMonkey® questionnaire. “Profiling Medical Directors working in Pharmaceutical Industry”. Developed for 23 Medical Directors working in Portugal. May 2015.

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3. SurveyMonkey® questionnaire. “Access to Medical Directors working in Pharmaceutical Industry in Portugal”. Developed for 42 HCPs working in Portugal (Anesthesiology, Cardiology, Endocrinology, General Surgery, Haematology, Internal Medicine, Neurology, Oncology, Orthopaedics, Pulmonology, Vascular Surgery). June 2015.

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IX – Appendices

APPENDIX 1

SurveyMonkey® questionnaires 1 and 2: "Profiling Medical Directors working in Pharmaceutical Industry"

1- Developed for a convenience sample of 23 Medical Directors working in Portugal

- Sent in May 2015. Open for 30 days. 11 complete answers retrieved

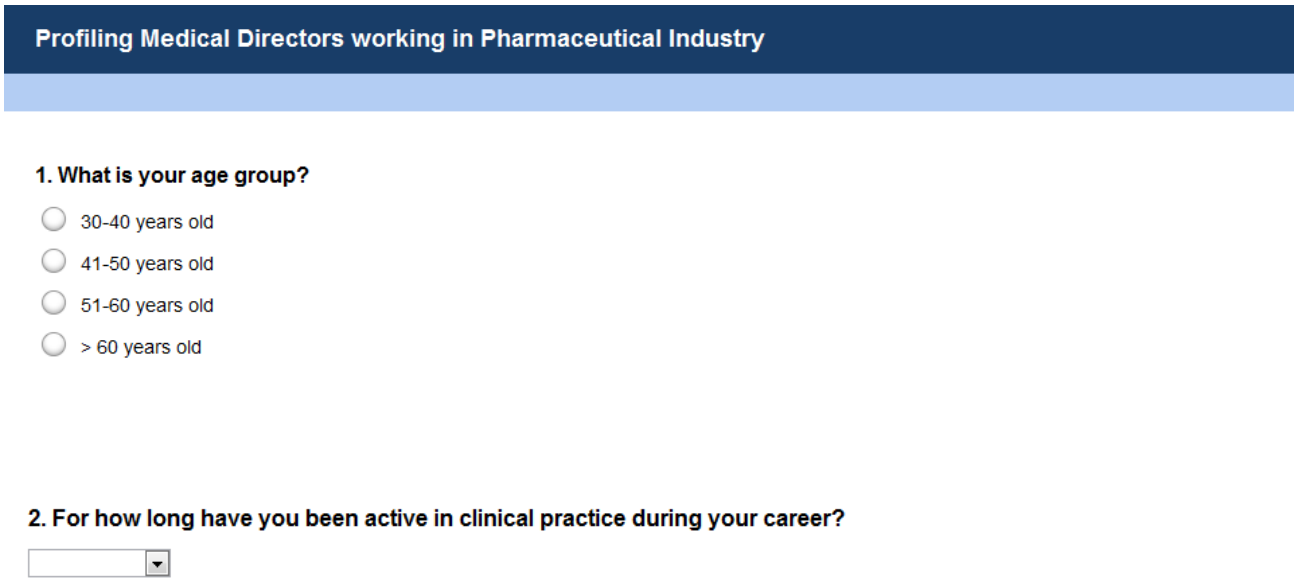
- 47,8% response rate

2-Developed for a convenience sample of 25 Medical Directors working in Sanofi Affiliates in Europe

- Sent in May 2015. Open for 30 days. 13 complete answers retrieved

- 52% response rate

Questions and respondents' view of the surveys:



3. What was your main reason for joining Pharmaceutical Industry?

- [ ] it was always my objective since Medical school
- [ ] I was tired and had no motivation in the clinical everyday work
- [ ] the conditions offered by the company were much better than my previous ones
- [ ] I wanted to try something different with my knowledge from clinical activity (e.g. research)
- [ ] I wanted to have an active role in the clinical development and access to new treatments in my country

Outro (especifique)

4. For how long have you been working in Pharmaceutical Industry?

5. Do you have any additional specialization other than Medical Degree?

6. If you responded affirmatively to the previous question please indicate which specialty(ies)/MSc/MBA/PhD or other degrees you have. Please specify all.

7. How do you prioritize the following traits as essential characteristics of a Medical Director?

- inspirational leader
- great people manager
- capability of building trustful relationships
- capable of delegating tasks
- deep knowledge about the business
- ability to cooperate transversally
- strategic mindset
- good political savvy
- fluent in english

8. Which are the main areas that you currently identify as your development needs?

- [ ] business management
- [ ] finance/legal skills
- [ ] team management skills
- [ ] communication and negotiation skills
- [ ] improve proficiency in foreign languages (english)
- [ ] time/email management skills
- [ ] improve work/life balance
- [ ] Outro (especifique)

9. Regarding your development path, which other roles do you consider to embrace in the future as possible career assignments?

- [ ] Continue to develop myself in the current role
- [ ] Become medical director of a multi-country organization
- [ ] Change to a more commercial position, such as BU head
- [ ] move to an above country position in one therapeutic area
- [ ] Become Country Manager
- [ ] Outro (especifique)

10. From the following activities, please select those in which you spend more time currently.

- [ ] attending internal meetings (including travel time and teleconference time)
- [ ] managing the mailbox, responding to information requests
- [ ] thinking strategically with team to drive medical input to the business
- [ ] coaching and developping people in the team and the company
- [ ] meeting external customers (HCPs, scientific societies, regulatory leaders, politicians)
- [ ] attending congresses, conferences, lectures, seminars related to business
- [ ] supporting other functions ensuring delivery (quality management, PhV, market access, clinical research, compliance)
- [ ] self development and training activities (university based or not~)
- [ ] Please add oher activity if needed

Ant. concluído

APPENDIX 2

SurveyMonkey® questionnaire 3: "Access to Medical Directors working in Pharmaceutical Industry in Portugal"

3-Developed for a convenience sample of 42 HCPs working in Portugal (Anesthesiology, Cardiology, Endocrinology, General Surgery, Hematology, Internal Medicine, Neurology, Oncology, Orthopedics, Pulmonology, Vascular Surgery).

-Sent in June 2015. Open for 30 days. 18 complete answers retrieved

-42,8% response rate

Questions and respondents' view of the surveys:

Acesso a directores médicos da Indústria Farmacêutica em Portugal

1. É importante para si ter acesso aos colegas do departamento médico de empresas da Indústria Farmacêutica?

nada importante | relativamente importante | muito importante

Outro (especifique)

2. Como valoriza o seu acesso atual aos Diretores Médicos de empresas da Indústria Farmacêutica?

nada importante | medianamente importante | muito importante

Outro (especifique)

3. Por favor classifique a relevância das suas interações atuais com Diretores Médicos de empresas da Indústria Farmacêutica.

nada relevantes | medianamente relevantes | muito relevantes

Outro (especifique)

4. Como classifica o seu conhecimento atual acerca das responsabilidades e tarefas de um Diretor Médico na Indústria Farmacêutica?

nenhum	baixo	moderado	bom	excelente
○	○	○	○	○

Outro (especifique)

5. Quais as principais características que considera como capacidades diferenciadoras de um Diretor Médico na Indústria Farmacêutica?

- ○ grau de conhecimento científico
- ○ experiência clínica prévia
- ○ experiência clínica atual
- ○ capacidade de comunicação
- ○ disponibilidade para projetos
- ○ inteligência emocional
- ○ capacidade de liderança
- ○ grau de conhecimento do mercado da saúde
- ○ capacidade de pensar "fora da caixa" e de gerar ideias inovadoras
- ○ acessibilidade
- ○ capacidade de escuta ativa e de "colocar nos sapatos do interlocutor"
- ○ capacidade de organização; equilibrio pessoal/profissional
- ○ Outro (especifique)

6. Que tipo(s) de suporte lhe é (são) prestado(s) atualmente por diretores médicos da Indústria Farmacêutica?

7. Que tipo(s) de suporte gostaria de receber por parte de Diretores Médicos de empresas da Indústria Farmacêutica e que não recebe hoje?

8. Atendendo à era digital em que hoje vivemos, e à dificuldade de gestão do tempo e da agenda de atividades, qual o meio pelo qual mais gosta/gostaria de ser contactado por um Diretor Médico da Indústria Farmacêutica?

- ○ presencial, através de reunião marcada previamente
- ○ por email
- ○ por telefone
- ○ por videoconferência
- ○ através de redes sociais, como o Linkedin
- ○ em congressos, conferências
- ○ não quero ser contactado por Diretores Médicos de empresas da IF
- ○ Outro (especifique)

Ant. Concluído